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THE PARLIAMENT OF THE COMMONWEALTH OF AUSTRALIA

HOUSE OF REPRESENTATIVES

INTELLECTUAL PROPERTY LAWS AMENDMENT BILL 2006

EXPLANATORY MEMORANDUM

(Circulated by authority of  
the Parliamentary Secretary to the Minister for Industry, Tourism and Resources,  
the Hon Bob Baldwin MP)

## INTELLECTUAL PROPERTY LAWS AMENDMENT BILL 2006

### Outline

The Bill amends the *Patents Act 1990*, the *Trade Marks Act 1995*, the *Designs Act 2003*, the *Plant Breeder's Rights Act 1994* and the *Olympic Insignia Protection Act 1987* (the Acts).

The amendments made by the Bill give effect to some outstanding aspects of the Government's response to the Intellectual Property and Competition Review (IPCR) Committee's report *Review of the Intellectual Property Legislation under the Competition Principles Agreement* and the Advisory Council on Intellectual Property, *Review of Enforcement of Industrial Property Rights*. The amendments made by the Bill also give effect to the first legislative changes to arise from the Review of the Trade Marks Legislation, which was concluded in 2005.

The Bill amends section 119 of the Patents Act to clarify that the prior user's rights include exploiting the product, method or process, that the prior use be only in Australia and that the prior use right may be assigned but not licensed. This amendment reaffirms the Government's commitment to ensuring that the legitimate interests of third parties are not compromised by the grant of a patent.

In order to further promote the efficient use of patents and promote competition the Bill adds a new provision to the existing compulsory licence provisions in the Patents Act. This provision will provide for a compulsory licence to be available as a remedy if a person has been found guilty of any proscribed anti-competitive conduct under the *Trade Practices Act 1974*.

The Bill also amends the Patents Act to allow for exemplary damages to be awarded by a court in patent infringement actions, for example, in the case of flagrant or wilful infringement of a patent. Allowing the award of exemplary damages will serve as a deterrent against patent infringement, which will in turn strengthen patent rights.

The Bill amends the provisions in the Patents Act that relate to springboarding of patents for pharmaceuticals. The purpose of this amendment is to allow springboarding as an exception to patent infringement on any pharmaceutical patent at any time for purposes solely in connection with gaining regulatory approval of a pharmaceutical product in Australia or another territory, consistent with Australia's international obligations. This amendment aims to bring Australia's springboarding provisions closer to those of competitor countries and improve the environment for generic pharmaceutical companies conducting research and development in Australia.

The Bill amends the Trade Marks Act to allow the Registrar of Trade Marks to revoke the registration of trade marks in certain circumstances. Frequently, the only recourse to rectify the Register of Trade Marks is through the courts. This amendment will provide a quicker and less expensive means of addressing incorrectly registered trade marks.

The Bill also amends the Trade Marks Act to make publicly available the majority of documents that relate to particular trade marks. This amendment will provide a quick and efficient system that simplifies the processing of requests for information on trade mark files whilst balancing the interests of applicants for registration who must sometimes file sensitive business information in order to obtain registration.

This Bill also makes a number of other minor and technical amendments to the Acts, including clarifying the effect of the Patents, Trade Marks, Designs and Plant Breeder's Rights Offices not being open for business. The Bill also makes some technical amendments to the Plant Breeder's Rights Act to facilitate integration of the administration of the Plant Breeder's Rights Act within IP Australia.

***Financial Impact Statement***

No additional cost to the Government is expected to result from the amendments contained in this Bill.

## **Regulation Impact Statements**

### PRIOR USE

#### PROBLEM OR ISSUE IDENTIFICATION

A patent is granted to the first person to apply to protect an invention. An invention is patentable if it is new and inventive. In order to determine whether an invention is new, it is compared with information publicly available anywhere in the world. Once a patent has been granted the patent owner (patentee) has the right to prevent others from using the invention while the patent is in force. A person who uses a patented invention without the permission of the patentee is said to 'infringe' the patent and can be sued by the patentee. Section 119 of the Patents Act provides a defence to an infringement action where a third party had been secretly using the invention before the patentee applied for the patent. If the use was not public then it cannot be used to show that the invention was not new and thereby invalidate the patent.

It has long been accepted that a patent should not deprive a party from continuing to do what they were doing before the patent was granted. On the other hand an inventor should not be deprived of patent protection by the secret acts of third parties, of which they can have no knowledge. Section 119 attempts to provide a balance between the rights of the patentee and those of the third party. It is intended to safeguard the rights of third parties who have independently used an invention before the priority date (the date from which an invention is regarded as being new) of an application for a patent.

The issue is particularly important to research-based organisations, especially where the technology is complex and involves substantial investment and long lead times to develop an invention so that it is commercially viable. In such circumstances it is likely that the organisation would keep their research secret and not apply for patent protection for a new product or process initially because they would waste a large proportion of the patent term before they had put their product on the market. Without the benefit of section 119, the grant of a patent to another for that product or process would prevent the organisation from continuing with the development of the product or process and recouping the costs of the R&D.

Another important issue is where a company makes many inventions in the course of its research. Most companies employ a selective patenting strategy where they will apply for patents only in respect of certain inventions. The choice will be based on a number of factors including cost and the competitive nature of the industry. A company is more likely to seek patent protection for inventions which can be copied easily to prevent their competitors from free-riding on the developments. However it is important for the company to be able to use and commercialise those inventions for which it does not have patents as they may have devoted considerable resources to their development. Section 119 permits companies to do this and hence this enhances competition where the products are subsequently available to consumers.

Concerns have been raised that the section does not provide the protection intended and this can inhibit competition. In particular it is not clear whether the prior use must be in Australia or whether it can be use anywhere in the world. If the use is not restricted to use in Australia, then the benefits of section 119 would extend to a person or company making or using an invention overseas. This would mean that competing R&D performed overseas could detrimentally affect subsequent R&D performed in Australia. The restriction of the use to Australia will protect Australian firms from possible claims of use in obscure jurisdictions overseas and consequential litigation.

Also it is not clear whether the provision is limited to commercial use, in which case a person who has developed a product or process but who has not taken definite steps to commercialise it will not be protected. This would be very serious for the majority of Australian companies that carry out research. If a company makes a development and does not apply for a patent, does not publish the development or does not use it commercially before a third party, generally an overseas company, applies for a patent in Australia, the company will not be able to continue with the development without the benefit of section 119. This would lessen competition in the market provided by such R&D companies.

A further concern is whether the right should be limited to the actual prior user or whether it can be assigned or licensed<sup>1</sup>. The actual prior user is the person or business regarded as the inventor of the invention. An invention made during the course of a person's employment will belong, in the majority of cases, to the employer. If the rights given by section 119 are not capable of assignment otherwise than in conjunction with the business concerned, they are of little value, especially to a university or research organisation whose only opportunity to exploit its work is by licensing or assignment. It is very common in Australia for the commercial exploitation of the products of R&D work to be carried out by a different party from that which conducted the R&D.

Also section 119 limits the use to making a product or using a process and it is not clear whether this extends to other aspects such as selling the product. The right would be of little value if the end product could not be sold and thereby provide a return on the investment in the R&D used to create it.

## OBJECTIVE

To clarify the scope of the rights provided under section 119 of the Patents Act to provide the correct balance between the rights of a patentee and those of a third party who has independently used an invention before the priority date of the patent.

## IDENTIFICATION OF OPTIONS

The Government has three options to clarify the scope of section 119 and balance the rights of patentees and third parties. These are:

### *Option 1*

Retain section 119 in its current form.

### *Option 2*

Adopt the recommendation of the IPCR Report that section 119 is amended to make it clear that the prior use is only in the patent area (i.e. Australia), that this use includes experimental use and that the benefit of the right is limited to the actual prior user.

This option serves to clarify the scope of the section without making any material changes. The IPCR Committee was divided as to whether the right should be limited to the actual prior user, with the majority considering that it should be so limited to avoid it becoming a *de facto* patent right.

### *Option 3*

Amend section 119 to make it clear that the prior use is only in the patent area, that the benefit of the right extends to assignees but not to licencees and that the use encompasses acts which would

<sup>1</sup> When a patent right is assigned, the right is transferred completely to a third party and the right owner does not retain any interest in the right. When a patent right is licensed, the licensee is authorised to use the right according to the terms of the licence. However the patent owner retains the right and may licence it to others on the same or different terms.

otherwise constitute an infringement of the patent. This means that the benefit of the section would extend to selling the product. (A patent gives the patentee the exclusive right to make, hire, sell, use or import the invention. A person who does any of these acts without the patentee's permission is said to 'infringe' the patent.)

There are 3 key differences between this option and option 2. The first is that the benefit extends to assignees. This is consistent with the minority view of the IPCR Committee who noted that the innovation process often required changing corporate arrangements. The second is that the use does not specifically refer to experimental use. Reference to experimental use could cause confusion because experimental use in terms of the infringement provisions of the Patents Act has generally been taken to refer to experimenting with an invention that has been patented. It does not refer to experiments made in order to develop an invention prior to patenting, which is the context in which the IPCR Committee considered experimental use. The third difference is to extend the nature of the use to acts otherwise constituting infringement. Submissions to the IPCR Committee expressed concern that the section did not extend to selling the product. Since section 119 provides a defence against infringement, it is reasonable to extend the use to all acts that constitute infringement.

## IMPACT ANALYSIS:

### *Impact group identification*

The same groups would be affected by the implementation of any one of the three options. These groups include:

- i. industry and the research sector including both users of the patent system and other producers who are competitors of those users, and IP professionals such as patent attorneys and lawyers ('industry')
- ii. consumers including those who use patented products and processes ('consumers')
- iii. any agency or group involved in the administration of the patent system including IP Australia, other Government agencies and the courts ('government')

The following qualitative analysis considers the impact in terms of costs and benefits for the identified groups for each of the three options.

### Option 1: Retain the current section 119

#### *Costs*

#### **Industry**

- Several submissions to the IPCR Committee indicated that the section does not give the protection intended and this can inhibit competition. For example if the use is not restricted to Australia but can be anywhere in the world, then the benefit will extend to competing R&D performed overseas to the detriment of R&D performed in Australia.
- The benefit of section 119 could also extend to non-secret use overseas since novelty and inventive step considerations in Australia currently only have regard to prior use in Australia. This would mean that overseas applicants for patents in Australia are in an advantageous position compared with local applicants because they do not have to keep their inventions secret. (This will be addressed when the novelty and inventiveness tests are amended as recommended to include prior acts anywhere in the world.)
- Uncertainty as to whether the section includes non-commercial use means that businesses may not be able to use or commercialise their inventions developed in the course of R&D but

for which they have not sought patent protection. Businesses therefore may not reap the full benefits from their R&D.

- Uncertainty as to the scope of the section may lead to costly and time-consuming court actions. The uncertainty affects the prior users in terms of what they can continue to do. It also affects patent holders who may commence infringement actions only to find that the 'infringer' can claim the defence against infringement under section 119.

### **Consumers**

- If non-commercial use is excluded this will lessen competition in the market that would have resulted from commercialisation of the R&D, leading to fewer products being available at higher prices.
- The section is limited solely to making a product or using a process and does not seem to include other aspects of exploitation. A business could therefore satisfy the requirements of the section but not be able to sell the product. Again this could result in reduced competition in the market.
- It is very common for commercial exploitation of the products of R&D work to be carried out by a different party to that which conducted the original R&D. If the benefit under section 119 is limited to the actual prior user, and does not extend to the assignee or successor in title, then it is of no value and many inventions will not be commercialised. Again this will lessen competition in the market.

### **Government**

- Uncertainty as to the scope of the section may lead to costly and time-consuming court actions.
- The option will not meet the Government's objective of increasing the certainty of the patent system. The Government believes that the patents legislation should provide certainty to both users of the patents system, in terms of the extent of the rights they have, and to third parties, who need to know what they can and cannot do in the light of the grant of a patent. Any uncertainty will be detrimental to both users and third parties and could be harmful for competition. Interest groups have identified a number of issues relating to the lack of certainty as to the scope of section 119.

### *Benefits*

### **Industry**

- Retention of the section gives a prior secret user of an invention some protection to balance the very extensive rights accorded to the patent owner of that invention.
- Section 119 encourages innovation in Australia by affording protection to Australian innovators who may have developed inventions but where they have been prevented from applying for patent protection. For example a business may have made a number of inventions during the course of R&D and, for cost reasons, has had to select only some for patent protection. The business will be able to continue to develop those inventions in the face of later patents, most of which will be granted to overseas firms.
- The two major ways recognised in law whereby an inventor can protect an invention are via patent protection or by maintenance of secrecy. There may be sound commercial reasons why a business chooses secrecy, such as where the invention can be reverse engineered. Section 119 recognises the rights of businesses in such circumstances and protects them from the threat of infringement actions so that they can continue to exploit their inventions and gain a return from their investment.
- Limiting the prior use to the actual prior user benefits patent holders because the opportunities to commercialise competing inventions will be reduced.

### **Consumers**

- If businesses can continue to develop their innovations in the circumstances described above, this will increase competition in the market by providing a greater range of products at lower prices than if section 119 did not exist.

### **Government**

- No legislative change will be needed.

Option 2: Adopt the recommendation of the IPCR Report

### *Costs*

### **Industry**

- This option will limit the prior use to the actual user and so will be of no value to many research organisations which are not able to commercialise their own inventions.
- Specific reference to experimental use could create uncertainty as to the ambit of the section because experimental use is not generally regarded as constituting infringement in other circumstances within the provisions of the Patents Act. Experimental use generally refers to use after the grant of a patent rather than before a patent application is made. Businesses therefore may be uncertain as to what further protection the amended section would give them and patent holders will not be sure whether the use will constitute an infringement of their patent.

### **Consumers**

- As discussed under option 1, limiting the use to the actual prior user may lessen competition in the market.
- The option does not address the issue of whether the section includes other aspects of exploitation with consequent costs to consumers as for option 1.

### **Government**

- Legislative change will be required.

### *Benefits*

### **Industry**

- The benefits of option 1 also apply to this option.
- Limiting the prior use to use in Australia will ensure that firms operating in the jurisdiction of the Australian patent area will not be disadvantaged by the grant of patents in Australia, the majority of which are granted to overseas applicants. It will protect these firms from possible claims of use in obscure jurisdictions overseas and consequential litigation.
- By including experimental use, businesses in Australia will be able to reap the full benefits from their R&D where they have not commercialised an innovation prior to patent protection being granted.
- The increased certainty that the prior use is limited to use in Australia and that it includes experimental use will encourage further investment in R&D.

### **Consumers**

- The benefits will be as for option 1.
- Including experimental use will mean more innovations are developed leading to increased competition and lower prices.

### **Government**

- The scope of the section will be clearer which will reduce the likelihood of costly and time-consuming court action. Section 119 was introduced into the Patents Act in 1990 and there

has been little reported activity under this section to date. However submissions to the IPCR Review pointed to the lack of clarity of the section.

- The changes will increase the certainty of granted patents which will help to encourage investment and technology transfer.

Option 3: Amend section 119 to limit prior use to the patent area, to extend the right to assignees and to specify that the use encompasses acts constituting infringement.

### *Costs*

#### **Industry**

- There may be uncertainty as to whether the section includes non-commercial use as discussed under option 1. However the Government response will indicate that the use is not restricted to non-commercial use. It is not necessary to specify the nature of the use in the section because this may place undue limitation on its scope. The Court will determine whether the section applies in any particular case, and it is appropriate for the Court to determine whether, in all the circumstances, a particular use falls within the section. The discussion above indicates the problems that may occur if reference is made to experimental use. Similar problems could occur if other types of use are specifically referred to in the section.
- Extending the benefit to assignees may disadvantage patent holders because this increases the likelihood of competing inventions being commercialised. Further extension to permit selling of the product will increase this competition to the patent holder's invention. However the competition will be from only a single competitor.

#### **Consumers**

- There will be no net costs to consumers.

#### **Government**

- Legislative change will be required.

### *Benefits*

#### **Industry**

- The benefits as described under options 1 and 2 also apply to option 3.
- Extending the right to assignees will benefit many research-based organisations that do not commercialise their own inventions. This provides an incentive for further R&D to take place because the organisation can profit from its work and hence this will stimulate innovation.
- Clarification of the section by this option will provide more certainty both for prior users and patent holders in terms of what the section provides as a defence against infringement.

#### **Consumers**

- The benefits of option 1 also apply to option 3.
- The clarification that the section encompasses acts constituting infringement means that businesses can fully exploit their inventions by selling their products. This will increase competition by increasing the range of products available to consumers and will lower prices.

#### **Government**

- The benefits of option 2 also apply to option 3.
- Government research organisations will benefit because they will be able to assign their technology.

## CONSULTATIONS

- The terms of reference of the IPCR required the Committee to consult with stakeholders and invite submissions from all interested parties and to hold hearings to afford interested parties the opportunity to make oral submissions.
- The Committee sought comments and written submissions on an Issues Paper released in September 1999 and met with groups and individuals to discuss issues of concern. It produced an Interim Report in April 2000, which presented the Committee's preliminary views on options for achieving the objectives, and sought further written submissions from interested parties. Some parties sought extra time to submit their comments and as a consequence the Committee was allowed additional time to deliver its final report.
- The review process also included public consultations and seminars and a roundtable discussion with experts on patents.
- Following publication of the final report, IP Australia sought comment from various interest groups (including the Institute of Patent and Trade Mark Attorneys of Australia (IPTA), the Advisory Council on Intellectual Property (ACIP), the Australian Federation of Intellectual Property Attorneys (FICPI Australia) and the Law Council) on the recommendations in relation to patents.
- An interdepartmental committee, with representatives from IP Australia, the Department of Industry, Science and Resources, the Attorney-General's Department, the Department of Communications, Information Technology and the Arts, the Department of Treasury, the Department of Foreign Affairs and Trade and the Australian Competition and Consumer Commission, was formed to consider the recommendations and make recommendations to Government.

## CONCLUSION AND RECOMMENDED OPTION

Section 119 attempts to balance the rights of a patentee with those of a third party who has secretly used an invention before the priority date of the patent. Submissions to the IPCR Committee expressed concerns that the section was not achieving this objective and consequentially has a detrimental effect on competition. The submissions also identified some lack of clarity as to the scope of the section. Options 2 and 3, which suggest amendments to section 119, will both assist in achieving these outcomes. At the same time neither of these options limit the patentee's rights to gain patent protection and exploit their invention.

Adoption of option 3 is likely to provide the greatest benefit to third parties. Currently the prior user right can only be assigned in conjunction with the business. Option 3 will permit assignment of the right *per se* thereby enabling Australian research-based organisations to assign their inventions to others to further develop and bring to the market. This will stimulate indigenous innovation as well as benefiting consumers in providing increased choice in the market. Enabling the right to be assigned but not licensed will limit the prior use to a single entity and this provides a balance with the patentee's interests in maintaining an exclusive right in the market for the product. Option 3 also provides certainty that the new products can be sold by clarifying that the prior user right extends to all acts that may constitute infringement, and that it is not limited solely to the making of a product or the using of a process.

Adoption of option 3 will also mean that the prior user right is limited to prior use in Australia. This will help to ensure that Australian firms that have previously developed technology in Australia but have chosen not to publish it or seek patent protection are not disadvantaged by the 90% of Australian patents granted to overseas applicants. Prior use anywhere in the world could lead to an obscure use being cited as a defence to infringement that would lead to costly and time-consuming litigation. Amendment of section 119 to indicate that the prior use includes experimental use may be unnecessarily limiting because the section is not presently limited to commercial use.

In view of this, and also considering the costs and benefits outlined above, it is recommended that the Government endorses option 3 to amend section 119 to make it clear that the prior use is only in the patent area, that the benefit of the right extends to assignees but not to licencees and that the use encompasses acts which would otherwise constitute an infringement of the patent.

## IMPLEMENTATION AND REVIEW

Amendments will need to be made to the Patents Act to implement option 3. Drafting instructions have been prepared. An evaluation of the revised requirements of section 119 will be undertaken 5 years after implementation of the legislation to assess how well it has met its objectives.

None of the options will impact on the compliance costs and paperwork burden for small business.

## COMPULSORY LICENCES

### PROBLEM OR ISSUE IDENTIFICATION

A granted patent is essentially a right to exclude others from using the patented invention. The patentee also has the right to choose not to exploit the invention. However, if their failure to use the invention at all, or to a sufficient extent, is contrary to the public interest then access to the invention can be obtained in certain circumstances. Section 133 of the Patents Act provides that a prescribed court can order a patentee to grant a licence to work their patented invention in certain circumstances. Subsection 133(2) allows the court to make the order if the reasonable requirements of the public with respect to the invention have not been satisfied and the patentee has given no satisfactory reason for failing to exploit the invention. Subsection 135(1) provides that the 'reasonable requirements of the public' have not been satisfied if:

- an existing trade or industry in Australia is unfairly prejudiced by the patentee's failure to work the invention, or an essential part of the invention, or to grant licences on reasonable terms;
- an Australian trade or industry is unfairly prejudiced by conditions imposed by the patentee on the working of the patent; or
- the patent is not being commercially worked in Australia but is capable of being worked.

The IPCR Committee considered the conditions currently prescribed for the grant of a compulsory licence to be outdated, poorly aligned to achieve their purpose and deficient, in that they do not include an explicit competition test and do not sufficiently take the legitimate interests of the patentee into account. However, the IPCR Committee acknowledged that 'the threat of a compulsory licence may lead to innovations being worked sooner and more widely than they would otherwise have been' and that the current provisions 'have a continuing impact on licence negotiations, notably between foreign rights owners and potential users of patents in Australia' (page 162).

The IPCR Committee goes on to say, at page 163, that 'the conditions for grant of a compulsory licence should be stringent' and has recommended that the existing compulsory licensing provisions be replaced with a stringent competition test. However, if the conditions for the grant of a compulsory licence are too stringent then the 'threat of a compulsory licence' would arguably be reduced.

It is difficult to determine the impact that the compulsory licensing provisions have on licensing negotiations, largely because of the small number of cases that have been heard — only three since 1903. In its 1984 review, *Patents, Innovation and Competition in Australia*, the Industrial Property Advisory Committee (IPAC) discussed this issue. It stated:

'It is something of an enigma that, despite the apparent number of situations in which these compulsory licensing provisions could be invoked, only 2 cases of petitions for compulsory licences are known to have gone to court in Australia. One reason for this might be that in fact the provisions in question are ineffectual; that persons who would be prospective applicants for compulsory licences perceive, and are advised, that...to petition would be too onerous or useless, particularly without access to related know-how. Another possible explanation for the dearth of petitions might be the very efficacy of the provision in question; that the prospect of obtaining compulsory licences induces patentees to refrain from misusing their patents to exact excessive profits, and to agree to grant licences on satisfactory terms. Insufficient empirical information is available to enable us to assess the validity of either of these contrasting possibilities.'

Although there has been one more application for a compulsory licence since the IPAC review, the effect of the compulsory licensing provisions on licence negotiations is still not clear. However, users of the system have advised the IPCR Committee and IP Australia that the existence of the provisions does impact on licensing negotiations and increases access to patented inventions.

The issue, therefore, is whether the compulsory licensing provisions need to be amended and, if so, how to amend the provisions without negating the indirect impact they currently appear to have on licence negotiations and access to patented inventions.

## OBJECTIVE

To ensure that the compulsory licensing provisions provide an appropriate level of access to patented inventions and strike an appropriate balance between the rights of patent owners and the public interest in access to patented inventions.

## IDENTIFICATION OF OPTIONS

The government has the following three options:

### *Option 1*

Continue to apply the existing compulsory licensing provisions.

### *Option 2*

Amend the compulsory licensing provisions by adopting the recommendation of the IPCR Committee that:

Section 135 of the Patents Act be repealed and that subsection 133(2) be amended to include an order requiring a compulsory license to be made if and only if all of the following conditions are met:

- a) access to the patented invention is required for competition in the (relevant) market;
- b) there is a public interest in enhanced competition in that market;
- c) reasonable requirements for such access have not been met;
- d) the order will have the effect of allowing these reasonable requirements to be better met; and
- e) the order will not compromise the legitimate interests of the patent owner, including that owner's right to share in the return society obtains from the owner's invention, and to benefit from any successive invention, made within the patent term, that relies on the patent.

Such orders should be obtainable on application first to the Australian Competition Tribunal, with rights of appeal to the full Federal Court.

### *Option 3*

Amend section 133 to include a competition test as one of the grounds on which a compulsory licence can be obtained, in addition to the existing provisions. Orders for compulsory licences will be obtainable from the Federal Court.

It should be noted that all three of these options would be consistent with Australia's international obligations under the World Trade Organization Agreement on Trade-Related

Aspects of Intellectual Property Rights (the TRIPS Agreement). In addition, none of the options will impact on the compliance costs and paperwork burden for small business.

## IMPACT ANALYSIS:

### *Impact group identification*

The same groups would be affected by the implementation of any one of the three options and are the same groups as those identified in the discussion of prior use, i.e. industry, consumers and government.

The following qualitative analysis considers the impact in terms of costs and benefits for the identified groups for each of the three options.

Option 1: Continue to apply existing compulsory licensing provisions

### *Costs*

#### **Industry**

- The IPCR Committee concluded that the existing provisions are not strong enough and should be replaced by a more stringent test that would better protect the interests of patentees. It may be the case that the existing provisions allow for access to patented inventions too easily and therefore impose a cost on patentees.

#### **Consumers**

- Access to a patented invention on the ground that such access is required for competition in the relevant market is not covered by the existing provisions. Therefore, adopting option 1 may impose a cost on consumers by not providing a means of increasing competition in the relevant market.

#### **Government**

- The existing provisions do not encompass access to patented inventions on competition grounds. Adopting options 2 or 3 would be more in line with the Government's competition policy than adopting option 1.

### *Benefits*

#### **Industry**

- Patent applicants are familiar with current requirements and will not have to familiarise themselves with new requirements.
- Interest groups have advised that the existing provisions encourage patent owners to license their patents on mutually agreed terms because alternative access to the invention by the compulsory licensing provisions is a significant threat. Therefore, the existing provisions provide for more ready access to new technology in the marketplace.
- The interests of the patentee are adequately protected by existing provisions that allow the patentee an opportunity to provide a satisfactory reason for failing to exploit the invention and, if a compulsory licence is granted, ensure they are paid either an agreed amount or an amount determined by the court. The infringement provisions in the Patents Act will pick up any other infringement of their patent, including if the compulsory licensee uses the invention outside the terms of the licence.

#### **Consumers**

- The IPCR Committee found that the threat of compulsory licences may lead to inventions being worked earlier and more widely than they might otherwise have been worked. The

existing provisions provide relatively broad conditions for the grant of a compulsory licence and, therefore, a greater incentive to patent owners to negotiate voluntary licensing arrangements rather than not use their invention. This gives consumers greater access to new technology.

- The existing provisions provide for access to patented inventions on broader public interest grounds than competition alone. They therefore take the interests of the public into account more than a competition test alone would.

### **Government**

- No legislative change will be needed.

Option 2: Adopt the recommendation of the IPCR Committee to replace the existing provisions with a competition test.

### *Costs*

### **Industry**

- The existing compulsory licensing provisions cover conduct that would not be encompassed by a competition test, such as where the invention is not being used commercially in Australia. A competition test would only pick up this conduct if the failure to use the invention resulted in anti-competitive conduct. Adopting this option would therefore result in a narrower test for the grant of a compulsory licence. While this could benefit patentees, it would reduce the access of other parties to patented inventions.

### **Consumers**

- By reducing the threat of compulsory licences, patentees will be in a stronger position when negotiating licensing arrangements. This could mean licencees will have to pay more for a licence, therefore increasing the cost of patented products in the market.

### **Government**

- Adopting the IPCR Committee's recommendation would result in more stringent conditions for the grant of a compulsory licence than are applied in Canada, the United Kingdom and the United States. The patents legislation in these countries contain similar grounds for compulsory access to patented inventions as the existing provisions in the Australian legislation. There is an emphasis on preventing industry in the relevant country from being prejudiced by the refusal of the patentee to work the invention or license the patent to another party (similar to paragraphs 135(1)(a) and (b) in the existing provisions). Each of these countries also provide for access to the invention where it is not being worked at all, or to a sufficient extent (similar to paragraph 135(1)(c)). Article 30 of the TRIPS Agreement allows member States to provide for compulsory access to patented inventions, but does not set an international standard for such access. compulsory licences, internationally, there is increasing focus on harmonisation of patent laws and Australia may attract criticism if it departs too far from international standards.
- The IPCR Committee recommended that applications for compulsory licences should be heard by the Australian Competition Tribunal (ACT). However, the Australian Competition and Consumer Commission (ACCC) advised that the ACT is not the appropriate body to hear applications for compulsory licences in the first instance because it is essentially a review body — its primary role being to reconsider certain decisions made by the ACCC. If the IPCR Committee's recommendation is accepted then jurisdiction to grant compulsory licences should remain with the Federal Court, but be removed from the state and territory Supreme Courts.

### *Benefits*

#### **Industry**

- Patentees will be in a stronger position when negotiating licences and will probably be able to procure a higher licence fee. This would mean that the 'reward' for the patentee's innovation is greater.

#### **Consumers**

- If there is a greater financial incentive to innovate then it may follow that more innovations will be produced.

#### **Government**

- By putting a competition focus on the grant of a compulsory licence, this option would be in line with the Government's competition policy.

Option 3: Amend section 133 to add a competition test to the existing provisions and restrict the jurisdiction to grant compulsory licences to the Federal Court.

### *Costs*

#### **Industry**

- There may be an increased cost to patentees because there will be an additional ground on which third parties can gain access to a patented invention. However, access could only be obtained under the competition test if the patentee is engaging in anti-competitive conduct.
- As with option 1, retaining the existing provisions may impose a cost on patentees by allowing easier access to their inventions than adopting option 2 would allow.
- Currently, applications for compulsory licences can be heard by the state and territory Supreme Courts and the Federal Court. If this option is adopted, the Federal Court alone would have jurisdiction to hear applications because the Supreme Courts do not have expertise in competition matters. This will mean that the cost of obtaining a compulsory licence will be more than if the ACT had jurisdiction to grant compulsory licences. However, as discussed under option 2, the ACT would not be an appropriate body to hear applications for compulsory licences and the cost of obtaining a compulsory licence under option 3 should not be more than under the existing provisions. Furthermore, the main reason for retaining the existing provisions is to maintain the indirect effect that the provisions have on licence negotiations and it should continue to be rare that a compulsory licence will be sought in the court.

#### **Consumers**

- There should be no costs to consumers.

#### **Government**

- There should be no costs to Government.

### *Benefits*

#### **Industry**

- The competition test will pick up activities that are not currently covered by the existing compulsory licensing provisions, so access by other parties to patented inventions may be increased by adding an additional ground on which they can obtain a compulsory licence.
- Retention of the existing provisions will have the same benefits as discussed under option 1.

## **Consumers**

- The addition of a competition test as a ground for compulsory access to patented inventions will mean that certain anti-competitive behaviour will be addressed. It will also act to discourage patentees from entering into anti-competitive practices.
- Retention of the existing provisions will have the same benefits as discussed under option 1.

## **Government**

- Adding a competition test to the existing provisions is also in line with the Government's competition policy.
- If this option is adopted then the Federal Court would be the appropriate body to hear applications for compulsory licences because it has expertise in both competition law and patents law.

## **CONSULTATIONS**

The consultations are the same as indicated in the discussion of prior use.

## **CONCLUSION AND RECOMMENDED OPTION**

Adopting option 1 would impose few costs on any of the impact groups, but also contains fewer benefits than option 3. Adopting option 2 would benefit patentees more than the other options because it would provide more stringent requirements for gaining access to patented inventions. However, this benefit to patentees would be outweighed by the costs imposed on consumers and other members of the industry impact group by resulting in higher licensing fees and, potentially, higher prices for patented inventions.

Overall, option 3 strikes the most appropriate balance between the interests of the general public and patent owners. Of all the options, it would impose the least cost on the impact groups, while retaining the benefits of the existing provisions as well as providing additional benefits.

By adding an additional ground on which a compulsory licence can be obtained, access to patented inventions may be increased slightly, but only in circumstances where there is anti-competitive conduct. In addition, the existing provisions only apply in certain circumstances where the patentee is engaged in conduct that is contrary to the public interest. The interests of the patentee are adequately protected by existing provisions that allow the patentee an opportunity to provide a satisfactory reason for failing to exploit the invention and, if a licence is granted, ensure they are paid either an agreed amount or an amount determined by the court. The infringement provisions in the Patents Act will pick up any other infringement of their patent, including if the compulsory licensee uses the invention outside the terms of the licence.

It is recognised that the patentee enjoys a limited monopoly right and it is not envisaged that the competition test would allow access to an invention to compete with the patentee, who may be the sole provider of the patented invention. The competition test should only apply where there is anti-competitive conduct that goes beyond the extent of the granted patent right.

Although option 3 will reduce access to the decision-making body by restricting jurisdiction to the Federal Court alone, the premise on which this recommendation is made is that the compulsory licensing provisions are rarely used directly. Rather, the indirect effect they appear to have on licensing negotiations is relied on more by industry so it should continue to be rare that a compulsory licence will be sought in the court.

In view of this, it is recommended that the Government endorses option 3 to add a competition test as an additional ground on which a compulsory licence can be obtained, and that orders for compulsory licences be obtained from the Federal Court.

## IMPLEMENTATION AND REVIEW

Amendments will need to be made to the Patents Act to implement option 3. An evaluation of the new compulsory licensing provisions will be undertaken 5 years after implementation of the legislation to assess how well it has met its objectives.

## SPRINGBOARDING ON PHARMACEUTICAL PATENTS

### BACKGROUND

#### Pharmaceuticals Industry in Australia

The pharmaceuticals industry in Australia includes originator companies (usually a subsidiary of a multinational company), biotechnology companies and generics companies, as well as a range of related service providers. The industry employs approximately 36,000 people. The value of Australian pharmaceutical exports totalled \$2.8 billion for the 2004-2005 fiscal year. Imports of pharmaceuticals are much greater than exports and were worth \$4.4 billion in 2003.

The prescription pharmaceuticals industry in Australia was valued at approximately \$6.9 billion (retail and hospital markets combined) in 2004. The top ten prescription pharmaceutical suppliers into the Australian market are multinational companies and they account for 60% of total pharmaceutical sales (ex manufacturer). Only three Australian companies were in the top 25 companies in Australia based on sales in 2004.

The generics retail (prescription) market is dominated by two Australian based companies which together hold 92 per cent of this market (estimated to be worth approximately \$600 million in 2004). The generics hospital market is dominated by two other Australian based companies which together hold 56 per cent of this market (estimated to be worth approximately \$116 million in 2004).

#### Generic Pharmaceuticals Industry in Australia

A generic version of a medicine has the same active ingredient, is manufactured to the same standard, and has the same clinical effect as the original version. The generic pharmaceuticals sector worldwide is expanding rapidly, fuelled by the expiration of patents on many high-selling medications and Government incentives to increase usage of low cost generics.

Forecasts suggest that the value of the generics sector in Australia will increase from approximately \$0.9 billion in 2004 (13% of total value) to \$2 billion by 2008. The generics sector is currently growing faster than the originators sector; growth that is being driven by the expiry of patents on those drugs that are, in Australia, in the top 100 drugs (based on cost to Government) on the Pharmaceutical Benefits Scheme (PBS). Twelve of the top twenty PBS-listed drugs (based on cost to Government) will have expired patents by 2008. According to one generic drug company the cost of these drugs to Government was approximately \$1.3 billion in 2003 and represented 28 million prescriptions. Generic versions of these drugs will be available in the Australian market soon after patent expiry, imported from overseas if they cannot be developed in Australia.

The generics sector in Australia now contains eight dedicated generics companies selling PBS-listed medications. Significant amounts are invested in generics research and development (R&D) in Australia each year by generics companies (up to \$36 million) and which has generated significant capital investment and skilled employment in Australia. The Generics Medicines Industry Association estimates its members employ approximately 3000 people and contribute 33% of pharmaceutical exports. Increasingly, the difference between the generics and originator sectors is becoming blurred as originator companies seek market share in generics and generics companies invest in innovative R&D.

To obtain approval for a generic version of a drug, generics companies need to demonstrate equivalence to the existing product. They do not need to do the level of clinical trials the originator does as they are relying on the originator's data, so the development of a generic is less expensive. It has been estimated that bringing a generic to market can cost between \$0.25 and 1 million and much of this cost is expended on bioequivalence and other studies. However, the generic drug cannot be registered until the originators' data exclusivity period has expired

and cannot go onto the market until the patent has expired (unless the generic manufacturer is prepared to challenge the patent or is licensed by the patent holder). The lead time for R&D and regulatory approval to bring a generic medicine to market is between two and six years, and sometimes longer. This means that if the patents surrounding a drug are not eligible for springboarding in Australia it can take two to six years after patent expiry for a generic company to bring the product to market if the development work is done in Australia. To ensure timely entry onto the market after patent expiry, generics companies seek to do the development they need to, and obtain regulatory approval, before patent expiry. It should be noted that generic versions of these drugs will be available in the Australian market soon after patent expiry, imported from overseas if they cannot be developed in Australia.

#### Current Springboarding Provision

The *Patents Act 1990* ('the Act') currently contains a limited provision that allows activity to be undertaken by generics manufacturers during the patent period to enable them to collect the information required to obtain regulatory approval, known as 'springboarding'. The springboarding provision was intended to allow earlier regulatory approval for generic pharmaceuticals, faster market entry upon patent expiry and prevent originator companies from receiving further de facto extension of patent term. This provision is however tied to the patent term extension scheme for pharmaceuticals which was inserted in the Act by the *Intellectual Property Laws Amendment Act 1998* ('the 1998 Act'). Springboarding can only be undertaken on pharmaceutical substance patents once an extension is granted.

There are broadly four types of pharmaceutical patent: those on the active pharmaceutical ingredient (API); the formulation of the medication; the process for making the API; and methods of use of the medication. Only patents which claim a pharmaceutical substance (ie API) are currently eligible for patent extension in Australia. Pharmaceutical products are frequently the subject of multiple patents which cover different aspects of the product. These patents are potentially of different types, some of which may not be eligible for extension. In some cases the most important (or 'blocking') patent may not be extended and thus the most important springboarding work cannot be done until this patent expires in Australia.

On 28 June 2002, the Prime Minister wrote to the Minister for Industry, Tourism & Resources, the Hon Ian Macfarlane MP, asking that an Interdepartmental Committee (IDC) be set up to examine the impact of patent extensions and springboarding provisions on generic manufacturers. The IDC concluded that under Australia's current patent scheme, due to differences in the pharmaceuticals regulatory approval process and intellectual property laws in other countries, approximately 66% of pharmaceutical patents expire later in Australia than overseas. The IDC identified that Australia's springboarding provisions were limited compared to those in competing markets (such as the USA, Canada and New Zealand; with Singapore having already implemented such provisions; and EU members required to introduce similarly broader provisions by 30 October 2005) and inhibit work being carried out in Australia to obtain regulatory approval in Australia and overseas. The IDC further concluded that under the current springboarding provisions, Australian manufacturers of generic drugs were prevented from competing in lucrative export markets on equal terms with their overseas competitors.

Pharmaceutical substance patents are granted an extension of patent term (and consequently become subject to springboarding) in recognition of the lengthy regulatory approval process required before pharmaceuticals can be marketed.

## PROBLEM

### *What is the Problem Being Addressed?*

Australia's current springboarding provisions place limitations on generic pharmaceutical R&D. The current springboarding provisions only allow springboarding on patents that have been extended after the extension has been granted. These provisions are thus more restrictive than similar provisions overseas, where springboarding is allowed on all pharmaceutical patents. In some circumstances this will mean that local generic companies cannot enter the domestic market on, or soon after, patent expiry on a pharmaceutical substance unless the development work has been conducted overseas. This disadvantages the Australian generics industry and provides an incentive for companies to move their development activity offshore.

### *Why is Government Action Needed to Correct the Problem?*

These disadvantages can only be removed by reforms to the current intellectual property (IP) regulatory framework.

## OBJECTIVES

### *What are the Objectives of Government Action?*

The objective of this policy is to encourage the retention and growth of a competitive generic pharmaceuticals R&D industry in Australia, by building critical mass in the industry, for example in companies that provide services in support of R&D, and associated skilled employment opportunities.

### *Is there a regulation/policy currently in place? Who administers it?*

The current regulatory framework is governed by the *Patents Act 1990* as amended by the *Intellectual Property Laws Amendment Act 1998* which is administered by IP Australia.

## OPTIONS

### *Option 1 – Status Quo*

Maintain the status quo.

### *Option 2 – Widen the Springboarding Provision*

The current springboarding provisions could be widened to allow springboarding on any pharmaceutical patent at any time for purposes related to generating information necessary to support an application for regulatory approval of a pharmaceutical product in Australia or another territory. In the latter case, any pharmaceutical product covered by a patent could not be exported unless the patent for that product has been granted an extension of term. Maintaining consistency with Australia's international obligations including the Australia-US Free Trade Agreement (AUS FTA) and the World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) limits Australia's capacity to implement springboarding more broadly.

## IMPACT ANALYSIS

*Who is affected by the problem and who will be impacted by the costs and benefits associated with the problem?*

### **Business**

Those businesses most affected by the problem are generic pharmaceuticals manufacturers. Some originator manufacturers and contract manufacturers that produce generic pharmaceuticals may also be affected. Companies that produce generic pharmaceuticals will benefit from this

proposed change through less restrictive legislation. Originator companies have argued that this change will undermine the value of their patents.

**Government**

There are unlikely to be significant costs or benefits to Government from these changes. There is no increase in administrative cost and, to the extent that generic medicines are able to enter the market more quickly, this proposal has the potential to increase competition and lower Pharmaceutical Benefits Scheme (PBS) costs.

**Consumers**

There are unlikely to be significant costs or benefits to consumers from these changes. Consumers may be better off depending on the extent to which an increase in competition results in the price of more prescription medicines falling below the patient co-payment.

*How will each proposed option affect existing regulations and the roles of existing regulatory authorities?*

Option 1 – Will not change the existing regulations, nor would it alter the roles of existing regulatory authorities.

Option 2 – The Australian Government Solicitor certifies that amendments to the *Patents Act 1990* would be required to implement Option 2. However, the operation of springboarding will not require IP Australia to take or cease to take any decision and therefore will not impact on the current role of IP Australia. This option involves reducing the level of regulation for generic companies by altering the timing and circumstances under which certain activity is allowed and therefore improves the business environment for generics companies wanting to undertake R&D in Australia.

*Identify and categorise the expected impacts of the proposed options as likely benefits or likely costs*

Table 1: Option 1

	<b>Benefits</b>	<b>Costs</b>
<i>Generic pharmaceutical manufacturers</i>	<ul style="list-style-type: none"> <li>• None</li> </ul>	<ul style="list-style-type: none"> <li>• Incentive to move approximately \$36 million per annum in generics R&amp;D offshore, to a country with wider springboarding regime;</li> <li>• Reduces investment attractiveness of sector;</li> <li>• Slows the demand for skilled employees; and</li> <li>• Slows the rate of technology transfer to Australia.</li> </ul>
<i>Originator Companies &amp; Biotechs</i>	<ul style="list-style-type: none"> <li>• More generous patent extension scheme and greater protection from domestic competition than in competitor countries.</li> </ul>	<ul style="list-style-type: none"> <li>• None</li> </ul>
<i>Government</i>	<ul style="list-style-type: none"> <li>• No change in legislation</li> </ul>	<ul style="list-style-type: none"> <li>• Generic medicines may not come to market as quickly as they would under Option 2.</li> </ul>
<i>Consumers</i>	<ul style="list-style-type: none"> <li>• None</li> </ul>	<ul style="list-style-type: none"> <li>• Prices of PBS medicines may not fall as quickly as they would under Option 2.</li> </ul>

Table 2: Option 2

	Benefits	Costs
<i>Generic pharmaceutical manufacturers</i>	<ul style="list-style-type: none"> <li>• Reduces the incentive to move R&amp;D offshore, retaining approximately \$36 million of generics R&amp;D per annum;</li> <li>• Reduction in regulatory barriers surrounding generic R&amp;D;</li> <li>• Increases the investment attractiveness of sector;</li> <li>• Improves the demand for skilled employees;</li> <li>• Improves the rate of technology transfer to Australia; and</li> <li>• No ongoing compliance costs.</li> </ul>	<ul style="list-style-type: none"> <li>• None</li> </ul>
<i>Originator Companies &amp; Biotechs</i>	<ul style="list-style-type: none"> <li>• None</li> </ul>	<ul style="list-style-type: none"> <li>• Diminution in scope of patent protection (in line with that in other competitor countries and consistent with international obligations).</li> </ul>
<i>Government</i>	<ul style="list-style-type: none"> <li>• No increased administration costs;</li> <li>• Generic medicines may come to market more quickly leading to increased competition and potentially lower cost to the PBS.</li> </ul>	<ul style="list-style-type: none"> <li>• Change in legislation</li> </ul>
<i>Consumers</i>	<ul style="list-style-type: none"> <li>• Increased competition between PBS suppliers may result in prices of prescription medicines falling below patient co-payments.</li> </ul>	<ul style="list-style-type: none"> <li>• None</li> </ul>

It should be noted that generic versions of these drugs will be available in the Australian market soon after patent expiry, imported from overseas if they cannot be developed in Australia.

It is difficult to quantify both the potential loss in investment by generics companies likely if the status quo under Option 1 is maintained and the value of the potential benefits in generic R&D if Option 2 is implemented. All three of the generic pharmaceutical companies that do significant generics R&D in Australia have facilities outside Australia, making it significantly more likely that they will move their remaining generics R&D offshore if they are significantly limited in what they can do in Australia, as they are under Option 1. Widened springboarding will remove the incentive to disinvest and will increase R&D expenditure in Australia because it will allow Australian generics companies to take advantage of Australia’s competitive advantages in R&D and clinical trials to gain regulatory approval in the domestic and overseas markets (although in the latter case under more limited circumstances). Option 2 will not increase compliance costs for business as the scheme does not require any administration by IP Australia or any other Government department.

## CONSULTATION

An IDC was established in 2002 to examine the issue of patent extensions and springboarding which was chaired by the Department of Industry, Tourism & Resources (DITR). DITR released

a discussion paper, consulted with stakeholders and took 17 submissions from interested parties including both originator and generic manufacturers. Generic companies were in favour of widened springboarding (Option 2) whereas originator companies favoured no change to the status quo (Option 1). A summary of the opinions of stakeholders that made submissions to the IDC is shown in Table 3.

Table 3: Summary of consultation

Industry Sector	For or Against Widened Springboarding	Comments
Generics (3 companies and a research organisation)	For	Strongly supportive of a widened springboarding scheme. Indicated that the current springboarding provisions are limiting and influence investment decisions. Strongly indicated that generic companies will relocate their R&D offshore if the current provisions are maintained.
Originators (10 companies and the industry association)	Against	Changes to springboarding generally unwelcome. Springboarding should remain linked to the extension of patent term scheme.
Biotechs (1 company and the industry association)	Against	Springboarding undermines patent rights and 'sends the wrong message'.

There has not been wide industry consultation again on this proposal because there is no indication that industry groups have changed their position. The generics industry has recently reiterated its opinion that generics R&D will be lost to overseas countries if the status quo is maintained. Despite opposition in the originators sector to the proposal to widen springboarding, it was acknowledged to the IDC during consultation sessions that they face generic competition as soon as the patent expires, from generic drugs produced overseas.

## CONCLUSION AND RECOMMENDED OPTION

The current IP regulatory framework restricts generic manufacturers from developing products in Australia. The proposal seeks to allow springboarding on any pharmaceutical patent at any time for purposes related to generating information necessary to support an application for regulatory approval of a pharmaceutical product in Australia or another territory. In the latter case, any pharmaceutical product covered by a patent could not be exported unless the patent for that product has been granted an extension of term. This change would bring Australia closer into line with other jurisdictions such as the US and with changes in the EU, which is important in maintaining Australia's competitiveness as an investment location for generics R&D.

Springboarding would allow generic manufacturers to more rapidly enter the Australian market post-patent expiry and has the potential to encourage greater investment by the generics sector in Australia. Accordingly, it is recommended that a widened springboarding exception to patent infringement be implemented.

## Notes on Clauses

### **Clause 1—Short title**

1. Clause 1 provides for the Act to be cited as the *Intellectual Property Laws Amendment Act 2006*.

### **Clause 2—Commencement**

2. Clause 2 provides for the commencement of the Act, setting out the commencement information in a table. Subclause 2(1) provides that each provision of the Act specified in column 1 of the table commences, or is taken to have commenced, as specified in column 2 of the table.

3. There are sixteen items in the table in subclause 2(1).

- (a) Item 1 explains that sections 1 to 3 all commence on the day on which the Act receives the Royal Assent.
- (b) Items 4, 7, 9, 11 and 13 explain that Part 1 of Schedule 3, and Schedules 5,6, 7-9, 11 and 13 to 15 will all commence on the day after the Act receives the Royal Assent.
- (c) Items 2, 3, 5, 6, 10 and 12 explain that Schedules 1, 2, Part 2 of Schedule 3, and Schedules 4, 10 and 12 commence on a day to be fixed by Proclamation or, at the latest, 6 months after Royal Assent.
- (d) Item 8 explains that Schedule 7 commences on the 28<sup>th</sup> day after the day on which this Act receives Royal Assent.
- (e) Items 14–16 explain that items 1–3 of schedule 16 commence on or immediately after earlier Acts to which the amendments relate.

### **Clause 3—Schedule**

4. This clause provides that each Act specified in a Schedule is to be amended or repealed according to the relevant provisions of that Schedule. Any item in a Schedule has effect according to its terms.

### **Schedule 1—Revoking registration of trade marks etc.**

#### *Trade Marks Act 1995*

5. Under the *Trade Marks Act 1995*, the Registrar of Trade Marks (the Registrar) examines applications for registration of trade marks against statutory grounds of rejection, and if satisfied that there are no grounds on which the application should be rejected, and that the application has been made in accordance with the Trade Marks Act, the Registrar must accept the application. The Registrar must then advertise the application to give third parties an opportunity to oppose the registration of the trade mark. If no party opposes registration, or if despite an opposition the Registrar decides there are no grounds on which the Registrar must refuse to register the trade mark, the Registrar must register the trade mark.

6. From time to time, the Registrar registers trade marks that, for one reason or another, should not be registered. These usually occur as the result of an administrative oversight or error. Examples include:

- when grounds on which the trade mark should have been rejected were inadvertently overlooked during examination of the application for registration of the trade mark. Such grounds can include prior registrations of similar trade marks for similar goods and/or services or information indicating that the trade mark is descriptive of the goods and/or services;

- oppositions to the registration of a trade mark that were not processed in accordance with the Trade Marks Act, resulting in the trade mark being registered without an opposition having been heard, even though a notice of opposition was filed within the correct time, or where an extension of time to file a notice of opposition was not processed in accordance with the Trade Marks Act;
- late notification of marks that have priority pursuant to their application under the *Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks 1989* (the Madrid Protocol) designating Australia, for a similar mark for similar goods and/or services;
- registered trade marks that otherwise do not meet the requirements of the *Trade Marks Act 1995* or the *Trade Marks Regulations 1995*, for example, because statutory procedures were not followed during the registration process.

7. While administrative errors of this sort are rare, they do occur from time to time. They have the effect of giving the owner of the incorrectly registered trade mark some of the benefits of a trade mark registration to which they are not entitled under the Trade Marks Act, and would not have received but for the oversight or error. For example such incorrect registrations can allow the registered owners to benefit from the reputation of the owner of a conflicting (correctly registered) trade mark. This owner would be forced to take action in the courts to protect their rights, which have been put into jeopardy by an administrative error or oversight on the part of the Registrar of Trade Marks. Also, the presence of two similar registered trade marks in the marketplace may confuse consumers about the relationship between the trade marks, the owners, and possibly the quality of the goods or services covered by the trade marks. Such confusion does not serve the public interest.

8. If a trade mark has been accepted in error, and this is realised before the trade mark proceeds to registration, the Registrar has the power to revoke the acceptance of the trade mark under section 38 of the Trade Marks Act, and is then able to examine the application once again in order to remedy the issue. This provides a simple and inexpensive administrative procedure for remedying deficiencies in a trade mark before it proceeds to registration.

9. However, if a deficiency is not realised until *after* the trade mark has been registered, there has hitherto been no similar straightforward administrative remedy. Instead, more expensive legal action would have to be pursued through the courts in order to rectify the situation.

10. The present system therefore does not fully serve the public interest in keeping invalid registrations off the Register.

11. To address this, Schedule 1 to the Bill gives the Registrar, in appropriate circumstances, the power to revoke the registration of a trade mark on his or her own initiative. This Schedule proposes to implement a comprehensive scheme for administrative revocation of the registration of a trade mark. It is intended that this scheme will provide a quicker and simpler way for users of the trade mark system to have administrative errors and oversights rectified rather than having to seek redress in the courts.

12. The proposed provision aims to strike an appropriate balance between the interests of the public and the interests of the registered owner in reaching a decision whether or not to revoke a registration.

## Item 1

13. This item repeals subsection 38(1) of the Trade Marks Act, and replaces it with a new provision that allows the Registrar to revoke the acceptance of a trade mark if he or she is *satisfied* that it is reasonable to do so taking into account all of the circumstances.

14. Subsection 38(1) of the Trade Marks Act as presently enacted allows the Registrar to revoke the acceptance of a trade mark application in certain circumstances. These circumstances relate to whether the application for registration of the trade mark was accepted because of an error or omission in the course of examination, or to 'special circumstances' of the case. This provision has been interpreted in a narrower manner than was originally intended, so that certain classes of errors or omissions, and certain types of special circumstances, have been held not to fall within the operation of the provision. One of the aims of the provision is to put beyond doubt that the Registrar may take account of *all* circumstances when deciding whether to revoke the acceptance of a trade mark, and not just a limited sub-class of circumstances.

15. Paragraph 38(1)(a) clarifies that the Registrar is able to take account of *any* circumstance that existed which should have prevented acceptance. It is not necessary that the Registrar knew or was in a position to know of the existence of the circumstances at the time the application was accepted for this paragraph to apply. This may include an error of judgement or omission on the part of the examiner, or information about the trade mark that was not available to the Registrar at the time of examination, for example:

- the examiner may have overlooked or discounted information that would lead, if properly considered, to the examiner rejecting the application; or
- an international application for a conflicting mark having an earlier priority date had not yet been filed in Australia.

The Registrar is not limited in what he or she may consider.

16. Paragraph 38(1)(b) clarifies that the Registrar must have regard to *all* the circumstances when deciding whether it is reasonable to revoke a registration. For example, the Registrar may consider that it is not reasonable to revoke acceptance if the applicant agrees to amend the application so that certain conditions and limitations are placed upon the trade mark. This consideration is not limited to the circumstances as they existed when the trade mark was accepted. Further, the Registrar is not limited in what he or she may consider.

17. The new provision will allow the Registrar to revoke acceptance of a trade mark only when this course of action is reasonable, taking account of all of the circumstances. The intention of this provision is to focus attention on the reasonableness of the Registrar's actions, and not on whether or not an 'error or omission' or a 'special circumstance' preceded the registration of the trade mark.

18. This provision ensures that the Registrar will be in a better position to effectively keep invalidly accepted trade mark applications from becoming registered, thus protecting the public interest.

## Item 2

19. This item is an application provision. The amendment to section 38 of the Trade Marks Act will apply to any trade mark application, whether accepted before, on or after commencement of the provision.

20. The amendment to subsection 38(1) applies prospectively, to any acceptance that the Registrar revokes after commencement of the provision.

### Item 3

21. Item 3 inserts a note into section 73 to highlight to readers that section 84C explains the effects of revocation of registration of a trade mark under sections 84A and 84B.

### Item 4

22. This item repeals the heading for Part 8, and substitutes a new heading, 'Amendment, cancellation and revocation of registration'.

### Item 5

23. This item inserts a new subdivision heading in Division 1 of Part 8, 'Amending Register'.

### Item 6

24. This item inserts a new subdivision heading in Division 1 of Part 8, 'Cancelling Registration'.

### Item 7

25. This item inserts a new subdivision heading in Division 1 of Part 8, 'Revoking registration'.

26. The item also adds new sections 84A, 84B, 84C and 84D, which relate to revoking registration of a trade mark by the Registrar, and the effects of such a revocation.

## Section 84A

27. Section 84A sets out the circumstances in which the Registrar may, but is not obliged to, revoke the registration of a trade mark.

28. Under subsection 84A(1), the Registrar may revoke the registration of a trade mark if he or she is satisfied that the following two criteria are satisfied:

- (a) the trade mark should not have been registered, taking account of all the circumstances that existed when the trade mark became registered (whether or not the Registrar knew then of their existence); and
- (b) it is reasonable to revoke the registration, taking account of all the circumstances.

29. Paragraph 84A(1)(a) clarifies that the Registrar is able to take account of *any* circumstance that existed which should have prevented registration. It is not necessary that the Registrar knew or was in a position to know of the existence of the circumstances for this paragraph to apply. An example of a circumstance of which the Registrar would not have been aware, and could not have been aware, is that of a late notification under the Madrid Protocol. This is a circumstance that the Registrar would be able to take into account when exercising the discretion to revoke registration. An example of a circumstance of which the Registrar may not have been aware, but could have been aware, is when a conflicting trade mark for similar goods and services is not taken into proper account during examination of the application for registration of the trade mark. This is another circumstance that the Registrar would be able to take into account when exercising the discretion to revoke registration.

30. Paragraph 84A(1)(b) clarifies that the Registrar must have regard to *all* the circumstances when deciding whether it is reasonable in all the circumstances to revoke a registration. This consideration is not limited to the circumstances as they existed when the trade mark became registered.

31. Subsection 84A(2) sets out the kind of circumstances that the Registrar *must* take into account under paragraph 84A(1)(a). These circumstances include the following:

- (a) any errors (including errors of judgment) or omissions that led directly or indirectly to the registration;
- (b) any relevant obligations of Australia under an international agreement;
- (c) any special circumstances making it appropriate:
  - (i) not to register the trade mark; or
  - (ii) to register the trade mark only if the registration were subject to conditions or limitations to which the registration was not actually subject.

32. However, the Registrar is obliged to take account of *all* the circumstances that existed at the time the trade mark became registered, and not just the circumstances listed in subsection 84A(2).

33. Paragraph 84A(2)(a) clarifies that *any* error of the Registrar may be taken into account in deciding whether to revoke a registration, and that the provision does not refer to a limited class of errors only. Paragraph 84A(2)(b) includes obligations under the Madrid Protocol. Paragraph 84(2)(c) clarifies that the sort of considerations that have hitherto been taken into account when exercising the discretion under subsection 38(1)(b) are still able to be considered when exercising the discretion under section 84A. However, such considerations will not limit the extent of the Registrar's discretion.

34. Subsection 84A(3) sets out the kind of circumstances that the Registrar *must* take into account under paragraph 84A(1)(b). These are circumstances on which a registered owner would be expected to rely in order to convince the Registrar that he or she should not revoke the registration. These circumstances include, but are not limited to, the following:

- (a) any use that has been made of the trade mark;
- (b) any past, current or proposed legal proceedings relating to the trade mark as a registered trade mark or to the registration of the trade mark;
- (c) other action taken in relation to the trade mark as a registered trade mark;
- (d) any special circumstances.

35. However, the Registrar is obliged to take into account *all* of the circumstances, and not just the circumstances listed in subsection 84A(3).

36. Paragraph 84A(3)(a) relates to use that has been made of the trade mark. Sufficient use of a trade mark can overcome several of the grounds on which an application for registration of a trade mark would otherwise be rejected or refused. Therefore if the Registrar is satisfied that, when the application for registration of the trade mark became registered, it should not have been registered because he or she is satisfied that some ground for rejection or refusal is made out, and if the use that the registered owner has made of that registered trade mark would overcome that ground of rejection or refusal, then the Registrar may conclude that revocation of the registration would not be reasonable in all the circumstances.

37. Paragraph 84A(3)(b) relates to court actions involving the registered trade mark. For example, if the registered owner is relying or intends to rely on the registered trade mark in an

infringement proceedings, the Registrar may conclude that it is not reasonable to revoke the registration of the trade mark.

38. Paragraph 84A(3)(c) intends to cover administrative actions that rely on the registered trade mark, such as opposing geographical indications under the *Australian Wine and Brandy Corporation Act 1980*.

39. Paragraph 84A(3)(d) relates to any special circumstances making it appropriate to revoke the registration or not to revoke the registration. This intends to cover the special circumstances considered under the presently enacted paragraph 38(1)(b) for revocation of acceptance. However, this paragraph does not limit the special circumstances to only those consideration.

40. Subsection 84A(4) limits the time in which the Registrar may give notice of the intention to revoke a registered trade mark. In order to revoke registration, the Registrar must notify the owner of the trade mark and any person recorded as claiming a right in the trade mark within 12 months of registering the trade mark.

41. A trade mark is considered to be registered on the day on which the particulars of the trade mark are entered onto the Register under the provisions of section 69 of the Trade Marks Act.

42. The period of 12 months represents a balance between the interests of the registered owner of the trade mark in having a registration that is not vulnerable to revocation by the Registrar for too long a period, and the interests of the public in not having invalid registrations on the Register.

43. Subsection 36(1) of the *Acts Interpretation Act 1901* applies to this 12 month time period.

44. It is acknowledged that some registrations for which revocation would be appropriate will be discovered outside of this 12 month period, and that in such circumstances the Registrar will be unable to make use of the revocation of registration provisions. However, recourse is still available to the courts in such situations, and this is considered an acceptable trade-off given the interest of the registered owners of trade marks in having strong rights arising from a registered trade mark.

45. Subsection 84A(4) requires the Registrar to notify the persons listed in paragraphs (a) and (b) of that subsection prior to revoking registration of a trade mark. This provision guarantees that these persons will be aware of the potential decision, and will be in a position to consider whether or not they wish to make a case before the Registrar to argue that the Registrar should not revoke the registration.

46. Subsection 84A(5) guarantees that the persons mentioned in subsection 84A(5) are given an opportunity to be heard before the Registrar revokes a registration. This hearing, as with all trade marks hearings may be by submissions, by requesting a formal hearing or both. In this hearing, they have an opportunity to give arguments as to why the Registrar should not revoke the registration. The issues they may wish to rely on include, but are not limited to, the considerations listed in subsection 84A(1), (2) and (3).

47. Subsection 84A(6) clarifies that the Registrar does not have a duty to consider whether to revoke a registration, whether or not the Registrar is requested to do so.

48. This means that third parties will not have a right to urge the Registrar to consider revocation of a trade mark in particular situations. Revocation of registration under section 84A is not intended to provide a way of settling competing claims to ownership of a trade mark. This

can be pursued through the courts, with section 86 of the Trade Marks Act providing for the Federal Court to cancel a registered trade mark. Nor is it intended to be a mechanism for parties to file *de facto* oppositions after a trade mark has been registered. This provision is only intended to provide an administrative mechanism to undo a registration where it was wrongly registered.

49. This subsection will not prevent third parties bringing potentially invalid registrations to the Registrar's attention. Nor will it prevent the Registrar from considering such submissions and acting on them. It clarifies that the Registrar is under no duty to consider any such input from third parties, so that such parties are not in a position to insist that the Registrar acts on their information. This is reasonable given the other remedies that such parties can access.

## **Section 84B**

50. Section 84B sets out a circumstance in which the Registrar is obliged to revoke the registration of a trade mark.

51. From time to time, notices of opposition or applications for extensions of time in which to file notices of opposition to registration of trade marks which are filed on time are, due to administrative delays in the Trade Marks Office or in sub-offices of the Trade Marks Office, not brought to the attention of the Registrar prior to the trade mark being registered. Trade marks may subsequently be registered without an opposition to the registration of the trade mark being considered as required under paragraph 68(1)(a) of the Trade Marks Act.

52. This provision will oblige the Registrar to revoke the registration if the notice or application is filed in the appropriate time, and the Registrar becomes aware of the facts within one month of the date that the notice was filed or the application was made. The Registrar will also be obliged to revoke the registration under this provision within one month from the date on which the notice was filed or the application was made.

53. If the Registrar becomes aware of the circumstances set out in paragraphs 84B(a) and (b) outside this one month period, or if the Registrar becomes aware of these circumstances within this one month period but does not, for whatever reason, revoke the registration before this month has elapsed, the Registrar will still be able to revoke the registration under section 84A, following the procedures set out in that section.

54. For a revocation under this provision, the registered owner will not have an opportunity to be heard before the registration is revoked. As this section only applies to trade marks that were registered purely as a result of an administrative oversight, and as the one month time is considered to be too short a time for the registered owner to have built up any rights in respect of the mark, it is considered that a hearing prior to the revocation of the registration would only delay unduly the overlooked opposition from proceeding. There is a strong public interest in such proceedings being processed expeditiously, to ensure that invalidly registered marks do not stay on the Register.

## **Section 84C**

55. This section sets out the effects of revoking registration of a trade mark.

56. By virtue of subsection (1), this provision applies whether the registration was revoked under section 84A or under section 84B.

57. Subsection (2) sets out the general rule — that the Act applies as if the registration has never occurred. According to the general rule, if a registration is revoked, the application for registration of a trade mark once more becomes a pending application. The term 'pending' is

defined in section 6 of the Trade Marks Act. Under the Trade Marks Act, the Registrar may deal with the now pending application in one of two ways:

- the Registrar would be able to revoke the acceptance under section 38, and then either examine or reject the application; or
- if a notice of opposition was filed, or an application for an extension of time in which to file a notice of opposition was made, then the Registrar would be able to hear the opposition or consider the application.

58. Paragraphs (a) to (e) set out a number of exceptions to this general rule. The exceptions to this general rule are described below.

***Paragraph 84C(2)(a)***

59. According to this paragraph, subsection 129(4) of the Trade Marks Act applies as if the trade mark had ceased to be registered at the time of revocation.

60. Section 129 relates to groundless threats of legal proceedings. It is a defence under subsection (4) that a trade mark is registered. Paragraph 84C(2)(a) is directed towards the case of the registered owner of a trade mark who, while a trade mark is registered, threatens to bring a legal action against another person. If the registration of the trade mark is subsequently revoked, then they may lose their defence under subsection 129(4), despite the fact that they may have acted in good faith when they threatened to bring the action. The intent of this provision is to ensure that such a person is still able to rely on section 129(4) after registration has been revoked.

***Paragraph 84C(2)(b) and subsection (3)***

61. Under section 142, the Commonwealth is not liable for loss or damage suffered by a person as a result of certain actions under Part 13 of the Trade Marks Act. Under this provision, the Commonwealth is not protected against liability for *any* actions, but only for actions under that Part. Under Part 13, the Commonwealth is only able to act to seize goods in respect of which a trade mark is registered if a notice of objection has been validly given. Only a registered owner of a registered trade mark may give a notice of objection.

62. Paragraph 84C(2)(b) is directed towards the situation that a registered trade mark is revoked under section 84A or 84B. In such a case, given that the result of revocation is that the registration is taken never to have occurred, the validity of the notice could be called into question, and it could be argued that the Commonwealth would not be protected from liability under section 142. This would be the case despite the fact that the Commonwealth had been acting in good faith on the basis of a notice that was ostensibly valid at the time that the Commonwealth acted. Therefore this paragraph clarifies that the Commonwealth's protection from liability would be maintained, despite revocation of the registration.

63. Subsection (3) clarifies that this paragraph does not by itself make the Commonwealth liable if the circumstances described in subparagraphs (2)(b)(i) and (2)(b)(ii) exist.

***Paragraph 84C(2)(c)***

64. According to this paragraph, the Part 14 of the Trade Marks Act applies as if the trade mark had ceased to be registered at the time of revocation.

65. The effect of this provision is that, for an offence under Part 14 of the Trade Marks Act that relies on the recklessness or knowledge as to the registration of a trade mark as one of its mental elements, the revocation of the registration will not alter whether or not this mental

element was made out. Therefore if a person has committed an offence under Part 14 in respect of a trade mark the registration of which is subsequently revoked, he or she will not be able to rely on the revocation of the registration in his or her defence.

***Paragraph 84C(2)(d) and (e)***

66. Section 230 of the Trade Marks Act protects registered owners of trade marks in certain passing off actions. For the purposes of this provision, as a result of paragraph 84C(2)(d), the trade mark is taken to have ceased from the date the registration was revoked. This will protect a defendant who, prior to the revocation, would have been able to rely on section 230 in a passing off action.

67. Paragraph 84C(2)(e) applies in a similar manner to an authorised user, the registration being taken to have ceased from the date when the authorised user became aware of the revocation. This will protect the interests of an authorised user.

68. Subsection (4) provides that the particulars of the trade mark, for example the name of the owner of the trade mark, just after the revocation is actioned are the same as those just before that revocation. This is to avoid confusion relating to any changes in particulars that may have occurred whilst the trade mark was registered.

69. Subsection (5) clarifies that, if the Registrar decides to revoke acceptance of a trade mark subsequent to revoking its registration, then the Registrar is not obliged to examine the application for registration a second time prior to rejecting it.

**Section 84D**

70. This section provides that the decision to revoke a registration under section 84A is appealable to the Federal Court of Australia.

71. A revocation under section 84B is not appealable to the Federal Court. A registered owner will still be able to make use of general administrative law remedies in relation to a disputed revocation under section 84B.

**Item 8**

72. Item 8 inserts after subsection 224(3) a new subsection (3A) that allows the Registrar to extend time periods for doing a relevant act where that relevant act has not been done in situations where the Registrar has revoked the registration of a trade mark. This may be necessary in some cases, as certain time limits prescribed in the Trade Marks Act or in the Trade Marks Regulations may have expired by the time the Registrar re-examines an application for registration or considers an opposition subsequent to revoking registration. The expression 'relevant act' is defined in subsection 224(8).

**Item 9**

73. Item 9 is an application provision. According to this item, the amendments to Part 8 and section 224 of the Trade Marks Act apply only to trade marks that became registered (that is, the particulars of which were entered into the Register under section 69) on or after commencement of this Schedule.

## **Schedule 2—Non-payment of fees relating to trade marks**

*Trade Marks Act 1995*

### **Items 1 and 2**

74. These items amend section 223 of the Trade Marks Act to repeal many of the fee payment requirements, and to provide that many of the details of how fees are paid will be prescribed in the *Trade Marks Regulations 1995*. This will enable this administrative function to be handled more flexibly by the Trade Marks Office, including streamlining fee payment methods and introducing modern methods of fee payment.

75. Item 1 repeals subsections 223(3), (4) and (5) and replaces them with provisions that enable the Regulations to provide for consequences which may result if a person does not pay fees in accordance with the Regulations.

76. Item 2 is an application provision, under which the amendments made by the Schedule will apply to all fees that become payable after the Schedule commences. Section 223 of the Trade Marks Act will continue to apply to all fees that were payable before that time.

77. These amendments will bring the fee payment provisions of the Trade Marks Act into line with the fee payment provisions in section 227 of the Patents Act and section 130 of the Designs Act 2003.

## **Schedule 3—Registration process for certification trade marks**

*Trade Marks Act 1995*

78. Part 16 of the Trade Marks Act sets out the requirements for the registration of a certification trade mark (CTM). A trade mark is a sign used to create a direct link between the goods and/or services to which the mark is applied and the trade origin of the goods and/or services, either directly or indirectly (e.g. through a brand). Section 17 of the Trade Marks Act provides the definition of a Trade Mark. A CTM, defined in section 169 of the Trade Marks Act, differs from a standard trade mark in that the sign is used or intended to be used to distinguish goods or services which meet the certification standards set by the owner of the CTM from those of other traders who have not sought certification.

79. Section 168 of the Trade Marks Act provides that the process for obtaining a CTM involves both the Trade Marks Office and the Australian Competition and Consumer Commission (the Commission).

80. In order to obtain a CTM:

- a) The trade mark owner must make an application to the Registrar of Trade Marks (the Registrar) for a CTM and provide the Registrar with a copy of the rules as soon as practicable after the application is filed (section 173(1) of the Trade Marks Act and regulation 16.1 of the Trade Mark Regulations);
- b) Once the Registrar is satisfied the trade mark application is made in accordance with the provisions of the Act and there are no grounds for rejecting it the Registrar forwards a copy of the prescribed documents including the application, a copy of the rules, and a copy of any amendments made to the application in the course of examination to the Commission (paragraph 174(1) of the Trade Marks Act);
- c) The Commission then considers the application, including the rules, in accordance with regulations (subsection 175(1) of the Trade Marks Act);

- d) Once the Commission has ascertained that the rules are acceptable and are not detrimental to the public interest, a certificate is issued (subsection 175(2) of the Trade Marks Act);
- e) The Registrar, upon notification, must accept the CTM (section 176 of the Trade Marks Act) and advertise the decision in the Official Journal (subsection 176(3) of the Trade Marks Act); and
- f) Once the CTM is registered, the details of the trade mark and a copy of the rules are published by the Registrar (section 179 of the Trade Marks Act).

81. The amendments are not aimed at changing the requirements an applicant for a CTM must fulfil, the documentation they must provide, or the rights that a CTM gives to the registered owner. The changes are targeted at the administrative aspects of how applications for CTMs are processed, and affect only the internal workings of the Trade Marks Office and the Commission. It is more appropriate for details of administrative arrangements affecting internal workings of agencies to be prescribed in the regulations.

### *Part 1-Amendments commencing on the day after Royal Assent*

#### **Item 1**

82. Item 1 repeals subsection 173(2) of the Trade Marks Act and substitutes new subsections 173(2) to 173(4).

83. Subsection 173(2) provides that the rules governing a CTM must specify the following:

- the standards a good or service must obtain before the certification trade mark may be applied to it. This may be a list of criteria a good or service must meet or pass e.g. geographical location of production, method of production, specific ingredients that must be used;
- the process by which it is determined whether or not the goods or services meet the standard set out in the rules e.g. it may identify a specific method of determining the strength of a material where the standard requires material to have a certain strength;
- the qualifications, skills or abilities a person must possess to be able to assess whether or not the goods or services meet the standards set by the owner of the certification mark e.g. an owner may decide that in order to be able to certify that goods or services meet criteria, a person must have a specific trade qualification and ten years experience in the industry;
- the requirements (including any other requirements about the use of the CTM) with which the owner, if he or she intends to use the CTM, and any approved user must comply in order to either start or continue to use the CTM trade mark e.g. payment of annual fees, continued compliance with the standards, manner in which the CTM must be used and displayed;
- dispute resolution procedures relating to whether goods and/or services meet the certification requirements;
- dispute resolution procedures relating to issues regarding the certification e.g. refusal to certify certain goods or services, incorrect use of the CTM on packaging, accreditation issues.

84. Subsection 173(3) provides that the rules must also include any other matters the Commission requires to be included. Subsection 173(4) provides that the rules may include any other matters the Commission permits to be included.

85. These new subsections have the effect of clarifying the previous requirements of the contents of the rules for use of a CTM and modernises the language in which they are expressed.

## **Item 2**

86. Item 2 is an application provision. Under item 2, the amendments to subsection 173(2) will apply to any rules filed on or after the commencement of the amendment.

## **Item 3**

87. Item 3 repeals paragraph 175(2)(a) of the Trade Marks Act and substitutes a new paragraph 175(2)(a). This amendment specifies that the Commission must be satisfied that the attributes (for example, the qualifications, skills or abilities) that the rules require an approved certifier to possess are sufficient to enable an approved certifier to competently assess whether or not the goods or services meet the standards set out in the rules using the methods set out in the rules.

88. Under the existing provisions, the wording was such that many applicants believed they had to specify who they intended to be authorised certifiers. This was particularly onerous and did not allow a CTM owner to expand his or her business or change certifiers if the specified authorised certifier changed for some reason for example ceasing business or no longer had the desire to be a certifier. Any change in the identity of the approved certifier would mean applying for a variation to the rules. It was never intended that the Commission would have to investigate each and every approved certifier to determine whether the approved certifier met the criteria set out in the rules. That was always intended to be the role of the trade mark owner.

89. The proposed amendments are intended to clarify that the CTM owner is responsible for determining whether an approved certifier possesses the qualifications, skills or abilities specified in the rules. As a consequence, the owner of the CTM is responsible for appointing and removing approved certifiers and monitoring the performance of approved certifiers.

## **Item 4**

90. Item 4 substitutes note 2 to paragraph 175(2)(a) of the Trade Marks Act with two notes. These notes reference the approved certifier to paragraph 173(2)(c) and certification requirements to paragraph 173(2)(a). This is a consequential amendment from the re-numbering of subsection 173(2) of the Trade Marks Act.

## **Item 5**

91. Item 5 is an application provision. Under item 5, the amendments to section 175 apply to considerations made by the Commission to rules filed for a CTM on or after the commencement of this part.

## **Item 6**

92. Item 6 amends the reference in note 2 to subsection 177(1) to refer to paragraph 173(2)(c) instead of paragraph 173(2)(a). This is a consequential amendment from the re-numbering of subsection 173 (2).

## **Item 7**

93. Item 7 amends the reference in note 2 to subsection 181(2) to refer to paragraph 173(2)(c) instead of paragraph 173(2)(a). This is a consequential amendment from the re-numbering of subsection 173 (2).

## *Part 2 – Amendments that will commence on proclaimed day or after 6 months*

### **Item 8**

94. Item 8 repeals section 174 of the Trade Marks Act and substitutes a new section 174. This paragraph provides that the regulations specify the conditions for sending of prescribed documents relating to the CTM application to the Commission.

95. The presently enacted section sets out in some detail the procedure that must be followed if the Registrar is satisfied that an application for registration of a CTM is made in accordance with the Act and that there are no grounds for rejecting the application.. The details set out in this provision relate to administrative procedures which do not have any impact upon the applicant or on the rights they are given by a CTM.

96. This amendment will enable the administrative procedures for sending documents to the Commission to be handled more flexibly by the Trade Marks Office and the Commission.

### **Item 9**

97. Item 9 is an application provision. Under item 9, section 174 applies to all CTM applications filed on or after commencement of section 174, as well as CTM applications the processing of which has not yet been finalised on commencement of section 174. This includes CTM applications currently before the Commission and those the Registrar has yet to send to the Commission. Item 9 also provides that rules already sent to the Commission do not have to be sent again.

### **Item 10**

98. Item 10 repeals subsection 176(1) of the Trade Marks Act and substitutes with a new subsection 176(1). This new subsection specifies that the Registrar must accept an application for registration of a CTM if the application has been made in accordance with the Act, there are no grounds for rejection, and the Commission has issued a certificate. If these criteria have not been met, the Registrar must reject the application.

99. However, before the Registrar rejects the application due to the application not being in accordance with the Trade Marks Act and/or there are grounds for rejecting the application, the Registrar must give the opportunity for the applicant to be heard.

100. Subsection 176(1) formerly specified the to be met in order for the Registrar to accept a CTM application. This amendment clarifies the requirements that must be satisfied before the Registrar is able to accept an application for a CTM.

### **Item 11**

101. Item 11 is an application provision. Under item 11, subsection 176(1) applies to all applications for registration of CTMs filed on or after commencement of subsection 176(1), as well as to all applications for registration of CTMs the processing of which has not yet been finalised on commencement of subsection 176(1). Item 11 clarifies that subsection 176(1) does not apply to CTM applications which have already been accepted or rejected prior to the commencement of subsection 176(1).

### **Item 12**

102. Item 12 repeals subsection 178(4) of the Trade Marks Act and substitutes a new provision requiring the Commission to notify a decision to approve a variation or not to approve a variation of the rules in accordance with the regulations.

103. The previous provision set out the administrative procedures to notify a decision to approve or not to approve a variation to the rules for CTMs. This amendment will allow the administrative procedures to be specified in the regulations, providing for greater flexibility as to how this decision will be notified in the future.

### **Item 13**

104. Item 13 repeals subsection 178(6) of the Trade Marks Act. The repealed subsection specified the administrative procedures the Commission must follow if approving a variation. This matter will be handled in regulations made under the new subsection 178(4), as outlined in item 12.

### **Item 14**

105. Item 14 is an application provision. Under item 14, the amendment to section 178 applies to all decisions made on or after commencement to approve or not to approve the variations of rules governing the use of certification trade marks.

### **Item 15**

106. Item 15 repeals section 179 of the Trade Marks Act and substitutes a provision whereby the Registrar must publish the rules in accordance with the regulations.

107. This amendment will allow regulations to be made allowing the rules to be published at an earlier stage than they are currently published. This will enable earlier access to the rules by the Commission and the public, who may have an interest in seeing the rules governing the CTM. It will also provide for more effective consultation and consumer awareness and more efficient processing of applications.

### **Item 16**

108. Item 16 is a saving provision, which clarifies that the Registrar does not need to republish rules that were already available under old section 179 of the Trade Marks Act, unless those rules are varied.

## ***Schedule 4—Availability of documents about trade marks***

### *Trade Marks Act 1995*

109. The Trade Marks Act does not provide for documents relating to trade marks to become available for public inspection. As a result, the only way that members of the public are able to access documents that relate to trade marks is under the *Freedom of Information Act 1982* (the FOI Act). This is in contrast to section 55 of the Patents Act and section 60 of the Designs Act, which provide for certain documents to be publicly available.

110. Third parties have an interest in viewing documents relating to trade marks for a number of reasons including:

- they intend to oppose the registration of a trade mark; or
- they wish to ascertain why a particular trade mark was accepted or rejected in order to facilitate the registration of their own trade mark.

111. In the interests of open, transparent government, and to facilitate the speedy access to trade mark documents by third parties, these new provisions provide that documents that are prescribed in the regulations will be available for public inspection after a certain date. This will then enable the Trade Marks Office to make such documents available, for example, by selling copies of them to members of the public on a cost recovery basis.

112. A trade mark applicant may be required to file sensitive business information, such as sales figures and advertising costs, in order to secure registration of the trade mark. It is appropriate that sensitive business information of this nature not be made available to the public. To give effect to this, the Trade Marks Act is also to be amended to give the Registrar a statutory power to require that information contained in documents be held in confidence. Regulations can be made under these provisions to ensure that such documents are not made available for public inspection.

113. If access to any documents not available for public inspection under the new provisions is required, a request can be made under the FOI Act for these documents. However, it is intended that if the Registrar has required that information in a particular document be treated in confidence, then that information would be exempted from release under section 45 of the FOI Act.

### **Item 1**

114. Item 1 inserts section 217A that requires the Registrar to make prescribed documents on a trade mark file available for public inspection while they are held in the Trade Marks Office at or after the time the particulars are published. Regulation 4.7 of the *Trade Mark Regulations 1995* prescribes the information that must be published and the manner in which it must be published under section 30 of the Trade Marks Act. According to section 204 of the Trade Marks Act, the information must be published as soon as practicable after the application is filed. The effect of this is that all prescribed documents will be available for public inspection from the time they are received and processed by the Trade Marks Office.

115. This provision would only apply to documents while they are held by the Trade Marks Office. Any documents that the Trade Marks Office returns, and which are therefore no longer held by the Trade Marks Office, are not required to be made available for public inspection under this provision.

116. The term 'document' has the meaning it has under section 25 of the *Acts Interpretation Act 1901*.

### **Item 2**

117. Item 2 is an application provision. The new provisions will only apply to trade mark applications filed on or after the commencement of the Schedule. Access to documents relating to trade mark applications filed prior to commencement will still have to be sought under the FOI Act.

### **Item 3**

118. Item 3 inserts section 226A that allows the Registrar to specify information in a document that has, or is to be filed, in relation to a trade mark to be held in the Trade Marks Office confidentially. This section also provides for the Registrar to specify conditions and/or limitations on documents specified to be held confidentially (for example, for a specified period of time) and allow the Registrar to vary or revoke such a requirement, condition or limitation (for example, to make a decision that a document would be no longer held in confidence).

119. Subsection (2) provides that regulations may provide for procedures to be followed in connection with the making, variation or revocation of a requirement under section 226A, or of conditions or limitation on such a requirement.

120. Determinations setting out the Registrar's requirements are not legislative instruments. Subsection (3) is included to assist readers, by highlighting that these determinations are not legislative instruments within the meaning of section 5 of the *Legislative Instruments Act 2003*.

#### **Item 4**

121. Item 4 is an application provision. Under this application provision, it will be possible to ask the Registrar to accept in confidence information contained in documents filed after the commencement of section 226A, whether or not an application for a trade mark registration was filed before, on or after this date. However, it will not be possible to ask the Registrar to require that documents filed before commencement be treated confidentially.

### ***Schedule 5—Relief for infringement of patents***

*Patents Act 1990*

122. Schedule 5 implements the Government's response to a recommendation of the Advisory Council on Intellectual Property's *Review of Enforcement of Industrial Property Rights*. This recommendation related to inserting provisions for exemplary damages into the Patents Act along the lines of section 115(4) of the *Copyright Act 1968*. This would be in addition to the court's ability to order either ordinary compensatory damages or an account of profits.

#### **Item 1**

123. Item 1 inserts a new subsection 122(1A) that will allow a court to award exemplary damages where a patent has been infringed, in addition to damages or an account of profits. The subsection sets out the factors that must be considered when determining whether to award exemplary damages such as the flagrancy of the infringement.

#### **Item 2**

124. This is an application provision, under which the amendment applies to any infringements that occur on or after commencement of the Schedule.

### ***Schedule 6—Exemption of continued prior use from patent infringement***

*Patents Act 1990*

125. Schedule 6 implements the Government's response to a recommendation of the Intellectual Property and Competition Review (IPCR) Committee's *Review of intellectual property legislation under the Competition Principles Agreement*. The Committee recommended that paragraphs 119(1)(a) and (b) of the Patents Act be amended to clarify that the prior use exemption from patent infringement be only in the patent area and that this use includes experimental use. The Committee also recommended that only the actual prior user should be able to have the benefit of section 119.

126. The Government accepted this recommendation in part, agreeing that the prior use should be limited to use in the patent area, but rejecting the notion that it was necessary to qualify that the prior use included experimental use. The Government also considered that assignees, but not licensees, of the prior user should also have the benefit of section 119. The Government further considered that the limitation of the prior use to making a product or using a process was too narrow, and instead considered that the prior use should encompass acts which would constitute an infringement of the patent.

#### **Item 1**

127. Item 1 repeals section 119 of the Patents Act and substitutes it with a new section 119.

128. Subsection 119(1) allows a person who had exploited a product, method or process in the patent area immediately before the priority date of the relevant claim of the patent to, after a patent has been granted, do any act that exploits the product, method or process without infringing the patent. The provision similarly provides for a person who had taken definite steps (whether contractually or otherwise) to exploit a method, product or process immediately before the priority date of the relevant claim of the patent to, after a patent has been granted, do any act that exploits the product, method or process without infringing the patent..

129. The 'patent area' is defined in Schedule 1 to the Patents Act. 'Exploit' is defined in subsection (5). This definition parallels the definition of the term in Schedule 1 to the Act, but in section 119 'exploit' is defined with respect to a product, method or process rather than with respect to an invention.

130. The reference to the 'relevant claim' in subsection 119(1) is to the claim of the patent that the prior user would have infringed if it were not for the prior use exemption. The priority date of a claim is defined in section 43 of the Patents Act.

131. The reference to 'product, method or process' is intended to cover everything that could be covered by a patent. It is intended to be construed expansively, and is not intended to limit the operation of the section.

132. As a result of this amendment, if a person had, before the relevant priority date, been doing one act that would have constituted exploitation of a product, method or process (for example, if they had been making a particular product, or using a particular method or process), then even when the patent has been granted, they would have a right to continue to do that act, but in addition, they would have the right to do any other act that would constitute an exploitation of that product, method or process (for example, they would have a right to sell the product they had been making, or to sell a product resulting from using the method or process).

133. Subsection 119(2) places a limitation on the prior use exemption. To benefit from the prior use exemption in subsection 119(1), the prior user must have been doing the act that constituted the prior use immediately before the relevant priority date. Subsection (2) clarifies that the infringement exemption in subsection 119(1) will not be available if, before the relevant priority date, the prior user had:

- stopped (other than temporarily) exploiting the product, method or process; or
- abandoned (other than temporarily) the steps to exploit the product, method or process.

134. New subsection 119(2) reflects the presently enacted subsection 119(4) and has not changed the effect of this subsection materially.

135. Subsection 119(3) places a further limitation on the prior use exemption. According to this subsection, if the prior user derived the product, method or process from the patentee or the patentee's predecessor in title, the prior user will only be able to have the benefit of the prior use exemption under subsection 119(1) if the conditions in paragraphs 119(1)(a) and (b) are satisfied. New subsection 119(3) reflects the presently enacted subsections 119(2) and 119(3) and does not change the effect of these subsections materially.

136. Subsection (4) allows the prior user to assign the whole of his or her prior use right under this section. The assignee may then have the full benefit of the prior use exemption. There is no provision for the prior user to licence his or her prior use right.

137. Subsection 119(5) defines the term ‘exploit’ for the purposes of section 119. The definition parallels the definition of ‘exploit’ in Schedule 1 to the Patents Act, except that it relates to a product, method or process rather than to an invention. The terms are intended to be interpreted similarly.

## **Item 2**

138. Item 2 is an application provision, under which the amendments made by this Schedule apply in relation to patents that are granted as a result of applications filed on or after commencement of the Schedule.

## **Schedule 7—Springboarding and patents**

### *Patents Act 1990*

139. The purpose of this schedule is to allow springboarding as an exception to patent infringement on any pharmaceutical patent at any time for purposes solely in connection with gaining regulatory approval of a pharmaceutical product in Australia or another territory, consistent with Australia’s international obligations.

140. Springboarding is a colloquial term that refers to using the subject matter of a patent to collect the data required to obtain regulatory approval of a generic version of the patented product, when the patent is still in force. Prior to these amendments, the Patents Act contained a limited provision that only allowed springboarding on pharmaceutical patents after they had received an extension of patent term. Consequently, Australia’s springboarding provisions were more limited than those in other competitor countries. More generous springboarding provisions overseas provide a powerful economic incentive for Australian based generics companies to conduct generics research and development, and subsequent manufacturing, overseas and then import their product into Australia on patent expiry. This amendment corrects this investment disincentive without impacting on the current market environment in Australia.

141. It is not intended that manufacturing quantities of the product for export, setting up to manufacture quantities prior to patent expiry or stockpiling quantities for later sale would be allowed, as these activities would be inconsistent with Australia’s international obligations in relation to the World Trade Organization’s Agreement on the Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement).

## **Items 1 and 2**

142. Items 1 and 2 repeal subsection 78(2) of the Patents Act, and make minor consequential amendments to the text of subsection 78(1).

## **Item 3**

143. Item 3 inserts a new section into the Patents Act, section 119A, that relates to a new infringement exemption, relating to acts for obtaining regulatory approval of pharmaceuticals.

144. Under subsection (1), the rights of a patentee of a pharmaceutical patent will not be infringed by a person exploiting an invention claimed in the patent if the exploitation is solely for:

- (a) purposes connected with obtaining the inclusion in the Australian Register of Therapeutic Goods (the ARTG) of goods that:
  - (i) are intended for therapeutic use; and

- (ii) are not medical devices, or therapeutic devices, as those terms are defined in the *Therapeutic Goods Act 1989* (the TG Act); or
- (b) purposes connected with seeking similar regulatory approval under a law of a foreign country or of a part of a foreign country, subject to subparagraph 119A(2).

145. The exclusive rights given by a patent are set out in section 13 of the Patents Act. Subject to the Patents Act, a patent gives the patent owner the exclusive rights, during the term of the patent, to exploit the invention and to authorise another person to exploit the invention. The term 'exploit' is defined in Schedule 1 to the Patents Act.

146. The ARTG is defined in Schedule 1 to the Patents Act and refers to the register maintained under section 9A of the TG Act. Item 1 of Schedule 16 to the Intellectual Property Laws Amendment Bill 2006 corrects the reference in this definition that previously referred to section 17 of the TG Act.

147. The expression 'pharmaceutical patent' is defined in subsection 119A(3).

148. The reference to 'inclusion' in paragraph 119A(1)(a), as qualified by subparagraph 119A(1)(a)(ii), is intended to cover both inclusion in the part of the ARTG referred to in paragraph 9A(3)(a) of the TG Act (for registered goods) and inclusion in the part of the ARTG referred to in paragraph 9A(3)(b) of the TG Act (for listed goods). As a result, springboarding off pharmaceutical patents will be available whether a good is to be included in the ARTG as a registered good or as a listed good.

149. The expression 'therapeutic use' used in subparagraph 119A(1)(a)(i) is defined in Schedule 1 to the Patents Act. As 'therapeutic use' is limited to use in humans under the Patents Act, this expression has a narrower meaning under the Patents Act than the equivalent expression has under the TG Act.

150. The reference to medical devices and therapeutic devices in subparagraph 119A(1)(a)(ii) clarifies that springboarding is not available when medical or therapeutic devices are included in the ARTG. Some device/medicine 'boundary' goods are included on the ARTG, which have some characteristics of a medical device and some characteristics of a medicine. The expressions 'medical device' and 'therapeutic device' have the same meaning that they have under the TG Act. Therefore springboarding is not available on patents relating to 'boundary' goods that are defined as a medical device or a therapeutic device under the TG Act, for the purpose of seeking inclusion of a medical device or a therapeutic device in the ARTG.

151. The reference to 'similar regulatory approval' in paragraph 119A(1)(b) is intended to limit the infringement exemption to regulatory approval in the foreign jurisdiction of goods that would not be classified as devices under Australian law, and to goods that are intended for therapeutic use in humans. The infringement exemption in section 119A will *not* apply to regulatory approval in a foreign jurisdiction for devices, or for goods intended for other than therapeutic use in humans.

152. Subsection 119A(2) is consistent with Australia's obligations under Chapter 17 of the Australia-United States Free Trade Agreement (AUS FTA).

153. A patentee's exclusive rights, set out in section 13 of the Patents Act, include the exclusive right to export the patented invention. Subsection (2) provides that, despite subsection (1), the patentee's exclusive right to export *will* be infringed, unless the conditions set out in subsection (2) are made out.

154. Under subsection (2), subsection (1) does not apply to export from Australia of certain goods for the purposes described in paragraph 119A(1)(b), unless the term of the patent covering those goods has been extended under Part 3 of Chapter 6 of the Patents Act.

155. The goods covered by this provision are goods that consist of or contain:

- (a) a pharmaceutical substance *per se* that is in substance disclosed in the complete specification of the patent, and in substance falls within the scope of the claim or claims of that specification; or
- (b) a pharmaceutical substance when produced by a process involving the use of recombinant DNA technology, that is in substance disclosed in the complete specification of the patent, and in substance falls within the scope of the claim or claims of that specification.

156. Under section 70, in order for a patent term to be extended, it must claim a pharmaceutical substance that meets the above descriptions.

157. Subsection (3) adds a new definition, 'pharmaceutical patent'. A pharmaceutical patent is defined as meaning a patent that claims:

- (a) a pharmaceutical substance; or
- (b) a method, use or product relating to a pharmaceutical substance, including any of the following:
  - (i) a method for producing a raw material needed to produce the substance;
  - (ii) a product that is a raw material needed to produce the substance;
  - (iii) a product that is a pro-drug, metabolite or derivative of the substance.

158. The term 'pharmaceutical substance' is defined in Schedule 1 to the Patents Act.

159. The definition of 'pharmaceutical patent' is intended to cover all patents that a generic pharmaceutical company would need to exploit in order to seek inclusion of a good other than a medical device or a therapeutic device on the ARTG. It is intended that patents claiming the following methods, products and uses relating to a pharmaceutical substance would be covered by the definition of 'pharmaceutical patent':

- (a) a pharmaceutical substance *per se*; or
- (b) a pharmaceutical substance when produced by a process that involves the use of recombinant DNA technology; or
- (c) a method of use of a pharmaceutical substance; or
- (d) a method of administering a pharmaceutical substance; or
- (e) a process for manufacturing a pharmaceutical substance ; or
- (f) a product or formulation incorporating a pharmaceutical substance or a mixture of pharmaceutical substances, including products such as layered or coated tablets; or
- (g) other features of the pharmaceutical substance such as the colour or shape of a pill or packaging; or

- (h) an apparatus or method specifically designed for manufacturing or testing a particular pharmaceutical substance.

160. The reference in subparagraph 119A(3)(b)(i) and (ii) to 'raw materials' is intended to cover *all* materials and substances required for production of the good. The reference in subparagraph 119A(3)(b)(iii) to 'pro-drug' is intended to cover pro-drugs that metabolise into pro-drugs, as well as pro-drugs that metabolise into pharmaceutical substances. The reference to 'metabolite' is intended to cover anything into which a metabolite is subsequently metabolised.

#### **Item 4**

161. Item 4 is an application provision.

162. According to this item, the amendments made by this Schedule will apply to any patents that are in force at or after the time that the Schedule commences. This is intended to cover all patents applied for and granted before commencement, as well as to patents applied for and granted after commencement.

163. It is also intended to cover patents that have ceased prior to commencement and which are restored after commencement.

164. The Schedule applies only to the exploitation of any patents as described in the previous paragraphs that occurs at or after the time that the Schedule commences. Subsection 78(2) as enacted immediately prior to commencement of this Schedule will continue to apply to any exploitation of patents that occurred prior to commencement.

### ***Schedule 8—Compulsory licensing of patents***

*Patents Act 1990*

165. Schedule 8 implements the Government's response to a recommendation from the IPCR Committee's *Review of Intellectual Property Legislation under the Competition Principles Agreement*.

166. The IPCR Committee recommended that section 135 of the Patents Act be repealed and that subsection 133(2) be amended to include an order requiring a compulsory license to be made if and only if all of the following conditions are met:

- (a) access to the patented invention is required for competition in the (relevant) market;
- (b) there is a public interest in enhanced competition in that market;
- (c) reasonable requirements for such access have not been met;
- (d) the order will have the effect of allowing these reasonable requirements to be better met; and
- (e) the order will not compromise the legitimate interests of the patent owner, including that owner's right to share in the return society obtains from the owner's invention, and to benefit from any successive invention, made within the patent term, that relies on the patent.

167. The IPCR Committee considered that the test for a compulsory licence should be stringent, and that a licence should only be granted if there is no other option for competition in the relevant market than by having access to the patented invention. It also considered that the

enhancement of competition in the relevant market that would be secured by grant of the compulsory licence would have to be material and substantial.

168. The Government accepted this recommendation in part, agreeing to make the compulsory licensing of patents subject to a competition test. However, the Government did not accept that a competition test should be the only test for compulsory licences. Instead, the Government agreed to retain the existing test for compulsory licences, but to add a competition test as an additional ground on which a compulsory licence can be obtained. The Government also considered that all applications for compulsory licences should be considered by the Federal Court in the first instance.

169. The IPCR Committee did not seek to draft the conditions that would need to be met for the grant of a compulsory licence. Rather than introducing a new competition-based test into the Patents Act, the Government considers that a compulsory licence should be obtainable as a remedy if the patentee is acting anti-competitively in contravention of Part IV of the *Trade Practices Act 1974*.

### **Item 1**

170. Item 1 omits the reference in subsection 133(1) to ‘a prescribed court’ (defined in Schedule 1 to the Patents Act as including the Federal Court and State and Territory Supreme Courts), and replaces it with a reference to the Federal Court. As a result, applications for compulsory licences for patents may only be made in the Federal Court.

### **Item 2**

171. This item repeals paragraphs 133(2)(a) and (b), and substitutes new paragraphs 133(2)(a) and (b).

172. The original paragraphs 133(2)(a) and (b) set out the two limbs of the existing test for grant of compulsory licences for patents; the ‘reasonable requirements of the public’ test and if the patentee has given no satisfactory reason for failing to exploit the invention. The ‘reasonable requirements of the public’ are set out in section 135 of the Patents Act. These limbs of the test have been moved into new subparagraphs 133(2)(a)(ii) and (iii). New subparagraph 133(2)(a)(i) reflects the former subsection 133(3A), which is repealed by item 3. It has been moved into this subparagraph to make clearer that it is a limb of the test for grant of a compulsory licence.

173. Paragraph 133(2)(b) represents the additional competition test for compulsory licences. Under this test, if the patentee has contravened or is contravening Part IV of the Trade Practices Act or an application law (as defined in section 150A of the Trade Practices Act) in connection with a patent, then a compulsory licence is available as a remedy for that contravention.

174. The Trade Practices Act is part of a national scheme of legislation restricting anti-competitive conduct. An ‘application law’ (as defined in section 150A of the Trade Practices Act) refers to the various State and Territory Competition Policy Reform Acts that are the State and Territory enactments comprising this national scheme.

### **Item 3**

175. Item 3 repeals subsection 133(3A). The text that was formerly in this subsection has been inserted into subparagraph 133(2)(a)(i) (see item 2).

### **Item 4**

176. Item 4 omits the reference in paragraph 133(5)(b) to ‘a prescribed court’, and replaces it with a reference to the Federal Court.

177. As a result, if the patentee and the applicant for the compulsory licence cannot agree to the amount to be paid for the compulsory licence, the Federal Court (rather than a prescribed court) will be able to determine that amount.

### **Item 5**

178. This item adds a new factor the court must take into account when determining the amount of the licence fee that is payable in respect of the compulsory licence, in addition to the economic value of the licence. According to this item, the court will have to take into account the desirability of discouraging contraventions of Part IV of the Trade Practices Act, or application laws as defined in section 150A of that Act.

### **Item 6**

179. Item 6 amends subsections 133(6) and 134(1) to omit the reference to ‘a prescribed court’, and replace it with a reference to the Federal Court.

180. As a result of the amendment to subsection 133(6), only the Federal Court, and not other prescribed courts, will be able to revoke a compulsory licence. The grounds on which a compulsory licence may be revoked are not altered.

181. As a result of the amendment to subsection 134(1), only the Federal Court, and not other prescribed courts, will be able to revoke a patent after grant of a compulsory licence.

### **Item 7**

182. Item 7 repeals paragraphs 134(2)(a) and (b), and substitutes new paragraphs 134(2)(a) and (b). These paragraphs outline the grounds on which a patent may be revoked after a compulsory licence has been granted. Subsection 134(1) of the Patents Act provides that an application for revocation of a patent after a compulsory licence has been granted may only be made after the end of the period prescribed in the *Patents Regulations 1991*.

183. Paragraph 134(2)(a) sets out the existing grounds on which a court may revoke a patent after grant of a compulsory licence. This text has been reformatted.

184. Paragraph 134(2)(b) introduces a new ground on which a court may revoke a patent after a compulsory licence has been granted. According to this ground, a patent may be revoked if the patentee is contravening Part IV of the Trade Practices Act or an application law (as defined in section 150A of the Trade Practices Act) in connection with the patent. Under this provision, if the compulsory licence has not remedied the anti-competitive conduct of the patentee that gave rise to the compulsory licence, or if the patentee is engaging in further anti-competitive conduct, the court would be able to revoke the patent.

### **Item 8**

185. Item 8 inserts new section 136A. This section specifies that proceedings under section 133 or 134 involving an allegation of contravention of ‘an application law’ that is a law of a State must be dealt with as if the law were a law of the Commonwealth.

186. This provision makes clear that the Patents Act is simply picking up the text of the State application law and applying it as Commonwealth law to give content to the legal question that the Federal Court must determine under the Patents Act.

187. It is intended that the ‘application law’ in the Territories will also be dealt with as if the law were a law of the Commonwealth. However there is no need to refer to ‘an application law that is a Territory law’, as the Federal Court has jurisdiction over the Territories. Therefore the

Federal Court is already able to deal with Territory law as if the law were a law of the Commonwealth.

### **Item 9**

188. Item 9 is an application provision. According to this provision, a compulsory licence can be granted under the new provision in respect of any patent, whether the patent was granted before, on or after commencement of the Schedule.

189. However, in determining whether to grant a compulsory licence, the court will only be able to take into account conduct of the patentee that occurred after commencement of the Schedule.

## ***Schedule 9—Specifying claims for innovation patents***

*Patents Act 1990*

### **Item 1**

190. Item 1 amends paragraph 40(2)(c) of the Patents Act to add the phrase ‘defining the invention’ at the end of that paragraph. As a result, a complete specification that relates to an application for an innovation patent will be required to end with at least one and no more than five claims defining the invention. The terms ‘claim’ and ‘invention’ are defined in the Dictionary in Schedule 1 to the Patents Act.

191. This amendment clarifies that the claims of an innovation patent define the invention.

### **Item 2**

192. Item 2 is an application provision. According to the provision, the amendment in item 1 will apply to all applications for innovation patents, whether they are filed before, on or after commencement.

## ***Schedule 10—Making divisional applications for innovation patents***

*Patents Act 1990*

193. Under section 79B of the Patents Act a divisional application for a standard patent can only be made if the initial standard patent application has not lapsed or been refused or withdrawn. The divisional application must be made in accordance with the regulations. This schedule clarifies that a divisional application from a granted innovation patent may only be made, in accordance with the regulations, between the period starting when the examination of the first innovation patent begins and ending when the first innovation patent either ends, ceases or is revoked.

### **Item 1**

194. Item 1 amends subsection 79C(1) of the Patents Act to clarify that a divisional application for an innovation patent must be made in accordance with the regulations.

### **Item 2**

195. Item 2 repeals subsection 79C(2) and inserts a new subsection 79C(2) that specifies that a divisional application for an innovation patent may only be made during the period starting when an examination of the first patent begins and ending when either the term of the first patent ends, the first patent is revoked, the first patent ceases or a is period prescribed in the regulations.

196. Subsection 79C(3) defines when an examination of the patent begins for the purposes of this section.

### **Item 3**

197. Item 3 is an application provision, under which the amendments made by Schedule 10 will apply to complete applications made on or after the commencement of the Schedule, whether the first patent concerned was granted before, on or after that commencement.

### **Schedule 11—Setting dates by regulations**

*Trade Marks Act 1995*

*Plant Breeder's Rights Act 1994*

198. The filing date of a trade mark application, defined in section 6 of the Trade Marks Act, and the priority date of a plant breeder's right application, determined under subsection 28(2) of the Plant Breeder's Rights Act, are important factors in determining whether and to whom a trade mark or plant breeder's right is granted. However, sometimes it is difficult to determine whether an application has been filed as only a partial application has been filed. Further with the advent of the internet and on-line lodgement of trade mark and plant breeder's right applications, disruption to these services could also affect the filing of these applications, therefore jeopardising applicant's rights.

199. Currently, section 6 of the Trade Marks Act and subsection 28(2) of the Plant Breeder's Rights Act do not provide the flexibility to determine the filing date if an application has been partially received, or if there is disruption to the on-line service.

200. On the other hand, section 30 of the Patents Act and section 21 of the Designs Act have this flexibility by allowing regulations to be made to determine the priority and filing dates for patent and design applications.

201. Introducing this flexibility in the Trade Marks Act and the Plant Breeder's Rights Act will provide the ability to accommodate circumstances that may otherwise jeopardise applicant's rights.

### **Items 1 and 3**

202. Item 1 inserts an additional line to subsection 28(2) of the Plant Breeder's Rights Act to provide that the priority date may be determined by the regulations.

203. Item 3 inserts additional paragraph (e) into the definition of 'filing date' in section 6 of the Trade Marks Act to provide that the filing date may be determined by the regulations.

204. These amendments will allow regulations to be made to ensure that applicant's filing and priority dates are not put in jeopardy when an applicant files a partial application or tries to file an application electronically during an unforeseen internet outage.

### **Items 2 and 4**

205. Items 2 and 4 are application provisions. The amendments to subsection 28(2) of the Plant Breeder's Rights Act and section 6 of the Trade Marks Act will apply to all plant breeder's rights and trade mark applications respectively that are lodged or filed on or after the commencement of the schedule.

## **Schedule 12—Effect of office not being open for business**

*Designs Act 2003*

*Olympic Insignia Protection Act 1987*

*Patents Act 1990*

*Plant Breeder's Rights Act 1994*

*Trade Marks Act 1995*

206. The Patent Office, Trade Marks Office, Designs Office and the Plant Breeder's Rights Office (the Offices) are located in Canberra. There are also sub-offices of the Patent, Trade Marks and Designs Offices located in each of the State capitals. Documents can be filed over the counter or sent by post to the Offices and sub-offices, or filed electronically (by facsimile or over the internet), to the Canberra offices.

207. A number of periods are prescribed for actions to be taken under the Acts. If a period to perform an action required to be performed by an Act ends on a weekend, a national public holiday, a local public holiday or a bank holiday in a place the action may be performed, subsection 36(2) of the *Acts Interpretation Act 1901* (the AIA) provides that the action may be done on the next working day in that place. This can cause anomalous results when there are public holidays that are not observed nationally.

208. There are several circumstances which are not covered by the provisions in subsection 36(2) of the AIA, such as the annual Australian Public Service holiday and emergency situations in which the Offices or a sub-office is not open for business (for example due to bush fires). It is important to provide certainty to users of the intellectual property system as to when an action, required by an Act to be done, may be done in these circumstances.

209. The amendments made by this Schedule specifies how an action, required by one of the Acts to be done, may be done when the Offices and/or a sub-office is not open for business. These amendments also allow regulations to specify when the Offices and sub-offices are not open for business.

### **Item 1**

210. Item 1 inserts a new sentence describing the effect of the provision into the simplified outline found in section 129 of the Designs Act.

### **Items 2–4, 7-8**

211. These items insert identical provisions into the Acts, referred to herein as 'the common provisions'.

212. Subsection (1) of the common provisions is the key operative provision, allowing for acts to be done on the next day on which the office or a sub-office is open for business in the case that the last day of a period provided by the relevant Act for the act to be done falls on a day on which the office or sub-office is not open for business. The reference in this subsection to 'in prescribed circumstances' will allow regulations to be made specifying the particular circumstances in which the act may be done, for example, whether particular acts can only be done at particular sub-offices.

213. Subsection (2) of the common provisions specifies when the Office or sub-office is not open for business. The provision provides that a day on which an Office or sub-office is not open for business may be identified either in the regulations (paragraph (2)(a)), or by a person identified in the regulations as being allowed to declare or identify that an Office or sub-office is

not open for business (paragraph (2)(b)). The provision also provides that when a person exercises this power to declare or identify that an Office or sub-office not open for business, they must notify the public in writing in the way prescribed in the regulations. This paragraph will allow a quick response to unforeseen circumstances when they occur and facilitate an Office in taking action to ensure intellectual property rights are not jeopardised by office closures.

214. Subsection (3) of the common provisions allows public holidays to be identified by reference to the fact that the day is declared as a public holiday under the law of a State or Territory. However, subsection (3) does not limit the way the declaration may identify the day.

215. Subsection (4) of the common provisions explicitly allows the person identified in paragraph (2)(b) to identify an office as being closed for business before, on or after the day on which the office will be, is or was actually closed for business. This allows closure of an Office with little or no notice, for example where the Offices are suddenly closed due to a bushfire approaching Canberra.

216. To assist readers, subsection (4) also explicitly identifies that the written notice referred to in paragraph (2)(b) is not a legislative instrument within the meaning of section 5 of the *Legislative Instruments Act 2003*.

217. According to subsection (5) of the common provisions, the provisions of this section will override any contrary section in the Act.

218. Subsection 36(2) of the AIA only operates for reckoning of time under an Act unless the contrary intention appears. Subsection (6) makes explicit that section 36(2) of the AIA does not apply to calculations of time periods referred to in subsection (1)

219. Subsection (7) of the common provisions allows regulations to be made that exclude the application of the provision to the calculation of time periods for certain prescribed acts. In this case, the method of calculating time periods found in subsection 36(2) of the AIA will apply to those prescribed acts.

220. In item 2, the reference to “a period provided by this Act ... or the regulations” is intended to cover periods provided by the *Designs Act 1906* or regulations made under that Act that still apply in some circumstances by virtue of Chapter 12 of the *Designs Act 2003*.

## **Item 5 and 6**

221. Item 5 inserts a definition of the PBR (Plant Breeder’s Rights) office into the Plant Breeder’s Rights Act.

222. Item 6 inserts a definition of the PBR sub-office into the Plant Breeder’s Rights Act.

## **Schedule 13—Extension of time**

### *Trade Marks Act 1995*

223. Under subsections 224(2) and (3) of the Trade Marks Act, the Registrar of Trade Marks (the Registrar) may extend the time for doing a ‘relevant act’ in certain situations. Subsection (7) provides for an application for an appeal to be made to the Administrative Appeals Tribunal for the review of a decision of the Registrar not to extend the time for the doing of ‘an act’. This right of review is limited to a decision of the Registrar not to extend the time for the doing of a ‘relevant act’.

224. This amendment clarifies that this right of review should be limited to a decision of the Registrar not to extend the time for the doing of a ‘relevant act’.

### **Item 1**

225. Item 1 amends subsection 224(7) of the Trade Marks Act to substitute a reference to ‘an act’ with a reference to ‘a relevant act’. The expression ‘relevant act’ is defined in subsection 224(8) of the Act.

### **Item 2**

226. Item 2 is an application provision, and provides that this amendment applies in relation to decisions made by the Registrar after commencement of the Schedule.

## **Schedule 14—Approving forms**

### *Plant Breeder’s Rights Act 1994*

227. There are four approved forms under the Plant Breeder’s Rights Act:

- the application for a plant breeder’s right (paragraph 26(1)(b));
- the detailed description of a plant variety to which an application for a plant breeder’s right relates (paragraph 34(3)(b));
- an application form for a declaration of essential derivation (paragraph 40(4)(b)); and
- the certificate granting a plant breeder’s right (subsection 44(10)).

228. Subsection 7(1) of the Plant Breeder’s Rights Act provides that approved forms are forms approved, by instrument in writing, by the Secretary. Subsection 7(2) provides that these approved forms are disallowable instruments. This subsection has the effect of making the four plant breeder’s rights approved forms legislative instruments under section 6 of the *Legislative Instruments Act 2003*.

229. As the four approved forms under the Plant Breeder’s Rights Act are essentially of an administrative, rather than a legislative, nature, it is not appropriate that these forms be legislative instruments. Therefore the amendments in this Schedule will provide that approved forms under the Plant Breeder’s Rights Act will no longer be legislative instruments for the purposes of the Legislative Instruments Act.

230. This amendment is consistent with the policy behind the Legislative Instruments Act. For example Part 1, Schedule 1 to the *Legislative Instruments Regulations 2004*, provides instruments approving forms are generally declared not to be legislative instruments.

### **Item 1**

231. Item 1 inserts into subsection 3(1) of the Plant Breeder’s Rights Act a definition of ‘approved form’.

### **Item 2**

232. Item 2 repeals section 7 of the Plant Breeder’s Rights Act, which currently governs approved forms under the Act.

### **Item 3**

233. Item 3 is a transitional provision. The effect of the provision is that people may continue to use forms that were prescribed under the repealed section 7, until such time as new forms are approved.

## **Schedule 15—Delegation**

*Designs Act 2003*

*Plant Breeder's Rights Act 1994*

### **Item 1**

234. Item 1 inserts the words 'the regulations' into subsection 124(1) of the Designs Act.

235. Section 124 of the Designs Act provides for the Registrar of Designs (Designs Registrar) to delegate all or any of their powers or functions under the Designs Act or any other Act to a prescribed employee or a prescribed class of employees. This amendment makes it explicit that the delegation of all or any of the Designs Registrar's powers or functions under the Designs Act, includes those powers and functions provided in the *Designs Regulations 2004*.

### **Item 2**

236. The Registrar of Plant Breeder's Rights (PBR Registrar) possesses a limited number of original statutory powers under the Plant Breeder's Rights Act. The majority of powers the PBR Registrar possesses are by virtue of delegations from either the Minister or the Secretary. Under subsection 59(1) of the Plant Breeder's Rights Act, the Minister may delegate any of the powers or functions of the Minister under the Act to the Registrar, to the Secretary, or to a Senior Executive Service (SES) employee or an acting SES employee in the Department. Under subsection 59(2) of the Plant Breeder's Rights Act, the Secretary may delegate any of the powers or functions of the Secretary to the PBR Registrar or to a SES or acting SES employee within the Department.

237. However, the Plant Breeder's Rights Act does not allow for delegation to any other employees, for example an Australian Public Service (APS) employee. This is in contrast to the Patents, Trade Marks and Designs Acts. Section 209 of the Patents Act, section 206 of the Trade Marks Act, and section 124 of the Designs Act provide for delegation of powers or functions under the respective Acts to a 'prescribed employee, or a prescribed class of employees'

238. As employees other than the Registrar must routinely carry out duties under the Plant Breeder's Rights Act, this item provides for the powers or functions under the Plant Breeder's Rights Act to be delegated to a prescribed employee or class of employees. This will allow for more efficient administration of the plant breeder's rights system. This amendment is also consistent with delegations of powers or functions for other intellectual property rights.

239. Item 2 repeals section 59 and inserts a new section 59. This amendment will enable wider delegation of the powers of the Minister, the Secretary and the PBR Registrar.

240. Subsection (1) and (2) are essentially the same as the currently enacted subsections. The only difference is that the subsections now have the term 'or the regulations' inserted. This amendment clarifies that the delegation of any of the powers or functions under the Plant Breeder's Rights Act includes those powers and functions provided in the *Plant Breeder's Rights Regulations 1994*.

241. Subsection 59(3) will allow the PBR Registrar to delegate his or her powers under the Plant Breeder's Rights Act and regulations to a prescribed employee or to employees in a prescribed class. Employees and classes of employees are to be prescribed in the Plant Breeder's Rights Regulations. The term 'employee' is defined in subsection 59(6), as meaning 'a person who is engaged under the *Public Service Act 1999* or otherwise for or on behalf of the Commonwealth and whose duties involve providing assistance to the Registrar.'

242. This provision will allow the PBR Registrar to delegate his or her powers, but will place a limit on the persons or the classes of persons to whom his or her power may be delegated.

243. Subsection 59(4) will allow a person to whom a power or function has been delegated by either the Minister or the Secretary (under subsections 59(1) and 59(2) respectively) to sub-delegate their powers or function. As with above, the person is only able to sub-delegate these powers to a prescribed employee or to prescribed classes of employees.

244. According to subsection 59(5), a power or function that is exercised or performed by an employee under a delegation under subsection 59(4) is taken to have been exercised or performed by the person who originally delegated the corresponding power or function. In the case of an original delegation under subsection 59(1) of the Plant Breeder's Rights Act, this will be the Minister. In the case of an original delegation under subsection 59(2) of the Plant Breeder's Rights Act, this will be the Secretary.

245. Paragraph 34AB(c) of the Acts Interpretation Act (AIA) provides that 'a function or power so delegated, when performed or exercised by the delegate, shall, for the purposes of the Act, be deemed to have been performed or exercised by the authority'. Subsection 59(5) ensures that the power or function is taken to have been performed or exercised by the Minister or Secretary, and not by the Registrar, so that it will be treated in the same manner as powers or functions delegated under subsections 59(1) or (2), as specified in the AIA.

246. Subsection 59(6) provides that if required by an instrument delegating a power or function, the employee must exercise the power or function under the direction or supervision of the person who delegated the power or another employee specified in the instrument. This provision will ensure delegated powers or functions are applied consistently and correctly.

247. Subsection 59(7) provides a definition of 'employee' that applies in subsection (3), (4), (5) and (6).

### **Item 3**

248. Item 3 is a saving provision. This provides that a delegation in force under section 59 of the Plant Breeder's Rights Act immediately before the commencement of this Schedule has effect on or after that commencement as if it had been made on that commencement. However, this does not prevent the revocation or variation of the delegation after that commencement.

## **Schedule 16 —Statute law revision amendments**

*Patents Act 1990*

*Trade Marks Act 1995*

### **Item 1**

249. Item 1 amends the definition of the phrase 'Australian Register of Therapeutic Goods' in Schedule 1 to the Patents Act. This amendment is consequential on the *Therapeutic Goods Amendment (Medical Devices) Act 2002*, and commences at the same time as Schedule 1 to that Act commenced, 4 October 2002.

250. Although this amendment commences retrospectively, it is technical only, in that it corrects a cross-reference to the *Therapeutic Goods Act 1989*, and makes no change to the substantive law. The amendment will therefore not adversely impact on any person.

## Item 2

251. Item 2 repeals subsection 84(2) of the Trade Marks Act, and substitutes a new subsection. This amendment commences immediately after the commencement of section 84 of the Trade Marks Act, on 1 January 1996.

252. Although this amendment commences retrospectively, it is a technical change only. The replacement of subsection 84(2) ensures that the words after subparagraph (b)(ii) are indented to indicate that they relate only to paragraph (b) and not to the whole subsection. This clarifies the interpretation of the subsection, and makes no change to the substantive law. The amendment will therefore not adversely impact on any person.

## Item 3

253. Item 3 replaces a reference to ‘paragraph (1)(a) or (b)’ in paragraph 206(2)(b) of the Trade Marks Act with a reference to ‘subsection 1’. This amendment is consequential on the amendment of subsection 206(1) made by the *Public Employment (Consequential and Transitional) Amendment Act 1999*, and commences at the same time as item 943 of Schedule 1 to that Act commenced, on 5 December 1999.

254. Although this amendment commences retrospectively, it is technical only, in that it corrects a drafting oversight, and makes no change to the substantive law. The amendment will therefore not adversely impact on any person.

s33

Re: s33

[SEC=IN-CONFIDENCE] - Notes Reply

File C2012/12282 - FOI 56

From: [Brendan Bourke@ipaaustralia.gov.au](mailto:Brendan.Bourke@ipaaustralia.gov.au)  
To: [redacted]  
Cc: [matthew.fomo@ipaaustralia.gov.au](mailto:matthew.fomo@ipaaustralia.gov.au), [redacted]  
Sent: 26-10-2010 4:11:47 PM

Hi [redacted]

I'm catching up on where things are at and noticed the following:

s33

all other redactions s47F

s33

s33

I have attached a copy, but Word and PDF versions are also available online at BillsNet:

[http://parlinfo.aph.gov.au/parlInfo/search/display/display.w3p;orderBy=alphaAss;page=7;query=\(Dataset%3AbillsPrevPar%20SearchCategory\\_Phrase%3A%22bills%20and%20legislation%22%20Dataset\\_Phrase%3A%22billhome%22\)%20Decade%3A%222000s%22%20Year%3A%222006%22;rec=4](http://parlinfo.aph.gov.au/parlInfo/search/display/display.w3p;orderBy=alphaAss;page=7;query=(Dataset%3AbillsPrevPar%20SearchCategory_Phrase%3A%22bills%20and%20legislation%22%20Dataset_Phrase%3A%22billhome%22)%20Decade%3A%222000s%22%20Year%3A%222006%22;rec=4)

<Attachment: IP Laws 2006 EM.doc>

p.s. Is a transcript of the third round available?

[redacted] --26/10/2010 02:26:45 PM-- [redacted] Great to see you yesterday, but sorry to hear you're leaving us. But just

Regards

Brendan

**Brendan Bourke**  
Assistant Director  
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IP Australia

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 Please consider the environment before printing this email

From: [redacted]  
To: [redacted]  
Cc: [brendan.bourke@ipaaustralia.gov.au](mailto:brendan.bourke@ipaaustralia.gov.au), [matthew.fomo@ipaaustralia.gov.au](mailto:matthew.fomo@ipaaustralia.gov.au), [redacted]  
Date: 26/10/2010 02:26 PM  
Subject: s33 [SEC=IN-CONFIDENCE:FTA]

[redacted]  
Great to see you yesterday, but sorry to hear you're leaving us. But just so you don't feel like you're missing out on TPP, here are the questions

s33

s33

I'll try to take some time to look at this in detail during this week and will be in touch to decide upon the best approach for responding.

Regards, M.

[redacted]  
Executive Officer  
FTA Commitments & Implementation Section  
Office of Trade Negotiations  
Department of Foreign Affairs & Trade

T: [redacted]  
F: +61 2 6112 3773(attachment [redacted] \* deleted by Brendan Bourke/CBR/IPAustralia)

s33

## Pharmaceutical intellectual property protection in Australia

### *Patent protection*

In Australia, the *Patents Act 1990 (Commonwealth)* provides for the extension of a pharmaceutical patent by up to five years beyond the standard 20 year patent term. In order to qualify for an extension, the patent must comply with section 70(3) the Act:

- *goods containing or consisting of the pharmaceutical substance (as disclosed and claimed in the patent) must be included in the ARTG (Australian Register of Therapeutic Goods); and*
- *the period beginning on the date of the patent and ending on the "first regulatory approval date" for the substance must be at least five years.*

The maximum length of an extension is five years, and the length of the extension is calculated according to the time between the date of the patent and the earliest first regulatory approval date. The 'date of the patent' is in most cases the date of filing the relevant complete patent specification.

### *Data Protection in Australia*

Clinical data protection is a form of intellectual property protection designed to shield the marketing approval data submitted by an originator pharmaceutical company from unauthorised use by a potential competitor.

Data protection is distinct from patent protection, and is granted on the date of the registration of the drug. The protection can effectively extend the marketing monopoly of the originator, beyond the life of the patent(s) by preventing a prospective generic market entrant from relying on the clinical trial data submitted by the originator in support of its marketing application.

The terms data exclusivity and data protection are sometimes used interchangeably, however they can be usefully distinguished:

- Data exclusivity prevents the reliance on the innovator's data for the purpose of obtaining market approval for a generic version of the medicine. In this instance the generic applicant cannot rely on either the data submitted by originator pharmaceutical company in the original application nor on any public available data in compiling a marketing application.
- A data protection regime only protects the pharmaceutical registration files – the data submitted by the originator sponsor to the regulatory authority for the purpose of obtaining market approval. This means that a generic company may compile a literature-based marketing approval application from publicly available data during the data protection period.

In Australia, this protection is only afforded to undisclosed data and is distinct from data exclusivity, which also prevents reliance by a third party on any relevant clinical data even where it is in the public domain.

Under the Australian *Therapeutic Goods Act 1989* (section 25A), a generic product may not rely on the clinical dataset of the originator product for 5 years from the date of registration of the originator product. Section 25A of the TGA Act is at **Attachment A**.

Australia's current IP protection provisions for biological medicinal products are consistent with its obligations under TRIPS and the *Australia US Free Trade Agreement (AUSFTA)*.

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***Bolar Provision (Springboarding)***

*Springboarding* is an exception to patent infringement, and is also known as the Bolar or “early working” exception. ~~This provision~~ Springboarding allows a generic producer to manufacture and supply quantities of a patented product in order to undertake the necessary studies to prepare and submit an application for marketing approval of a generic version of that product in order to rapidly “springboard” their generic product onto the market once the brand name patent expires.

In the absence of any permitted springboarding, such conduct during the term of a patent would amount to infringement of the patent – manufacturers of generic products would therefore have to wait until the patent expires before commencing the process of obtaining regulatory approval. As a result, it could take a number of years post patent expiry before a generic version of a drug could be approved by regulatory authorities.

In Australia, section 119A of the *Patents Act 1990 (Commonwealth)* (**Attachment B**) provides that a pharmaceutical patent is not infringed by exploitation of an invention for purposes solely in connection with obtaining marketing approval and inclusion on the Australian Register of Therapeutic Goods.

Section 119A permits springboarding at any time during the life of a pharmaceutical patent, regardless of whether its term has been extended, provided that the patent is exploited solely for the purposes of obtaining regulatory approval in Australia. ~~of~~

The exemption under section 119A also applies for the purpose of obtaining regulatory approval overseas. However the exemption only applies to the export of goods for the purpose of obtaining regulatory approval overseas where the export occurs during the extended term of a patent and the goods contain a pharmaceutical substance that is disclosed and claimed in that patent.

**Attachment A**

**Data Protection /exclusivity**

TGA Act provides for a period of 5 years

**25A When the Secretary must not use protected information**

(1) When evaluating therapeutic goods for registration, the Secretary must not use information about other therapeutic goods that is protected information.

(2) Information is *protected information* if:

- (a) the information was given to the Secretary in relation to an application to register therapeutic goods (the *new goods*):
  - (i) not being therapeutic devices; and
  - (ii) consisting of, or containing, an active component; and
- (b) the information is about the active component and is not available to the public; and
- (c) when the application to register the new goods was lodged:
  - (i) no other therapeutic goods consisting of, or containing, that active component were included in the Register; and
  - (ii) no such therapeutic goods had been included in the Register at any time before then; and
- (d) the new goods became registered on or after the commencement of this subsection; and
- (e) 5 years have not passed since the day the new goods became registered; and
- (f) the person in relation to whom the new goods are registered has not given the Secretary permission in writing for the Secretary to use the information.

(3) For the purposes of subsection (2), an *active component*, in relation to therapeutic goods, is a substance that is, or one of the substances that together are, primarily responsible for the biological or other effect identifying the goods as therapeutic goods.

(4) The use of protected information contrary to subsection (1) does not render the Commonwealth, the Secretary or a delegate of the Secretary liable to a person in respect of loss, damage or injury of any kind suffered by the person as a result of, or arising out of, the use of that information.

*Attachment B*

**119A Infringement exemptions: acts for obtaining regulatory approval of pharmaceuticals**

(1) The rights of a patentee of a pharmaceutical patent are not infringed by a person exploiting an invention claimed in the patent if the exploitation is solely for:

- (a) purposes connected with obtaining the inclusion in the Australian Register of Therapeutic Goods of goods that:
  - (i) are intended for therapeutic use; and
  - (ii) are not medical devices, or therapeutic devices, as defined in the *Therapeutic Goods Act 1989*; or
- (b) purposes connected with obtaining similar regulatory approval under a law of a foreign country or of a part of a foreign country.

(2) Subsection (1) does not apply to the export from Australia of goods for purposes described in paragraph (1)(b) unless the term of the patent has been extended under Part 3 of Chapter 6 and the goods consist of or contain:

- (a) a pharmaceutical substance *per se* that is in substance disclosed in the complete specification of the patent and in substance falls within the scope of the claim or claims of that specification; or
- (b) a pharmaceutical substance when produced by a process that involves the use of recombinant DNA technology, that is in substance disclosed in the complete specification of the patent and in substance falls within the scope of the claim or claims of that specification.

(3) In this section:

***pharmaceutical patent*** means a patent claiming:

- (a) a pharmaceutical substance; or
- (b) a method, use or product relating to a pharmaceutical substance, including any of the following:
  - (i) a method for producing a raw material needed to produce the substance;
  - (ii) a product that is a raw material needed to produce the substance;
  - (iii) a product that is a pro-drug, metabolite or derivative of the substance.

# TPP - springboarding and data protection [SEC=IN-CONFIDENCE] - Notes Reply

**From:** [Brendan.Bourke@ipaaustralia.gov.au](mailto:Brendan.Bourke@ipaaustralia.gov.au)  
**To:** [REDACTED]  
**Cc:** [REDACTED] matthew.forno@ipaaustralia.gov.au, [REDACTED] More...  
**Sent:** 15-11-2010 10:15:08 AM

Hi [REDACTED]

Attached is the data protection/springboarding paper prepared by Jamie with our changes added I have made only minor changes.

Sorry for the delay but [REDACTED]

<Attachment: Data Protection paper - TGA final (IPA comments).doc>

Regards

all redactions s47F

Brendan

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TPP: patent certification/linkage [SEC=IN-CONFIDENCE] - Notes Memo

From: [Brendan.Bourke@ipaaustralia.gov.au](mailto:Brendan.Bourke@ipaaustralia.gov.au)  
To: s47F  
Cc: Matthew Forno/OU=CBR/IPAustralia@IP\_Australia  
Sent: 02-12-2010 5:07:49 PM

all other redactions s33

Hi s47F

Sorry I couldn't get back to you earlier. [REDACTED]

Patent linkage is related to springboarding and was dealt with under Art 17.10.4 of AUSFTA. I provided some background on patent linkage in the document I sent over to you last week setting out [REDACTED]

IP Australia also issued an Official Notice in 2004 on the issue.

<http://www.ipaustralia.gov.au/pdfs/news/Official%20Notice%20correction%20-%20TG%20Act%20-%20V2.pdf>

Basically, a requirement for a certificate by a generic manufacturer that they would not infringe a patent was inserted into the TGA.

[REDACTED]

[REDACTED]

[REDACTED]

<Attachment: 20101126 IP Australia [REDACTED]>

Brendan

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File C2012/12382 - FOI 63

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**Fw: TPP: [REDACTED] [SEC=IN-CONFIDENCE] - Notes Memo**

**From:** [Tanya.Duthie@ipaaustralia.gov.au](mailto:Tanya.Duthie@ipaaustralia.gov.au)  
**To:** Brendan Bourke/OU=CBR/IPAustralia@IP\_Australia  
**Sent:** 23-06-2011 10:12:51 AM

all other redactions s33

Email drafted last night, in case you haven't got it

----- Forwarded by Tanya Duthie/CBR/IPAustralia on 23/06/2011 10:10 AM -----

From: s47F  
To: s47F tanya.duthie@ipaaustralia.gov.au, kirrily.peters@innovation.gov.au, <Peter.Lunn@innovation.gov.au>, "Chesworth, Peter" <Peter.Chesworth@innovation.gov.au>  
Cc: s47F matthew.forno@ipaaustralia.gov.au  
Date: 23/06/2011 09:56 AM  
Subject: Fw: TPP: [REDACTED] [SEC=UNCLASSIFIED]

Dear all,

Please see below report from our Chief TPP negotiator on the discussion in Vietnam [REDACTED] We will be preparing a PPQ which we will distribute for your info.

Kind regards,

s47F

A/g Director  
International Intellectual Property Section  
Office of Trade Negotiations  
Department of Foreign Affairs and Trade  
Tel: s47F  
Fax:+61 2 6112 1482

[REDACTED]

all redactions s33

## **TRANS-PACIFIC PARTNERSHIP TRADE GOALS TO ENHANCE ACCESS TO MEDICINES**

President Obama announced in November 2009 the United States' intention to participate in the Trans-Pacific Partnership (TPP) negotiations in order to conclude an ambitious, 21st-century Asia-Pacific trade agreement that reflects U.S. priorities and values. Through this agreement, the United States is seeking to create a platform for regional integration across the Asia-Pacific that will boost trade and investment among the TPP partners, enhance economic growth and living standards, and support the creation and retention of jobs.

As part of this initiative, the Office of the United States Trade Representative (USTR) has presented a variety of trade proposals to TPP partners that are aimed at promoting access to medicines in TPP partner markets. These proposals are the product of a new strategic initiative, **Trade Enhancing Access to Medicines (TEAM)**, which is designed to deploy the tools of trade policy to promote trade in, and reduce obstacles to, access to both innovative and generic medicines, while supporting the innovation and intellectual property protection that is vital to developing new medicines and achieving other medical breakthroughs.

The TEAM initiative reflects fresh thinking about trade and access to medicines. It is about more than *allowing* access to medicines. It is about working with trading partners to develop strong and common standards to help *drive* access – propelling the TPP countries to the front of the line for important innovative medicines and for generic competition, while promoting U.S. jobs and exports.

**Under the TEAM approach, the United States proposes to work with its current TPP partners – Australia, Brunei Darussalam, Chile, Malaysia, New Zealand, Peru, Singapore, and Vietnam – to achieve the following goals in the TPP:**

- **Expedite access to innovative and generic medicines through a “TPP access window”:** Promote the availability of life-saving and life-enhancing medicines in TPP markets and simultaneously establish a pathway for generics to enter those markets as quickly as possible by conditioning obligations to apply certain pharmaceutical-specific intellectual property protections on the requirement that innovators bring medicines to TPP markets within an agreed window of time.
- **Enhance legal certainty for manufacturers of generic medicines:** Enhance legal certainty for producers of generic medicines throughout the TPP region by means of patent exceptions and incentives for generic medicines, while maintaining a balance of intellectual property protection for innovators.
- **Eliminate tariffs on medicines:** Immediately eliminate duties on medicines and medical devices, thereby decreasing costs for hospitals, clinics, aid organizations and consumers, among others. This includes ensuring that any existing tariffs on amoxicillin, penicillin, and anti-malarial medicines, for example, are eliminated.

- **Reduce customs obstacles to medicines:** Minimize import barriers, such as discriminatory, burdensome, and unpredictable customs procedures, that impede access to innovative and generic medicines.
- **Curb trade in counterfeit medicines:** Make customs and criminal enforcement measures available to prevent medicines bearing counterfeit trademarks from entering TPP markets, and thus support efforts of TPP countries to address the serious risks to patients posed by such counterfeits.
- **Reduce internal barriers to distribution of medicines:** Guarantee importing, exporting, and distribution rights with respect to medicines and minimize internal barriers that can stand in the way of efficiently distributing medicines to those in need.
- **Promote transparency and procedural fairness:** To ensure the fairest possible opportunity for both generic and innovative medicines to enter TPP markets, require respect for basic norms of transparency and procedural fairness in the operation of national government healthcare reimbursement programs.
- **Minimize unnecessary regulatory barriers:** Promote transparent and non-discriminatory regulatory structures to facilitate the availability of safe and efficacious medicines to the public, while also improving coherence of future rules across the region.
- **Reaffirm TPP Parties' commitment to the Doha Declaration on TRIPS and Public Health:** Incorporate important understandings on the availability of public health measures, based on the Doha Declaration on the TRIPS Agreement and Public Health.

The goals listed above demonstrate how the Obama Administration is coordinating and deploying trade policy tools to help reduce potential barriers to access to medicines, while also supporting innovation and the development of new medicines by the U.S. pharmaceutical and other health industries.

Trade policy alone cannot solve the challenges relating to access to medicines. The Obama Administration is addressing these challenges on every front: through foreign assistance and development programs, through foreign policy initiatives, and through close engagement with various countries as they work domestically on public health issues. These other Administration initiatives are coordinated by various U.S. agencies, including the U.S. Agency for International Development (USAID), and through various programs, such as the President's Emergency Plan for AIDS Relief (PEPFAR). The goals listed above reflect a commitment to work closely with trading partners to help improve access to medicines by eliminating barriers to trade in medicines and reaffirming the Doha Declaration on TRIPS and Public Health.

In addition to the goals listed above, the TEAM initiative includes new approaches to developing trade policy within the U.S. Government. USTR will convene a TEAM Task Force composed of

experts throughout the government to consider innovative trade policy approaches to promoting access to medicines. Through the TEAM Task Force and direct agency-to-agency discussions, USTR will continue to consult regularly with experts from USAID, PEPFAR and other components of the Global Health Initiative, and all other Federal departments and agencies with relevant expertise. The Task Force will report to the interagency Trade Policy Staff Committee.

Reflecting the principles underlying the TEAM initiative, the U.S. Government will continue to seek out new ideas from all sources, including from the public at large, U.S. trading partners, U.S. federal and state government representatives, and stakeholders, including innovative and generic pharmaceutical industry representatives in the relevant Industry Trade Advisory Committees, as well as health-oriented non-governmental organizations.

## **BACKGROUND**

**The challenges are significant.** Many factors constrain access to safe and effective medicines of assured quality around the world. For example, poor distribution networks for medicines, rooted in a lack of basic infrastructure, transportation, hospitals, clinics and healthcare professionals, can prevent access to medicines.

Other obstacles can also limit access to medicines. For example, taxes or tariffs may be levied on donated medicines or on medicines that are supplied at cost, and the increased expense associated with those levies is then passed directly to healthcare institutions and patients. Discriminatory and non-transparent regulatory regimes, unnecessarily burdensome customs requirements and other trade barriers also hinder the provision of both innovative and generic medicines to those who urgently need them.

At the same time, counterfeit medicines impede access to real lifesaving medicines. Counterfeit and substandard medicines, often distributed by criminal networks, harm or kill sick people across the globe, with the developing world disproportionately affected. In fact, the World Health Organization (WHO) estimates that “in over 50 percent of cases, medicines purchased over the Internet from illegal websites that conceal their physical address have been found to be counterfeit.”

Intellectual property plays an important role in providing the incentives necessary for the development and marketing of new medicines. An effective, transparent, and predictable intellectual property system is necessary for both manufacturers of innovative medicines and manufacturers of generic medicines. Available evidence indicates that patent protections have expired for the vast majority of medicines on the WHO’s Model List of Essential Medicines, further highlighting the large volume of important medicines that were developed under intellectual property protections and that subsequently became available in generic form upon the expiration of those intellectual property protections.

**The United States is a global leader.** The Obama Administration is working to promote access to medicines in many ways, including through foreign assistance and development programs, foreign policy initiatives, and trade policy. The Administration's initiatives implement methods of strengthening sustainable health systems, investing in country-led health plans, improving coordination among stakeholders, and promoting research and innovation. On September 22, 2010, President Obama announced a new U.S. global development policy – the first ever for a U.S. Administration. The Global Development Policy recognizes that development is vital to U.S. national security and is a strategic, economic and moral imperative for the United States. It provides clear policy guidance to all U.S. government agencies and enumerates the core objectives, operational model, and modern architecture needed to implement this guidance. The Administration's Global Health Initiative (GHI), announced by the President in May 2009, embodies the core tenets of the development policy. GHI is helping to build sustainable capacity in the public sectors of our partner governments and at their national and community levels so that developing countries themselves can manage their health system and provide basic services over the long term. The President's Emergency Plan for AIDS Relief, which includes HIV/AIDS, TB and the Global Fund, is the largest component of the GHI. Since its inception, PEPFAR has promoted access to medicines and other products through many means, including by improving supply chain management and procurement systems, and by training health workers. In addition to GHI, many other U.S. programs are having a positive impact on health and facilitating access to medicines.

The United States also makes significant contributions to international organizations that work to address global health challenges. In addition to direct aid, the United States tries to facilitate the discovery, development and distribution of medicines in a number of innovative ways, including through the appropriate diffusion of technology and knowledge. For example, the United States, through the National Institutes of Health, was the first patent holder to share its patents with the newly established Medicines Patent Pool Foundation, which has recently been joined by the Gilead Corporation. U.S. action catalyzed G-8 leaders to voice support for the Foundation, which in turn helped Gilead Corporation to enter into an arrangement with the Patent Pool Foundation.

The United States also recognizes the challenges faced by least developed countries. For example, the WTO adopted a U.S. proposal to extend until 2016 the transition period during which these countries may opt not to implement WTO provisions concerning patent protection for medicines. Working closely with African countries, the United States was also instrumental in reaching agreement at the WTO to create a permanent mechanism to allow countries to issue compulsory licenses when necessary to export lifesaving medicines to countries in need. U.S. trade agreements support this mechanism.

**USTR's role.** USTR is responsible for developing and coordinating U.S. international trade, commodity, and direct investment policy, and for overseeing trade and investment negotiations with other countries. USTR is led by the U.S. Trade Representative, a Cabinet member who

serves as the President's principal advisor, negotiator, and spokesperson on trade issues. USTR is part of the Executive Office of the President. Through an interagency structure, USTR coordinates trade policy and frames issues for presidential decision.

**The Trans-Pacific Partnership.** The TPP is a key initiative through which the Administration seeks to advance the United States' multi-faceted trade and investment interests in the Asia-Pacific region by negotiating an ambitious, 21st-century trade agreement along with Australia, Brunei Darussalam, Chile, Malaysia, New Zealand, Peru, Singapore, and Vietnam. This initial group of like-minded countries shares the goal of creating a platform for regional integration across the Asia-Pacific and boosting trade and investment among themselves, thereby enhancing economic growth and living standards and supporting the creation and retention of jobs. This region includes some of the world's most robust economies and accounts for more than 40 percent of global trade.

s33 exemption

**FW: TPP IP [REDACTED] CONFIDENCE:FTA] - Notes Memo**

[SEC=IN-

**From:** s47F  
**To:** [REDACTED] "karl.brennan@innovation.gov.au" <karl.brennan@innovation.gov.au>, "Brendan Bourke (brendan.bourke@ipaaustralia.gov.au)" <brendan.bourke@ipaaustralia.gov.au>  
**Cc:** s47F "matthew.forno@ipaaustralia.gov.au" <matthew.forno@ipaaustralia.gov.au>, "Trotman, Paul" <Paul.Trotman@innovation.gov.au>  
**Sent:** 26-09-2011 01:36:22 AM

Sorry, first day back and already forgetting things! Attachments now included...

M.

all other redactions s33

s47F

A/g Director  
 FTA Commitments & Implementation Section  
 Office of Trade Negotiations  
 Department of Foreign Affairs & Trade

s47F

---

**From:** s47F  
**Sent:** Monday, 26 September 2011 11:28 AM  
**To:** s47F 'karl.brennan@innovation.gov.au'; Brendan Bourke (brendan.bourke@ipaaustralia.gov.au)  
**Cc:** s47F matthew.forno@ipaaustralia.gov.au; 'Trotman, Paul'  
**Subject:** TPP IP [REDACTED] [SEC=IN-CONFIDENCE:FTA]

Good morning all,

[REDACTED]

[REDACTED], I realise we have a pretty short turnaround, but would be most appreciative of any initial comments you may have on the text (in as much detail as you are able to provide in the time frame) by noon Monday 11 October.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Kind regards,

s47F

all other redactions s33

A/g Director  
FTA Commitments & Implementation Section  
Office of Trade Negotiations  
Department of Foreign Affairs & Trade  
Tel: s47F  
Fax: 02 6112 3773

<Attachment: TPP Chicago slides - AU.pdf> <Attachment: TPP - Selected IPR Provisions - September 2011 - provided to Australia.pdf>

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From: [Brendan Bourke@ipaustralia.gov.au](mailto:Brendan.Bourke@ipaustralia.gov.au)  
To: [REDACTED]  
Cc: [REDACTED] Dana Busic<OU=CBR/IPAustralia@IP\_Australia, Matthew Forno<OU=CBR/IPAustralia@IP\_Australia>  
Sent: 01/09/2011 1:02:11 PM

Thanks [REDACTED] could perhaps add the following to what you already have:

Australia already has a strong IP system that balances the needs of innovators, generic pharmaceutical companies and the public.

**Brendan Bourke**  
Assistant Director  
International Policy & Cooperation  
Business Development & Strategy Group  
IP Australia



P + 61 2 6283 2148 | F + 61 2 6283 7999  
E [brendan.bourke@ipaustralia.gov.au](mailto:brendan.bourke@ipaustralia.gov.au)  
A 47 Bowes Street, Woden ACT 2606 | PO Box 200, Woden ACT Australia 2606  
Visit us at <http://www.ipaustralia.gov.au>

♣ Please consider the environment before printing this email

From: [REDACTED]  
To: "Brendan Bourke (brendan.bourke@ipaustralia.gov.au)" <brendan.bourke@ipaustralia.gov.au>  
Cc: [REDACTED]  
Date: 01/09/2011 12:18 PM  
Subject: FW: Media Question on TPP to Health [SEC=IN-CONFIDENCE-FTA]

IN-CONFIDENCE-FTA

Sorry about this, as discussed, request is below, and here is the response I'm proposing on the broader issue (not cleared yet by JK, but based on other correspondence we've dealt with:

*The Government is aware of the concerns of the Public Health Association of Australia and other stakeholders about proposals relating to patents in the Trans-Pacific Partnership Agreement (TPP) negotiations. As part of the Government's ongoing consultation process for the TPP, the Department of Foreign Affairs and Trade has previously met with the Public Health Association of Australia to discuss their views in relation to health and pharmaceutical issues in the TPP. Retaining the ability to ensure access to quality, affordable medicines for Australian consumers is a priority for the Government, and a TPP outcome that would negatively impact upon the integrity of the PBS would not be accepted.*

However, grateful your urgent advice on the specific question:

Would the government consider allowing any extension of patent rights for US drugs?  
As also discussed, Health are seeking a response ASAP (preferably by 1pm).

Many thanks, M.

[REDACTED]  
Executive Officer  
FTA Commitments & Implementation Section  
Office of Trade Negotiations  
Department of Foreign Affairs & Trade  
T: [REDACTED]  
F: 02 6112 3773

IN-CONFIDENCE-FTA

From: [REDACTED]  
Sent: Thursday, 1 September 2011 11:51 AM  
To: [REDACTED]  
Subject: FW: Media Question on TPP to Health [SEC=UNCLASSIFIED]

UNCLASSIFIED

After all that it was your email address that was wrong!

SP

From: [REDACTED]  
Sent: Thursday, 1 September 2011 11:39 AM  
To: [REDACTED]  
Cc: [REDACTED]  
Subject: Media Question on TPP to Health [SEC=UNCLASSIFIED]

H [REDACTED]

As discussed please find below a question received by our MO in relation to the TPP. It would be greatly appreciated if you could advise the best way to handle. Please note our MO has requested a response by this afternoon so your early advice would be greatly appreciated.

[REDACTED]  
Policy and Analysis Branch  
Pharmaceutical Benefits Division  
[REDACTED]

----- Forwarded by Carla De Campo<MINISTERHealth on 01/09/2011 10:31 -----

01/09/2011 10:23  
To: [REDACTED]  
cc: [REDACTED]  
Subject: Fw: Philip Morris seeks data on teenage smokers [SEC=UNCLASSIFIED]

s33

all other redactions s47F

---01/09/2011 12:18:44 PM---IN-CONFIDENCE-FTA Sorry about this, as discussed, request is below, and here is the response I'm pro

Classification: [SEC=UNCLASSIFIED]

Carla/Paul - can u respond to MM.

[REDACTED]

Press Secretary  
Office of the Hon Nicola Roxon MP  
Minister for Health and Ageing

cc: [REDACTED]

all redactions s47F

----- Original Message -----

[REDACTED]

Subject: RR: Phillip Morris seeks data on teenage smokers [SEC=UNCLASSIFIED]

[REDACTED] .can I get government response on this statement below from the Public Health Assn?. Would the government consider allowing any extension of patent reights for US drugs?

Trans-Pacific Partnership Agreement proposals increase corporate rights, reduce access to affordable medicines, say public health and fair trade groups  
\*Leaked US proposals in the Trans-Pacific Partnership Agreement (TPPA) being negotiated by Australia, the US, New Zealand, and six other countries would increase the rights of pharmaceutical companies to charge higher prices for medicines for longer, and reduce the rights of consumers to have access to affordable medicines. These proposals are to be debated at the TPPA negotiations next week in Chicago\*, said Dr Deborah Gleeson of the Public Health Association of Australia.  
\*US pharmaceutical companies have lobbied the US government to propose even more changes than were conceded in the Australia-US Free Trade Agreement in 2004,\* explained Dr Gleeson. \*The attached table compiled by US and Australian intellectual property law experts give details of the impact the proposals would have on Australian law\*, see [www.aifinst.org.au](http://www.aifinst.org.au).  
\*Pharmaceutical companies already have rights under current patent law to charge monopoly prices for medicines for 20 years. Extensions of patent periods and delays in the marketing of cheaper generic drugs benefit these companies, but disadvantage consumers, and would increase the cost of medicines to the public health system,\* said Dr Patricia Randall of the Australian Fair Trade and Investment Network .  
Dr Randall explained that the US proposals include:  
\* Lowering Australian standards to allow more patents which make only slight changes to an existing medicine, thus enabling the repeated extension or 'ever-greening' of patents  
\* Removal of public rights to object to new patents before they are granted, which would make it easier for unjustified patents to be granted  
\* Removal of current Australian flexibility to disallow the patenting of medical procedures, which could impose huge future costs on hospitals  
The pharmaceutical companies are also lobbying for extension of periods of data exclusivity which would delay generic drugs, including data exclusivity for biological drugs for 12 years, and elimination of Australian safeguards against patent abuse and 'ever-greening' which Parliament inserted at the time of the Australia-US Free Trade Agreement in 2004.  
\*The 2010 Productivity Commission Report on Bilateral and Regional

-----Original Message-----

From: [REDACTED]  
Sent: Thursday, 4 September 2014 9:10 AM  
Subject: Phillip Morris seeks data on teenage smokers [SEC=UNCLASSIFIED]

Classification: [SEC=UNCLASSIFIED]

Interesting article thought you might be interested in.

<http://www.belfasttelegraph.co.uk/news/local-national/uk/firm-seeks-data-on-teenage-smokers-16041793.html#ixzzWm7vumv>

Press Secretary  
Office of the Hon Nicola Roxon MP  
Minister for Health and Ageing

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TPP IP  
- Notes Memo

[SEC=IN-CONFIDENCE:FTA]

**From:** s47F  
**To:** "karl.brennan@innovation.gov.au"  
<karl.brennan@innovation.gov.au>, "Brendan Bourke (brendan.bourke@ipaustalia.gov.au)"  
<brendan.bourke@ipaustalia.gov.au>  
**Cc:** s47F  
"matthew.forno@ipaustalia.gov.au" <matthew.forno@ipaustalia.gov.au>, "Trotman, Paul"  
<Paul.Trotman@innovation.gov.au>  
**Sent:** 26-09-2011 01:28:26 AM

all other redactions s33

Good morning all,

[Redacted content]

Many thanks, and feel free to call me if you need anything further.

Kind regards,

s47F

A/g Director  
FTA Commitments & Implementation Section  
Office of Trade Negotiations  
Department of Foreign Affairs & Trade

Tel: s47F

Fax: 02 6112 3773

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Re: FW: TPP IP  
CONFIDENCE] - Notes Reply

[SEC=IN-

From: [Brendan.Bourke@ipaaustralia.gov.au](mailto:Brendan.Bourke@ipaaustralia.gov.au)

To: s47F

Cc: peter.lunn@innovation.gov.au, Matthew Forno/OU=CBR/IPAustralia@IP\_Australia

Sent: 12-10-2011 2:41:07 PM

all other redactions s33

Hi s47F

Attached are IP Australia's comments on [redacted]

The first part (page 1) sets out IP Australia's position [redacted]

The second part (pages 2-6) provides a comparison of the proposal with Australian law. [redacted]

<Attachment: IP Australia comments on [redacted].doc>

s47F

Regards

**Brendan Bourke**  
Assistant Director  
International Policy & Cooperation  
Business Development & Strategy Group  
IP Australia



P + 61 2 6283 2148 | F + 61 2 6283 7999 | M s47F

E [brendan.bourke@ipaaustralia.gov.au](mailto:brendan.bourke@ipaaustralia.gov.au)

A 47 Bowes Street, Woden ACT 2606 | PO Box 200, Woden ACT Australia 2606

Visit us at <http://www.ipaustralia.gov.au>

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**Fw: TPP IP  
- Notes Memo**

**[SEC=IN-CONFIDENCE]**

**From:** [Brendan.Bourke@ipaaustralia.gov.au](mailto:Brendan.Bourke@ipaaustralia.gov.au)  
**To:** s47F  
**Cc:** Matthew Forno/OU=CBR/IPAustralia@IP\_Australia  
**Sent:** 13-10-2011 4:58:01 PM

all other redactions s33

Hi s47F

Attached is the final document. The only changes are some additional background under items [redacted] shown as marked up text in the attached.

<Attachment: IP Australia comments on [redacted]>

**Brendan Bourke**  
Assistant Director  
International Policy & Cooperation  
Business Development & Strategy Group  
IP Australia



P + 61 2 6283 2148 | F + 61 2 6283 7999 | s47F  
E [brendan.bourke@ipaaustralia.gov.au](mailto:brendan.bourke@ipaaustralia.gov.au)  
A 47 Bowes Street, Woden ACT 2606 | PO Box 200, Woden ACT Australia 2606

Visit us at <http://www.ipaustralia.gov.au>

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----- Forwarded by Brendan Bourke/CBR/IPAustralia on 13/10/2011 04:53 PM -----

From: Brendan Bourke/CBR/IPAustralia  
s47F  
peter.lunn@innovation.gov.au, Matthew Forno/CBR/IPAustralia@IP\_Australia  
Date: 12/10/2011 02:41 PM  
Subject: Re: FW: TPP IP [redacted] [SEC=IN-CONFIDENCE]

Hi s47F

Attached are IP Australia's comments on the [redacted]

The first part (page 1) sets out IP Australia's position [redacted]

The second part (pages 2-6) provides a comparison of the proposal with Australian law. [REDACTED]

[attachment "IP Australia comments on [REDACTED] deleted by Brendan Bourke/CBR/IPAustralia]

s47F

Regards

**Brendan Bourke**

Assistant Director

International Policy & Cooperation

Business Development & Strategy Group

IP Australia

all other redactions s33



P + 61 2 6283 2148 | F + 61 2 6283 7999 | s47F

E [brendan.bourke@ipaaustralia.gov.au](mailto:brendan.bourke@ipaaustralia.gov.au)

A 47 Bowes Street, Woden ACT 2606 | PO Box 200, Woden ACT Australia 2606

Visit us at <http://www.ipaustralia.gov.au>

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Emailing: [REDACTED] [SEC=IN-CONFIDENCE:FTA] - Notes Memo

From: s47F  
To: brendan.bourke@ipaaustralia.gov.au  
Sent: 09-06-2011 4:41:15 PM

all other redactions s33

Brendan, attached is a paper Medicines Australia gave me today, which I think was also passed to Philip Noonan at their meeting with him in the last couple of days (they said I could also send it on to you). Meeting basically focussed on general update and explanation of negotiation/TPP process, [REDACTED]

[REDACTED]

[REDACTED]

Asked if we could do an IP specific stakeholder session at next consultations, I confirmed it's being considered and was something I would see as valuable, but would depend on timing, resourcing etc..

M.

s47F

Executive Officer  
FTA Commitments & Implementation Section  
Office of Trade Negotiations  
Department of Foreign Affairs & Trade

T: s47F  
F: +61 2 6112 3773

(See attached file: [REDACTED])

<Attachment: [REDACTED]>

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In cooperation with the United States Patent and Trademark Office (USPTO), the International Intellectual Property Institute is conducting a series of projects investigating the effects of U.S. government technical assistance programs, U.S. TRIPS-Plus free trade agreements, and specialised intellectual property courts from around the world.

Alexander Koff, chair of the global practice at Whiteford, Taylor & Preston, is an IIPi consultant. Mr. Koff will conduct meetings in Australia for these IIPi-USPTO projects from the afternoon of Tuesday 19 July through Friday 22 July. Here is a brief overview of the studies and a summary of what Mr. Koff would like to discuss:

1. TRIPS-Plus and Technical Assistance

a. TRIPS-Plus

- i. Study. In order to determine whether TRIPS-Plus FTAs promote economic growth in FTA-partner countries, IIPi is conducting a series of case studies. By analysing economic data and using anecdotal evidence from U.S. TRIPS-Plus trade partners, these case studies will provide a clearer picture of the effects that TRIPS-Plus FTAs have had on FTA-partner countries.
- ii. Discussion. Mr. Koff would explore whether there are any illustrative examples that can help shed light on whether TRIPS-Plus provisions help, hurt, or is neutral from the perspective of those located in Australia. (Note: the ultimate audience for the report in this example is the people in Australia, not the United States.)

b. Technical Assistance.

- i. Study. To better understand why U.S. and global development programs do not give higher priority to capacity building and technical assistance involving IPR, IIPi is studying the relationships between current technical assistance and capacity-building programs to the growth of American exports and other business activities.
- ii. Discussion. Mr. Koff will explore whether U.S. IP technical assistance has helped to facilitate U.S. exports to Australia. (Note: the ultimate audience for the report in this example is the people in the U.S. who may

be seeking to export to Australia and understanding how U.S. technical assistance to the IP sector in Australia has encouraged, discouraged, or had no effect on U.S. exports to Australia. They are seeking the perceptions of those in Australia on whether U.S. technical assistance to the IP sector has made any difference – positive or negative – in facilitating U.S. exports to Australia and, if so, in what way.)

- c. Who. Mr. Koff is interested in speaking with chambers/associations, corporations, law/accounting firms, media, NGOs, or others willing to share a new perspective on TRIPS-Plus provisions and technical assistance.
- d. Background. IIPi retained an economic consulting firm to assist with the USPTO studies, and the firm is conducting a macro-economic analysis of the data. But the firm does not have sufficient data to show, at a casual level, that TRIPS-Plus provisions help Australia's economy or increase U.S. exports. But IIPi can get data to help answer the question whether IP provisions help Australia's economy or IP technical assistance helps U.S. exports. IIPi is asking Mr. Koff to travel to Australia to obtain illustrative examples to help be sure the stories and perception on the ground correlate with what their economic analysis firm is seeing in the data and to help fill in any gaps with some illustrative examples.

## 2. Specialised IP Courts.

- a. Study. The objective of the study is to investigate the effect of specialised IP courts, divisions and tribunals on producing consistent case outcomes, the level of expertise in the nation's judiciary, and the conduct of commerce in IP-dependent industry sectors.
- b. Discussion. Mr. Koff will survey IP practitioners, judges, policy-makers, legal scholars, economic experts, and public officials to assess the effect of functioning IP courts, divisions, and tribunals on producing consistent case outcomes in similar factual situations, the level of IP expertise in a nation's judiciary, and the conduct of commerce in IP-dependent sectors.

For more information, please contact Susie Christensen at Foley & Associates on 02 9229 8556 or by email at [susie@foley.net.au](mailto:susie@foley.net.au).

**Roundtable: Public Health and the Trans Pacific Partnership Agreement**

**Wednesday 3 August 2011**

**9.30-11.30am**

**Department of Foreign Affairs and Trade  
RG Casey Bld, John McEwan Crescent, Barton ACT**

**Proposed Agenda**

- 9.30 Welcome and introductions; overview of the Public Health Association's concerns about the TPPA ( [REDACTED], PHAA)
- 9.40 Overview of the TPPA negotiations, chapters and proposed provisions (Jonathan Kenna, DFAT)
- 9.50 Intellectual property and pharmaceuticals in the TPPA negotiations ( [REDACTED], DFAT)
- 10.00 Investment provisions and the TPPA ( [REDACTED], DFAT)
- 10.10 Strategies and tactics in negotiating the TPPA with the U.S.T.R. ( [REDACTED] )
- 10.20 Investment provisions and public health regulation (including tobacco plain packaging) ( [REDACTED] )
- 10.30 Open discussion of concerns and options
- 11.30 Close (tea and coffee provided by DFAT)

**Roundtable: Public Health and the TPPA  
Wednesday 3 August 2011**

**Participant list**

**Department of Foreign Affairs and Trade**

**Mr Jonathan Kenna**

Assistant Secretary, Trade Commitments Branch

[REDACTED]  
FIA Commitments and Implementation Section

[REDACTED]  
FIA Commitments and Implementation Section

**Public Health Association**

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

all redactions s47F

[Redacted]

**FW: Analysis of US IP proposals for the TPPA and their impact on Australian law [SEC=UNCLASSIFIED] - Notes Memo**

**From:** [REDACTED]  
**To:** "Brendan Bourke (brendan.bourke@ipaaustralia.gov.au)" <brendan.bourke@ipaaustralia.gov.au>  
**Sent:** 31-08-2011 02:49:24 AM

UNCLASSIFIED

Hi Brendan, this came through today, so thought I'd shoot over to you as well. I've thanked them for the information and confirmed we're aware of the issues they raise.

Thanks, M.

[REDACTED]

Executive Officer  
FTA Commitments & Implementation Section  
Office of Trade Negotiations  
Department of Foreign Affairs & Trade

all redactions s47F

T: [REDACTED]  
F: 02 6112 3773

**From:** deborah.[REDACTED] **On Behalf Of** Deborah Gleeson

**Sent:** Tuesday, 30 August 2011 10:55 PM

**To:** [REDACTED]

**Cc:** [REDACTED]

**Subject:** Analysis of US IP proposals for the TPPA and their impact on Australian law [SEC=UNCLASSIFIED]

Dear [REDACTED]

Please find attached a chart, prepared by the US consumer advocacy group Public Citizen, that analyses the impact the US proposals for intellectual property provisions in the TPPA would have for Australian patent law. The content of the chart has been reviewed by two Australian IP legal experts.

We have also attached a briefing memo that summarises the information.

We hope you find this information useful in preparing for the Chicago round of negotiations.

Please feel free to contact me ([REDACTED] or [REDACTED] [REDACTED]) if you have any questions. The authors' email contacts are also on the chart if you wish to contact them for any clarifications or extra information.

Regards,  
Deborah

--

Deborah Gleeson MPH PhD  
Research Fellow  
School of Public Health and Human Biosciences  
La Trobe University VIC 3086

National Convener  
Political Economy of Health Special Interest Group  
Public Health Association of Australia

T: +61 3 9479 3262  
[REDACTED]

UNCLASSIFIED

**File C2012/12282 - FOI 167**

<Attachment: Chart on US TPPA Proposal, Australian Law and Access to Medicines.pdf><Attachment: Briefing Memo Aust IP law and US TPPA proposals 30 Aug 2011.docx>

**Summary of chart of changes to intellectual property law resulting from  
US TPPA proposals**

**30 August 2011**

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

Comparative Analysis of the United States' TPPA Intellectual Property Proposal and Australian Law  
Public Citizen, August 29, 2011. Contact: [pmaybarduk@citizen.org](mailto:pmaybarduk@citizen.org); [bkilic@citizen.org](mailto:bkilic@citizen.org). For more information, see [www.citizen.org/access](http://www.citizen.org/access).



*Dangers for Access to Medicines in the Trans-Pacific Partnership Agreement:*  
**Comparative Analysis of the U.S. Intellectual Property Proposal and  
Australian Law**

Comparative Analysis of the United States' TPPA Intellectual Property Proposal and Australian Law  
 Public Citizen, August 29, 2011. Contact: [pmaybarduk@citizen.org](mailto:pmaybarduk@citizen.org); [bkilic@citizen.org](mailto:bkilic@citizen.org). For more information, see [www.citizen.org/access](http://www.citizen.org/access).

Issue	US TPPA Proposal	Australia Patent Act 1990	Analysis
<b>Third-Party Opposition</b>	Article 8.7. (... ) Where a Party provides proceedings that permit a third party to oppose the grant of a patent, a Party shall not make such proceedings available before the grant of the patent.	Section 59 The Minister or any other person may, in accordance with the regulations, oppose the grant of a standard patent on one or more of the following grounds, but on no other ground: (a) that the nominated person is either: (i) not entitled to a grant of a patent for the invention; or (ii) entitled to a grant of a patent for the invention but only in conjunction with some other person; (b) that the invention is not a patentable invention; (c) that the specification filed in respect of the complete application does not comply with subsection 40(2) or (3).  <i>Australian law provides for pre-grant opposition as well as post-grant challenges. Standing rules ensure that any person can formally challenge the</i>	Pre-grant opposition is a safeguard against patent abuse, improvidently granted patents and unwarranted pharmaceutical monopolies. Pre-grant opposition supports appropriate generic competition and access to medicines. The U.S. proposal would eliminate pre-grant opposition in TPPA countries. More information on the U.S. proposal on pre-grant opposition is available at <a href="http://citizen.org/access">citizen.org/access</a> . <sup>1</sup>  Pre-grant opposition allows third parties to formally oppose a patent application by submitting information and analysis to patent examiners, under an adversarial administrative process. Pre-grant opposition helps improve patent quality and the accuracy of patent claims. This process helps to prevent pharmaceutical monopolies based on meritless patents that contribute little to innovation but greatly to price.

<sup>1</sup>For further discussion of the U.S. strategy to eliminate patent pre-grant opposition, see Public Citizen, HealthGAP, I-MAK and Third World Network, "Analysis of the Leaked U.S. Paper on Eliminating Patent Pre-Grant Opposition," available at <http://www.citizen.org/documents/analysis-of-leaked-US-paper-on-eliminating-pregrant-opposition.pdf>.

Comparative Analysis of the United States' TPPA Intellectual Property Proposal and Australian Law  
 Public Citizen, August 29, 2011. Contact: [pmaybarduk@citizen.org](mailto:pmaybarduk@citizen.org); [bkilic@citizen.org](mailto:bkilic@citizen.org). For more information, see [www.citizen.org/access](http://www.citizen.org/access).

		<p><i>validity of a patent at each stage of the prosecution process.</i></p> <p><i>After the patent office accepts and publishes a patent application, any person may oppose that application within three months. The opposition can only be based on grounds mentioned in Section 59, e.g. lack of novelty or inventive step etc.</i></p> <p><i>A patent may be revoked after its grant. A third party may seek revocation of a patent independently (Section 138) or file as a counter-claim in infringement proceedings (Section 121).</i></p> <p><i>Re-examination provides another means by which third parties can challenge a patent. Re-examination can be requested on grounds of lack of novelty or inventive step (Section 97), although under the Intellectual Property Laws Amendment -Raising the Bar Bill 2011 (The Bill 2011) currently before Parliament, the admissible grounds for challenges would be broadened.</i></p>	<p>The pre-grant opposition system in Australia provides a relatively inexpensive mechanism for resolving disputes concerning patent validity. According to data provided by IP Australia, third parties oppose only about 1.5% of accepted applications. At the end of opposition proceedings, the patent office most commonly restricts the scope of the claims of the opposed patent. Pre-grant opposition in Australia improves patent quality with minimal interference to well-drafted patent applications.<sup>2</sup></p> <p>The absence of pre-grant opposition would make patent examination less informed and would be likely to increase the number of cases before the courts. Costs associated with the patent opposition system would likely rise. It would create market uncertainty for generics firms, and lead to low-quality patents and unjustified drug monopolies until post-grant challenges could reach a successful conclusion.</p>
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<sup>2</sup> Australia recently considered whether to abolish its pre-grant opposition system and found that there was no evidence that the system was significantly problematic or subject to abuse. Australia has proposed various ways to streamline the process and make it yet more efficient and more effective. Compare to claims in the U.S. leaked paper, <http://www.citizen.org/documents/Leaked-US-TPPA-paper-on-eliminating-pre-grant-opposition.pdf>.

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<p><b><i>Protection of New Forms, Uses, or Methods of Using a Known Product</i></b></p>	<p>Article 8.1. The Parties confirm that: patents shall be available for any new forms, uses, or methods of using a known product; and a new form, use, or method of using a known product may satisfy the criteria for patentability, even if such invention does not result in the enhancement of the known efficacy of that product.</p>	<p><i>The Australian Patent Act defines invention as "a manner of manufacture" within the meaning of s.6 of the Statute of Monopolies' in Schedule 1 of the Patents Act. This statute, in turn, refers to "a manner of new manufacture." A patentable invention can be a product, method, system or process.</i></p> <p><i>This preliminary requirement precludes patentability of a new use of a known substance that takes advantage of a known property. Australian case law establishes that such cases do not meet the standards of patentable subject matter.</i></p> <p><i>A patentable invention is required to provide some material advantage in a field of economic endeavour and pertain to the useful arts rather than the fine arts. A new use of a known substance is patentable provided the use takes advantage of a previously unknown property.</i></p>	<p>Patents for new forms, uses, and methods of using known medicines can enable patent "evergreening," and particularly when enhanced efficacy is not required, can lead to unwarranted extensions of pharmaceutical monopolies.</p> <p>The AUSFTA provides that patents shall be available for any new uses or methods of using a known product (Article 17.9.1). This provision had limited effect. New uses and methods taking advantage of known properties do not always qualify as a 'new manner of manufacture.'</p> <p>But the U.S. TPPA proposal expressly requires patent eligibility for new forms -- e.g., a patent on a tablet -- and rejects any enhanced efficacy requirements. This could undermine limits set by Australia's new manner of manufacture test and gut standards of patentability in Australian law. Under the U.S. proposal, new patents can be granted for minor variations to pharmaceutical substances or methods related to their administration that contribute nothing to enhancing medical care -- e.g., changes in formulations, drug dosage regimes, drug</p>
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			<p>delivery, and even packaging systems to aid in the administration of drugs (including their use in therapeutic treatments).</p>
<p><b>Exclusions from Patentability</b></p>	<p>Article 8.2. Each Party shall make patents available for inventions for the following:</p> <ul style="list-style-type: none"> <li>(a) plants and animals, and</li> <li>(b) diagnostic, therapeutic, and surgical methods for the treatment of humans and animals</li> </ul>	<p><i>The Patent Act does not specifically exclude methods of treatment from patentability. The weight of case law supports the patentability of methods of treatment. A new therapeutic effect of a known substance – referred to as second or subsequent use -- is generally eligible for patent protection.</i></p>	<p>The TRIPS Agreement allows countries to exclude methods of medical treatment from patentability. This is an important flexibility recognized by many countries, for moral and ethical reasons and to avoid hospitals and medical professionals paying royalties on the standard of care.</p> <p>In Australia, the patentability of methods of treatment has been hotly debated. Courts have indicated the legislature may exclude these inventions from patentability if it so chooses. If adopted, the U.S. TPPA proposal would tie the hands of the Australian legislature and eliminate a flexibility recognised by the TRIPS Agreement and the AUSFTA (Article 17.9.2).</p> <p>While the U.S. proposes to bind countries to this standard through the TPPA, it has omitted the essential safeguards and balancing features of its own law. While U.S. law authorizes patents for surgical methods, it also prevents medical practitioners from being sued for patent infringement in the course of medical</p>

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			<p>activity (35 USC 287 (c)). (Nevertheless, other groups including universities, medical education companies, and hospitals can be held liable for involuntary infringement.)</p> <p>The absence of such safeguards in Australian law raises concerns among medical practitioners and researchers. Adopting the U.S. proposal, without adopting the corresponding safeguards in U.S. law, opens up prospects for additional costs imposed on Australia's healthcare system. Hospitals might be required to obtain licenses for patented treatments that they offer, and doctors might be asked to pay royalties for the patented diagnostic, therapeutic and surgical methods they use.</p>
<p><b><i>Patent Term Adjustment (For Patent Prosecution Period)</i></b></p>	<p>Article 8.6. Placeholder Provision</p>	<p>Section 67. The term of a standard patent is 20 years from the date of the patent.</p> <p><i>Australia does not provide patent term adjustment for perceived delays in the patent prosecution period.</i></p>	<p>Patent term adjustments allow patent owners to push back the date of patent expiry. They delay market entry of competing generic drugs and thus restrict access to affordable medicines.</p> <p>The AUSFTA provides that if there are "unreasonable delays" in a Party's issuance of patents, that Party shall provide a means to adjust the term of the patent (Article 17.9.8.) -</p>

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			<p>meaning push the date of expiry further into the future. Australia maintains that its patent system does not unreasonably delay patent issuance.</p> <p>The U.S. could seek to introduce a new standard or provide a new forum through the TPPA for challenging Australia's position regarding perceived delays in patent prosecution.</p>
<p><b><i>Patent Term Extension (For Regulatory Review Period)</i></b></p>	<p>Article 9.4. Placeholder Provision</p>	<p>Section 70 (1) 1) The patentee of a standard patent may apply to the Commissioner for an extension of the term of the patent if the requirements set out in subsections (2), (3) and (4) are satisfied.</p> <p><i>The term of an Australian patent relating to a pharmaceutical substance per se may be extended up to five years beyond the standard patent term. This extension aims to compensate for perceived delays only in the context of drug regulatory approval, and not in patent prosecution.</i></p> <p><i>A pharmaceutical substance per se includes compounds, active metabolites, compositions, drug delivery systems etc.</i></p>	<p>Patent term extensions significantly delay market entry of generic drugs and restrict access to affordable medicines.</p> <p>Australian law currently allows extensions on patents for pharmaceutical substances <i>per se</i>. Courts have expanded the range of qualifying substances.</p> <p>The U.S.-KOREA free trade agreement (KORUS) expressly requires patent extensions for formulations, methods, and improvement patents. The U.S. might propose similar or additional terms in the TPPA, potentially expanding the number of medicines eligible for patent extensions, and/or tying extension</p>

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			<p>standards, which Australian courts or the legislature could otherwise change, to a new international obligation.</p>
<p><b><i>Protection of Test Data Submitted for Marketing Approval</i></b></p>	<p>Article 9.2. Placeholder provision</p>	<p><i>Australian law provides five years of data exclusivity to therapeutic goods containing new active components (Therapeutic Goods Act 1989, Section 25A).</i></p> <p><i>The law defines active component as a substance that is, or substances that together are, primarily responsible for the biological or other effect identifying the goods as therapeutic goods. Data exclusivity is not provided for new dosage forms, routes of administration, indications or combinations with other active ingredients.</i></p>	<p>Data exclusivity prevents regulatory authorities from relying on established data regarding drug safety and efficacy to register generic medicines. Data exclusivity delays generic market entry and is inconsistent with medical ethical standards against duplicating tests on humans or vertebrate animals.</p> <p>Australian law limits data exclusivity for conventional pharmaceuticals to a maximum five years. The AUSFTA is arguably Australia law-plus, providing <i>at least</i> five years (Article 17.10.01). No maximum period is defined.</p> <p>The AUSFTA also grants at least three years additional data exclusivity for new uses or indications for an existing pharmaceutical product (Article 17. 10.2). But data exclusivity provisions in Australian law do not apply to such inventions. The U.S. might advance a new proposal in the TPPA designed to guarantee these additional years of data exclusivity for new uses or indications.</p>

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			<p>The U.S. may also seek as many as twelve years exclusivity for biologics (biotech medicines). This would represent a major change to Australian law with potentially dramatic financial consequences.</p>
<p><i>Patent Linkage</i></p>	<p>Article 9.3. Placeholder Provision</p>	<p>Therapeutic Act 1989, Section 26B (1)                  (1) The certificate required under this subsection is either:                  (a) a certificate to the effect that the applicant, acting in good faith, believes on reasonable grounds that it is not marketing, and does not propose to market, the therapeutic goods in a manner, or in circumstances, that would infringe a valid claim of a patent that has been granted in relation to the therapeutic goods; or                  (b) a certificate to the effect that:                      (i) a patent has been granted in relation to the therapeutic goods; and                      (ii) the applicant proposes to market the therapeutic goods before the end of the term of the patent; and                      (iii) the applicant has given the patentee notice of the application for registration or</p>	<p>Under patent linkage, even spurious patent claims can serve as barriers to generic drug registration.</p> <p>Controversially, the AUSFTA introduced patent linkage in Australia. Australia sought to limit its effect through statutory measures imposing penalties for linkage evergreening. The United States Trade Representative attacked these safeguards, making specific reference to the interests of pharmaceutical patent owners.<sup>4</sup></p> <p>This raises a serious concern that the United States may seek to limit or eliminate Australian safeguards against linkage evergreening in the TPPA.</p>

<sup>4</sup> USTR Robert Zoellick in a letter to Australian Trade Minister Mark Vaile, November 17, 2004.

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		<p>listing of the therapeutic goods under section 23.</p> <p><i>This requirement links drug regulatory approval to patent status. But Australian law also includes safeguards against 'linkage evergreening,'<sup>3</sup> by which pharmaceutical companies seek to extend product monopolies. The safeguards, introduced in Section 26C and 26D, include a penalty for evergreening activities and a mechanism for damages to be paid to the government for proven evergreening practices.</i></p>	
<p><b>Judicial and Administrative Presumption of Patent Validity</b></p>	<p>Article 10.2. (---) In civil and administrative proceedings involving patents, each Party shall provide for a rebuttable presumption that a patent is valid, and shall provide that</p>	<p>Section 20. Nothing done under this Act or the PCT guarantees the granting of a patent, or that a patent is valid, in Australia or anywhere else.</p> <p><i>There is no presumption of patent validity in Australian law.</i></p> <p><i>In practice, Australian Courts tend to effectively re-examine a patent de novo when its validity is questioned, e.g. as a counterclaim in an</i></p>	<p>The U.S. TPPA proposed provision is AUSFTA-plus and would require significant changes to Australian law.</p> <p>The AUSFTA requires parties to provide a rebuttable presumption that a patent is valid in proceedings concerning the grant of provisional measures in relation to enforcement of a patent (Article 17.11.18).</p> <p>The U.S. TPPA proposal extends this</p>

<sup>3</sup> See, Faunce T. & Lexcin C.: 'Linkage' pharmaceutical evergreening in Canada and Australia, Aust. New Zealand Health Policy. 2007; 4: 8.

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	<p>each claim of a patent is presumed valid independently of the validity of the other claims.</p>	<p><i>infringement proceeding.</i></p> <p><i>Historically, the Commissioner of Patents in opposition proceedings and in re-examination has revoked acceptance (in opposition) or revoked the patent (in re-examination) if the patent was clearly invalid. However, the Raising the Bar Bill proposes a change to this, requiring the Commissioner to determine whether the patent is valid on the balance of probabilities. In other words, the Raising the Bar bill would remove any effective presumption of validity that administrative proceedings in Australia may apply.</i></p>	<p>presumption to civil and administrative proceedings and requires each claim of a patent to be presumed valid independently of the validity of the other claims. When read in conjunction with eliminating pre-grant opposition and a likely provision on patent linkage, this provision threatens the integrity of the Australian patent system and overrides current reform proposals designed to improve the quality of patents. The judicial and administrative presumption of patent validity gives rise to costly and one-sided court procedures, and makes it harder to challenge unwarranted patents.</p> <p>This presumption was only introduced into the U.S. Patents Act in 1952. Since then there has been overwhelming evidence that patent quality is not high enough to justify the continuation of this presumption under U.S. patent law.</p>
<p><b>Compensation of Damages for IP Infringement</b></p>	<p>Article 12.3. Each party shall provide that</p> <p>b) in determining damages for</p>	<p>Section 122</p> <p>(1) The relief which a court may grant for infringement of a patent includes an injunction (subject to such terms, if any, as the court thinks fit) and, at the option of the</p>	<p>Unless a strong side letter is included or other understanding reached, the U.S. TPPA proposal is AUSFTA-plus, and would require amending Australian law.</p>

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	<p>infringement of intellectual property rights, its judicial authorities shall consider, <i>inter alia</i>, the value of the infringed good or service, measured by the suggested retail price or other legitimate measure of value submitted by the right holder</p>	<p>plaintiff, either damages or an account of profits.</p> <p><i>IP damages in Australia are intended to be compensatory. The remedies include either damages or an account of profit made by the infringing activity. An Australian court can order additional damages, which serve a punitive purpose, depending on the flagrancy of the infringement and the need for deterrence (Section 122(1A)).</i></p> <p><i>In cases of innocent infringement, the infringer may avoid the need to pay damages or account for the profits made (Section 123).</i></p>	<p>A provision in the AUSFTA requires the Parties' courts to consider submissions made by a right holder on the value of the infringed good or service, including the suggested retail price (Article 17.11.6).</p> <p>Nevertheless, side Letter 2 of the AUSFTA permits Australia to maintain its current provisions on calculation of damages. Currently, a court is not required to consider such a submission, but has discretion to do so.</p> <p>The U.S. TPPA proposal could eliminate this discretion.</p> <p>Additionally, the language in the U.S. TPPA proposal may communicate a stronger preference for the use of retail price, rather than other measures of value submitted by rights holders, when compared to the AUSFTA. Damages calculated based on retail price strongly favour the interests of rights holders. A suggested retail price is a hypothetical price; generally greater than the damage suffered by the right holder. Further, suggested retail prices submitted by a right holder may turn out to be inflated or otherwise inaccurate and higher than actual retail prices. This would lead to an</p>
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			<p>unrealistic determination of damages, which would empower rights holders in court settlements and discourage defendants from litigating cases where there is uncertainty.</p> <p>Australian courts can better balance the competing interests in infringement suits by maintaining the compensatory approach to damages, filtering claims and continuing to determine appropriate calculations for damages case-by-case.</p>
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*Dangers for Access to Medicines in the Trans-Pacific Partnership Agreement:*  
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Issue	US TPPA Proposal	Australia Patent Act 1990	Analysis
<b>Third-Party Opposition</b>	Article 8.7. (... ) Where a Party provides proceedings that permit a third party to oppose the grant of a patent, a Party shall not make such proceedings available before the grant of the patent.	Section 59 The Minister or any other person may, in accordance with the regulations, oppose the grant of a standard patent on one or more of the following grounds, but on no other ground: (a) that the nominated person is either: (i) not entitled to a grant of a patent for the invention; or (ii) entitled to a grant of a patent for the invention but only in conjunction with some other person; (b) that the invention is not a patentable invention; (c) that the specification filed in respect of the complete application does not comply with subsection 40(2) or (3).  <i>Australian law provides for pre-grant opposition as well as post-grant challenges. Standing rules ensure that any person can formally challenge the</i>	Pre-grant opposition is a safeguard against patent abuse, improvidently granted patents and unwarranted pharmaceutical monopolies. Pre-grant opposition supports appropriate generic competition and access to medicines. The U.S. proposal would eliminate pre-grant opposition in TPPA countries. More information on the U.S. proposal on pre-grant opposition is available at <a href="http://citizen.org/access">citizen.org/access</a> . <sup>1</sup>  Pre-grant opposition allows third parties to formally oppose a patent application by submitting information and analysis to patent examiners, under an adversarial administrative process. Pre-grant opposition helps improve patent quality and the accuracy of patent claims. This process helps to prevent pharmaceutical monopolies based on meritless patents that contribute little to innovation but greatly to price.

<sup>1</sup>For further discussion of the U.S. strategy to eliminate patent pre-grant opposition, see Public Citizen, HealthGAP, I-MAK and Third World Network, "Analysis of the Leaked U.S. Paper on Eliminating Patent Pre-Grant Opposition," available at <http://www.citizen.org/documents/analysis-of-leaked-US-paper-on-eliminating-pregrant-opposition.pdf>.

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<p><b><i>Protection of New Forms, Uses, or Methods of Using a Known Product</i></b></p>	<p>Article 8.1. The Parties confirm that: patents shall be available for any new forms, uses, or methods of using a known product; and a new form, use, or method of using a known product may satisfy the criteria for patentability, even if such invention does not result in the enhancement of the known efficacy of that product.</p>	<p><i>The Australian Patent Act defines invention as "a manner of manufacture" within the meaning of s.6 of the Statute of Monopolies' in Schedule 1 of the Patents Act. This statute, in turn, refers to "a manner of new manufacture." A patentable invention can be a product, method, system or process.</i></p> <p><i>This preliminary requirement precludes patentability of a new use of a known substance that takes advantage of a known property. Australian case law establishes that such cases do not meet the standards of patentable subject matter.</i></p> <p><i>A patentable invention is required to provide some material advantage in a field of economic endeavour and pertain to the useful arts rather than the fine arts. A new use of a known substance is patentable provided the use takes advantage of a previously unknown property.</i></p>	<p>Patents for new forms, uses, and methods of using known medicines can enable patent "evergreening," and particularly when enhanced efficacy is not required, can lead to unwarranted extensions of pharmaceutical monopolies.</p> <p>The AUSFTA provides that patents shall be available for any new uses or methods of using a known product (Article 17.9.1). This provision had limited effect. New uses and methods taking advantage of known properties do not always qualify as a 'new manner of manufacture.'</p> <p>But the U.S. TPPA proposal expressly requires patent eligibility for new forms -- e.g., a patent on a tablet -- and rejects any enhanced efficacy requirements. This could undermine limits set by Australia's new manner of manufacture test and gut standards of patentability in Australian law. Under the U.S. proposal, new patents can be granted for minor variations to pharmaceutical substances or methods related to their administration that contribute nothing to enhancing medical care -- e.g., changes in formulations, drug dosage regimes, drug</p>
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			<p>activity (35 USC 287 (c)). (Nevertheless, other groups including universities, medical education companies, and hospitals can be held liable for involuntary infringement.)</p> <p>The absence of such safeguards in Australian law raises concerns among medical practitioners and researchers. Adopting the U.S. proposal, without adopting the corresponding safeguards in U.S. law, opens up prospects for additional costs imposed on Australia's healthcare system. Hospitals might be required to obtain licenses for patented treatments that they offer, and doctors might be asked to pay royalties for the patented diagnostic, therapeutic and surgical methods they use.</p>
<p><b><i>Patent Term Adjustment (For Patent Prosecution Period)</i></b></p>	<p>Article 8.6. Placeholder Provision</p>	<p>Section 67. The term of a standard patent is 20 years from the date of the patent.</p> <p><i>Australia does not provide patent term adjustment for perceived delays in the patent prosecution period.</i></p>	<p>Patent term adjustments allow patent owners to push back the date of patent expiry. They delay market entry of competing generic drugs and thus restrict access to affordable medicines.</p> <p>The AUSFTA provides that if there are "unreasonable delays" in a Party's issuance of patents, that Party shall provide a means to adjust the term of the patent (Article 17.9.8.) -</p>

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			<p>meaning push the date of expiry further into the future. Australia maintains that its patent system does not unreasonably delay patent issuance.</p> <p>The U.S. could seek to introduce a new standard or provide a new forum through the TPPA for challenging Australia's position regarding perceived delays in patent prosecution.</p>
<p><b><i>Patent Term Extension (For Regulatory Review Period)</i></b></p>	<p>Article 9.4. Placeholder Provision</p>	<p>Section 70 (1) 1) The patentee of a standard patent may apply to the Commissioner for an extension of the term of the patent if the requirements set out in subsections (2), (3) and (4) are satisfied.</p> <p><i>The term of an Australian patent relating to a pharmaceutical substance per se may be extended up to five years beyond the standard patent term. This extension aims to compensate for perceived delays only in the context of drug regulatory approval, and not in patent prosecution.</i></p> <p><i>A pharmaceutical substance per se includes compounds, active metabolites, compositions, drug delivery systems etc.</i></p>	<p>Patent term extensions significantly delay market entry of generic drugs and restrict access to affordable medicines.</p> <p>Australian law currently allows extensions on patents for pharmaceutical substances <i>per se</i>. Courts have expanded the range of qualifying substances.</p> <p>The U.S.-KOREA free trade agreement (KORUS) expressly requires patent extensions for formulations, methods, and improvement patents. The U.S. might propose similar or additional terms in the TPPA, potentially expanding the number of medicines eligible for patent extensions, and/or tying extension</p>

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			<p>standards, which Australian courts or the legislature could otherwise change, to a new international obligation.</p>
<p><b><i>Protection of Test Data Submitted for Marketing Approval</i></b></p>	<p>Article 9.2. Placeholder provision</p>	<p><i>Australian law provides five years of data exclusivity to therapeutic goods containing new active components (Therapeutic Goods Act 1989, Section 25A).</i></p> <p><i>The law defines active component as a substance that is, or substances that together are, primarily responsible for the biological or other effect identifying the goods as therapeutic goods. Data exclusivity is not provided for new dosage forms, routes of administration, indications or combinations with other active ingredients.</i></p>	<p>Data exclusivity prevents regulatory authorities from relying on established data regarding drug safety and efficacy to register generic medicines. Data exclusivity delays generic market entry and is inconsistent with medical ethical standards against duplicating tests on humans or vertebrate animals.</p> <p>Australian law limits data exclusivity for conventional pharmaceuticals to a maximum five years. The AUSFTA is arguably Australia law-plus, providing <i>at least</i> five years (Article 17.10.01). No maximum period is defined.</p> <p>The AUSFTA also grants at least three years additional data exclusivity for new uses or indications for an existing pharmaceutical product (Article 17. 10.2). But data exclusivity provisions in Australian law do not apply to such inventions. The U.S. might advance a new proposal in the TPPA designed to guarantee these additional years of data exclusivity for new uses or indications.</p>

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			<p>The U.S. may also seek as many as twelve years exclusivity for biologics (biotech medicines). This would represent a major change to Australian law with potentially dramatic financial consequences.</p>
<p><i>Patent Linkage</i></p>	<p>Article 9.3. Placeholder Provision</p>	<p>Therapeutic Act 1989, Section 26B (1)                  (1) The certificate required under this subsection is either:                  (a) a certificate to the effect that the applicant, acting in good faith, believes on reasonable grounds that it is not marketing, and does not propose to market, the therapeutic goods in a manner, or in circumstances, that would infringe a valid claim of a patent that has been granted in relation to the therapeutic goods; or                  (b) a certificate to the effect that:                      (i) a patent has been granted in relation to the therapeutic goods; and                      (ii) the applicant proposes to market the therapeutic goods before the end of the term of the patent; and                      (iii) the applicant has given the patentee notice of the application for registration or</p>	<p>Under patent linkage, even spurious patent claims can serve as barriers to generic drug registration.</p> <p>Controversially, the AUSFTA introduced patent linkage in Australia. Australia sought to limit its effect through statutory measures imposing penalties for linkage evergreening. The United States Trade Representative attacked these safeguards, making specific reference to the interests of pharmaceutical patent owners.<sup>4</sup></p> <p>This raises a serious concern that the United States may seek to limit or eliminate Australian safeguards against linkage evergreening in the TPPA.</p>

<sup>4</sup> USTR Robert Zoellick in a letter to Australian Trade Minister Mark Vaile, November 17, 2004.

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		<p>listing of the therapeutic goods under section 23.</p> <p><i>This requirement links drug regulatory approval to patent status. But Australian law also includes safeguards against 'linkage evergreening,'<sup>3</sup> by which pharmaceutical companies seek to extend product monopolies. The safeguards, introduced in Section 26C and 26D, include a penalty for evergreening activities and a mechanism for damages to be paid to the government for proven evergreening practices.</i></p>	
<p><b>Judicial and Administrative Presumption of Patent Validity</b></p>	<p>Article 10.2. (---) In civil and administrative proceedings involving patents, each Party shall provide for a rebuttable presumption that a patent is valid, and shall provide that</p>	<p>Section 20. Nothing done under this Act or the PCT guarantees the granting of a patent, or that a patent is valid, in Australia or anywhere else.</p> <p><i>There is no presumption of patent validity in Australian law.</i></p> <p><i>In practice, Australian Courts tend to effectively re-examine a patent de novo when its validity is questioned, e.g. as a counterclaim in an</i></p>	<p>The U.S. TPPA proposed provision is AUSFTA-plus and would require significant changes to Australian law.</p> <p>The AUSFTA requires parties to provide a rebuttable presumption that a patent is valid in proceedings concerning the grant of provisional measures in relation to enforcement of a patent (Article 17.11.18).</p> <p>The U.S. TPPA proposal extends this</p>

<sup>3</sup> See, Faunce T. & Lexcin C.: 'Linkage' pharmaceutical evergreening in Canada and Australia, Aust. New Zealand Health Policy. 2007; 4: 8.

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	<p>each claim of a patent is presumed valid independently of the validity of the other claims.</p>	<p><i>infringement proceeding.</i></p> <p><i>Historically, the Commissioner of Patents in opposition proceedings and in re-examination has revoked acceptance (in opposition) or revoked the patent (in re-examination) if the patent was clearly invalid. However, the Raising the Bar Bill proposes a change to this, requiring the Commissioner to determine whether the patent is valid on the balance of probabilities. In other words, the Raising the Bar bill would remove any effective presumption of validity that administrative proceedings in Australia may apply.</i></p>	<p>presumption to civil and administrative proceedings and requires each claim of a patent to be presumed valid independently of the validity of the other claims. When read in conjunction with eliminating pre-grant opposition and a likely provision on patent linkage, this provision threatens the integrity of the Australian patent system and overrides current reform proposals designed to improve the quality of patents. The judicial and administrative presumption of patent validity gives rise to costly and one-sided court procedures, and makes it harder to challenge unwarranted patents.</p> <p>This presumption was only introduced into the U.S. Patents Act in 1952. Since then there has been overwhelming evidence that patent quality is not high enough to justify the continuation of this presumption under U.S. patent law.</p>
<p><b>Compensation of Damages for IP Infringement</b></p>	<p>Article 12.3. Each party shall provide that</p> <p>b) in determining damages for</p>	<p>Section 122</p> <p>(1) The relief which a court may grant for infringement of a patent includes an injunction (subject to such terms, if any, as the court thinks fit) and, at the option of the</p>	<p>Unless a strong side letter is included or other understanding reached, the U.S. TPPA proposal is AUSFTA-plus, and would require amending Australian law.</p>

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	<p>infringement of intellectual property rights, its judicial authorities shall consider, <i>inter alia</i>, the value of the infringed good or service, measured by the suggested retail price or other legitimate measure of value submitted by the right holder</p>	<p>plaintiff, either damages or an account of profits.</p> <p><i>IP damages in Australia are intended to be compensatory. The remedies include either damages or an account of profit made by the infringing activity. An Australian court can order additional damages, which serve a punitive purpose, depending on the flagrancy of the infringement and the need for deterrence (Section 122(1A)).</i></p> <p><i>In cases of innocent infringement, the infringer may avoid the need to pay damages or account for the profits made (Section 123).</i></p>	<p>A provision in the AUSFTA requires the Parties' courts to consider submissions made by a right holder on the value of the infringed good or service, including the suggested retail price (Article 17.11.6).</p> <p>Nevertheless, side Letter 2 of the AUSFTA permits Australia to maintain its current provisions on calculation of damages. Currently, a court is not required to consider such a submission, but has discretion to do so.</p> <p>The U.S. TPPA proposal could eliminate this discretion.</p> <p>Additionally, the language in the U.S. TPPA proposal may communicate a stronger preference for the use of retail price, rather than other measures of value submitted by rights holders, when compared to the AUSFTA. Damages calculated based on retail price strongly favour the interests of rights holders. A suggested retail price is a hypothetical price; generally greater than the damage suffered by the right holder. Further, suggested retail prices submitted by a right holder may turn out to be inflated or otherwise inaccurate and higher than actual retail prices. This would lead to an</p>
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			<p>unrealistic determination of damages, which would empower rights holders in court settlements and discourage defendants from litigating cases where there is uncertainty.</p> <p>Australian courts can better balance the competing interests in infringement suits by maintaining the compensatory approach to damages, filtering claims and continuing to determine appropriate calculations for damages case-by-case.</p>
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Weatherall**

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October 2011

Intellectual Property in ACTA and the TPP:  
Lessons Not Learned

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## Intellectual Property in ACTA and the TPP: Lessons Not Learned

Kimberlee Weatherall\*

### 1 Introduction

The world has seen a renewed push in international intellectual property (IP) lawmaking in recent times. This can be seen in multilateral forums, in particular in the World Intellectual Property Organization (WIPO);<sup>1</sup> in bilateral forums, where Europe in particular appears to have increased its efforts to negotiate more detailed IP provisions in trade agreements than it has in the past,<sup>2</sup> and in plurilateral and regional contexts, most notably through the negotiations for the Anti-Counterfeiting Trade Agreement (ACTA), concluded late 2010,<sup>3</sup> but also in the Asia-Pacific Region via current negotiations for a ‘Trans-Pacific Partnership’ between (at present) Brunei Darussalam, Chile, New Zealand, Singapore, Australia, Peru, the United States, Vietnam and Malaysia.<sup>4</sup>

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<sup>1</sup> According to an address by Francis Gurry, Director-General of WIPO, to the 15<sup>th</sup> Biennial Copyright Symposium in Sydney, Australia on 13-14 October 2011, there is a real prospect of a Diplomatic Conference to agree a Treaty on Audiovisual Performances, with 96 per cent of the provisions and ancillary instruments agreed to. There has also been progress on both an international instrument on exceptions and limitations for the visually impaired, and a treaty on Broadcasting Organizations.

<sup>2</sup> *Strategy for the Enforcement of Intellectual Property Rights in Third Countries*, 2005 O.J. (C 129) 3 (providing that the European Commission’s strategy includes a number of actions similarly modeled on U.S. practices, including an indication of the intention to ‘revisit the approach to the IPR chapter of bilateral agreements, including the clarification and strengthening of the enforcement clauses’ using existing E.U. Directives and regulations as an important approach to revising the IP standards); see also *Free Trade Agreement, E.U.-South Korea*, signed Oct. 6, 2010 (representing the bilateral trade agreement of the ‘new generation,’ including a chapter with extensive obligations on geographical indications and enforcement). EU negotiations with India for a trade agreement, which commenced in 2006, are also said to be at an advanced stage. It is also worth noting that although the US President’s trade negotiating authority has not been renewed, which would allow new bilateral negotiations by the US, three bilateral agreements which have been pending before Congress for some time, with Colombia, Panama, and South Korea, were passed on 12 October 2011: see US Trade Representative Ron Kirk, ‘Statement on Congressional Passage of Trade Agreements, Trade Adjustment Assistance and Key Preference Programs’, 12 October 2011.

<sup>3</sup> The final text of the *Anti-Counterfeiting Trade Agreement* (following legal review) was published on 3 December 2010, and is available at the website of the Commonwealth of Australia Department of Foreign Affairs and Trade, *Anti-Counterfeiting Trade Agreement* (opened for signature 31 March 2011) (not yet in force) (‘the ACTA’) <http://www.dfat.gov.au/trade/acta/index.html>.

<sup>4</sup> This list is current as at 15 October 2011. See further below, Part 3 page 9 and following.

In this paper I am interested in what ACTA as it emerged from the negotiating process has to teach us about the negotiation of international agreements in IP, and in whether we can see any evidence that those lessons have been learned or are being applied to the TPP negotiations. As I will show below, the ACTA text that emerged from several years' controversial negotiations was a quite different beast from the original aspirations of the negotiating parties. ACTA as it was finalised retreated significantly from earlier proposals: it contains more safeguards, and less detailed and stringent provisions, than was feared or expected by many commentators. This suggests that even in negotiations among 'IP-enthusiast' countries there are limits to the consensus on the appropriate scope of IP-protective measures. ACTA, therefore, as the closest thing we have to a 'high protection consensus', ought to be seen as a kind of ceiling to what is possible or desirable for the present. As I will further show, however, this is far from the approach being adopted by the US in the TPP negotiations. The US' apparent determination to treat its existing FTAs, and ACTA, as a floor, rather than a ceiling, may well undermine the whole purpose of the TPP negotiations.

## 2 The ACTA, and what we can learn from it

The Anti-Counterfeiting Trade Agreement, or ACTA, is a plurilateral agreement addressing a range of matters relating to the enforcement of all forms of IP, both civil and criminal. The stated goal of the agreement was to provide 'a high-level international framework that strengthens the global enforcement of intellectual property rights'.<sup>5</sup> It was negotiated among a limited set of countries: Australia, the United States of America, Japan, the 27 nations of the European Union (EU), Mexico, Switzerland, Canada, Singapore, South Korea, New Zealand and Morocco. ACTA was concluded in December 2010 following several years of negotiation, and eight of the eleven negotiating countries officially signed the agreement on 1 October 2011.<sup>6</sup> The Agreement has six chapters, but the core obligations are found in Chapter 2, which deals with general obligations, civil enforcement, border measures, criminal enforcement, and enforcement in the digital

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<sup>5</sup> This statement is drawn from one of the many ACTA 'Fact Sheets' published by the negotiating parties in the course of the negotiations. The wording of these fact sheets was agreed between the parties so that consistent documents were issued by all the negotiating governments. For this phrase, see European Union, 'The Anti-Counterfeiting Trade Agreement', 5 June 2008.

[http://trade.ec.europa.eu/doclib/docs/2008/june/tradoc\\_139085.pdf](http://trade.ec.europa.eu/doclib/docs/2008/june/tradoc_139085.pdf).

<sup>6</sup> The Agreement was signed on 1 October 2011 by the United States, Australia, Canada, Japan, Morocco, New Zealand, Singapore and South Korea. The European Union, Mexico, and Switzerland have not yet signed but issued a statement affirming their intention to sign as soon as practicable. ACTA will enter into force when six instruments of ratification, acceptance or approval have been deposited: art 40.

environment. Subsequent chapters deal with enforcement practices, international cooperation, and the administration of the Agreement through an ACTA Committee.

ACTA was controversial from the outset of negotiations, which were conducted with a low degree of transparency, and continues to be the subject of debate, particularly in Europe where it has been alleged that, contrary to representations during the negotiations, the text goes beyond present EU law.<sup>7</sup> These controversies are not the subject of this paper.<sup>8</sup> The decision to limit the membership of ACTA in the negotiating phase was a deliberate one, designed to bypass negotiating blocks that had emerged in multilateral forums such as WIPO or the World Trade Organization (WTO),<sup>9</sup> and further the goal of creating a ‘gold standard’ for IP enforcement by including only countries willing to countenance the highest, or strongest, IP enforcement rules. It is worth remembering that over a decade ago, a group of developed countries put together the first proposals for the TRIPS Agreement.<sup>10</sup> One way the ACTA negotiations could be described as an important post-TRIPS attempt to undertake similar ‘North-North’ negotiations on areas of IP where the TRIPS agreement has been found to be lacking.<sup>11</sup> In the longer term, the expectation is that standards established in ACTA will be extended to other countries, either by those countries acceding to the treaty directly,<sup>12</sup> or by the inclusion of the ACTA standards in other bilateral or regional trade agreements.<sup>13</sup> The preamble of ACTA, after all, refers to the impact of infringement of the *world* economy; it will be difficult effectively to address global counterfeiting and piracy without significantly broadening the membership of ACTA.

ACTA’s goal of setting an ambitious, strong set of IP enforcement standards was fulfilled to some degree. The provisions of ACTA are far more elaborated than any other existing multilateral agreement. The obligations included in ACTA extend considerably

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<sup>7</sup> Anselm Kamperman Sanders, Dalindyabo Bafana Shabalala, Anke Moerland, Meir Pugatch, Paolo Vergano, *The Anti-Counterfeiting Trade Agreement (ACTA): An Assessment* (Report for the Directorate-General for External Policies of the Union, Directorate B), June 2011.

<sup>8</sup> For a discussion, see Kimberlee Weatherall, ‘Politics, Compromise, Text, and the Failures of the Anti-Counterfeiting Trade Agreement’ (2011) 33 *Sydney Law Review* 229 (hereafter Weatherall, *Politics, Compromise, Text*); see also Peter Yu, ‘Six Secret (and Now Open) Fears of ACTA’ (2011) 64 *Southern Methodist University Law Review*.

<sup>9</sup> Weatherall, *Politics, Compromise, Text*, above n8, 237; also Yu, above n 8.

<sup>10</sup> A similar ‘small group’ negotiating process was used to generate the developed country proposal for the TRIPS Agreement: see Drahos with Braithwaite, *Information Feudalism* (Earthscan 2001), 137-138.

<sup>11</sup> Enforcement has been described as the ‘Achilles’ Heel’ of TRIPS: Jerome Reichman and David Lange, ‘Bargaining Around the TRIPS Agreement: The Case for Ongoing Public-Private Initiatives to Facilitate Worldwide Intellectual Property Transactions’ (1998) 9 *Duke Jnl Comp. & Int’l L* 11, 34.

<sup>12</sup> As contemplated under ACTA Article 43.

<sup>13</sup> Kimberlee Weatherall, *Politics, Compromise, Text*, above n 8, 236; see also Anselm Kamperman Sanders, et al, above n7, 9.

beyond TRIPS as the latter relates to enforcement. Examples of ‘TRIPS-plus’ provisions include the obligations to provide for an account of profits as a remedy for IP infringement,<sup>14</sup> to provide statutory or at least additional damages<sup>15</sup> and legal costs,<sup>16</sup> obligations on an infringer or alleged infringer to provide information about the origin and distribution network of the infringing goods,<sup>17</sup> powers for customs authorities to provide right holders with information where goods have been seized at the border,<sup>18</sup> broader criminal provisions including secondary criminal liability for aiding and abetting activities<sup>19</sup> and liability of corporate persons,<sup>20</sup> an optional ‘camcording’ offence, and provisions on enforcement in the digital environment that have no equivalent in TRIPS and include detail not found in the relevant WIPO Treaties.<sup>21</sup> In sum, ACTA is ‘significantly more stringent and rightholder friendly than the TRIPS Agreement’.<sup>22</sup> As noted above, the strength of these provisions has generated considerable controversy, particularly, in recent times, in Europe.<sup>23</sup>

However, the final text of ACTA concluded in December 2010 is very different from the early leaked texts that started to emerge in January 2010.<sup>24</sup> The Final Text retreats from some of earlier proposals for even stronger and less qualified IP enforcement measures. If we are trying to understand what ACTA can teach us about the

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<sup>14</sup> ACTA Article 9(2).

<sup>15</sup> ACTA Article 9(3).

<sup>16</sup> ACTA Article 9(5). Legal costs including attorneys’ fees are optional under TRIPS Article 45.

<sup>17</sup> ACTA Article 11. Under TRIPS Article 47, some more limited information is required.

<sup>18</sup> ACTA Article 22. Under TRIPS, Members *may* give competent authorities the authority to provide information to right holders.

<sup>19</sup> ACTA Article 23(4).

<sup>20</sup> ACTA Article 23(5).

<sup>21</sup> *WIPO Copyright Treaty*, adopted by Diplomatic Conference 20 December 1996, 36 ILM 65 (entered into force 6 March 2002); *WIPO Performances and Phonograms Treaty*, adopted by Diplomatic Conference 20 December 1996, 36 ILM 76 (entered into force 20 May 2002). These treaties provide basic obligations in relation to anti-circumvention law and the protection of electronic rights management information. The ACTA provisions on digital enforcement include further elaboration on anti-circumvention and rights management information provisions, in addition to some very broad, general level obligations concerning digital enforcement generally. As will be seen below, more detailed proposals relating to digital enforcement did not survive the negotiating process.

<sup>22</sup> Kamperman Sanders et al, above n7, 6.

<sup>23</sup> Kamperman Sanders et al, above n7. See also ‘Opinion of European Academics on the Anti-Counterfeiting Trade Agreement’, published on <http://www.iri.uni-hannover.de/acta-1668.html> (an opinion, issued by a well-regarded set of academics, that ACTA is not consistent with the European *acquis communautaire*).

<sup>24</sup> Earlier negotiating texts of ACTA, both ‘official’ and leaked, are collected at <https://sites.google.com/site/iipenforcement/acta>.

present dynamics of international IP lawmaking, what ACTA *failed* to achieve is equally significant to what was achieved in terms of enforcement standard-setting. While the ACTA text illustrates areas where the ‘coalition of the willing’ agreed on the appropriateness of a measure, proposals removed from the text point to areas where there is a lack of consensus.

Without purporting to be comprehensive, the following table illustrates some key changes that occurred between January 2010 (the date of the first full leaked text of the agreement) and the final legal text as published in December 2010. Table 1 does not capture the full extent of those amendments, particularly the ways that nuances in language in individual provisions have created a different agreement from what was originally proposed.

**Table 1: The January Leaked Text of ACTA versus the Final Text of December 2010**

Issue	ACTA January 2010 Leaked Text <sup>25</sup>	ACTA December 2010 Final Text
Preamble	None.	Preamble referring both to the importance of enforcement on the one hand, and the need for balance, and to ensure that measures do not become barriers to trade on the other.
Distribution of policing resources	Not mentioned.	General provision that ACTA creates no obligations regarding allocation of resources to IP enforcement versus other policing (Article 2.2)
TRIPS Article 7 and 8 <sup>26</sup>	Not mentioned.	Applied to the ACTA (Article 2.3)
Privacy	No general provision although mentioned in some articles.	General provision allowing protection of privacy (Article 4).
Proportionality, fairness	Some mention in some proposals for some provisions.	General provision on fairness, protection of the rights of participants, and

<sup>25</sup> Note that in the case of this leaked text dating from January 2010 there is much bracketed text and proposals of varying stringency. In this table, the more stringent proposals are included, better to illustrate the difference between the strongest aspirations for the agreement demonstrated by various parties, and the final outcome of the negotiations.

<sup>26</sup> TRIPS Articles 7 and 8 are concerned with technology transfer, balancing rights and obligations under intellectual property, the ability of states to act in the public interest, and the ability to have provisions to prevent abuse of intellectual property rights.

		proportionality (Article 6).
Injunctions	No safeguards or limitations; proposal for injunctions against intermediaries whose services are used for infringement.	Parties can limit remedies against government/third parties authorised by government to remuneration. Injunctions against third parties to prevent infringing goods entering channels of commerce (Article 8).
Measure of damages	One proposal would require judicial authorities to consider measures of damage submitted by the right holder.	Judicial authorities need only have <i>authority</i> to consider <i>legitimate</i> measures of value submitted by the right holder.
Statutory damages	Must have statutory damages or presumptions.	Must have statutory damages, presumptions, or, at least for copyright, additional damages.
Destruction of implements	Addresses destruction of materials/implements used in infringement.	Addresses destruction of materials/implements <i>predominantly</i> used in infringement.
Border Measures: scope	All IPRs potentially covered, including patents, geographical indications, and designs.	Patents and undisclosed information excluded from the Chapter. Otherwise parties required not to discriminate unjustifiably between IPRs. <sup>27</sup>
Border Measures: points for seizure	Export, import, and in-transit.	Export and import required; in-transit seizures optional.
Border measures: disclosure of information	Party required to authorise its authorities to provide certain information to a right holder where goods found to infringe.	Party <i>may</i> give authorities authority to provide certain information (not limited to cases where the goods have been found to be infringing).
Criminal Enforcement: copyright.	Copyright piracy <u>on a commercial scale</u> <sup>4</sup> (and hence criminal) to include: <ul style="list-style-type: none"> <li>• Significant wilful copyright infringements with no direct or indirect motivation of financial gain; and</li> <li>• Wilful copyright infringement for commercial advantage or private financial gain.</li> </ul>	Copyright piracy on a commercial scale to include <u>at least those [acts]</u> carried out as commercial activities for direct or indirect economic or commercial advantage <sup>4</sup> .

<sup>27</sup> As I have set out elsewhere, this language arguably allows parties to exclude other IP rights, such as geographical indications, provided some justification is given: see Weatherall, *Politics, Compromise, Text*, above n8, 247.

Criminal enforcement: trade mark	Criminal enforcement to cover trade mark infringement caused by confusingly similar trade mark goods.	Criminal enforcement only to cover wilful trade mark counterfeiting; no reference to <i>confusingly similar</i> marks.
Criminal enforcement: camcording	Offence required for knowingly copying or transmitting the public of a film, taken from a performance in a cinema.	This offence optional.
Criminal enforcement: <i>ex officio</i>	<i>Ex officio</i> powers to be conferred for all offences in the ACTA.	<i>Ex officio</i> powers only required <i>in appropriate cases</i> , meaning freedom to party to determine what is appropriate.
Digital Environment: Intermediaries	Detailed proposals for protection of intermediaries subject to obligations to act (eg to have notice and take down), based on US or EU Safe Harbours.	No detail; obligation to apply enforcement to infringement over digital networks, in such a manner as to avoid creating barriers to legitimate activities. Protection for online service providers is a possibility mentioned in footnote 13.
Digital Environment: <i>Graduated Response</i> .	Some reference in the text to an obligation to have a policy to address online infringement, one example of which would be a policy providing for termination of the accounts of repeat infringers.	No reference to any such idea; only a provision that parties will <i>endeavour</i> to promote cooperative efforts within the business community to address online infringement, <i>preserving fundamental principles</i> such as freedom of expression, fair process, and privacy.
Digital Environment: anticircumvention law	Proposals to require bans on circumvention of access and copy controls.	Technological measures covered by the rules are largely left to law of the party: see footnote 14.
ACTA Committee	Some suggestion in the text that Committee might have powers to <i>monitor</i> implementation and to undertake dispute resolution.	Committee has role of <i>reviewing</i> implementation and operation. No dispute resolution. A party can request consultations with another party regarding implementation.

Overall, the finalised version of the ACTA introduced a series of safeguards, exceptions and protections for users and parties to litigation, backed away from significant strengthening of the enforcement apparatus in relation to patents and geographical indications;<sup>28</sup> left the scope of border measures in the hands of individual

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<sup>28</sup> In particular, by removing patents and arguably removing geographical indications from the provisions on border measures. On the detail of how this works, see Weatherall, *Politics, Compromise, Text*, above n8, 244-254.

countries, almost completely abandoned any attempt to dictate the way that enforcement will occur in the digital environment or the ways that intermediaries in that environment will be regulated,<sup>29</sup> and significantly watered down the provisions on criminal enforcement. In all these areas, the countries who have, historically, been the most enthusiastic proponents of strong IP law and strong IP enforcement, could not reach agreement.

The lack of consensus is more significant in some areas than others. For example, it is arguable that both the US and EU (and other negotiating countries like Singapore, and Australia) could agree on the principle that internet intermediaries ought to have some shield from full copyright liability, in return for their taking some action to assist rightholders enforce their rights online. Both the US<sup>30</sup> and EU<sup>31</sup> have their own schemes for shielding intermediaries, although they operate in quite different ways.<sup>32</sup> The lack of consensus on this issue is more likely owing to the failure to agree to language that sufficiently accommodates the different existing systems, than to the principle underlying those systems.<sup>33</sup> On the other hand, the differences in relation to criminal copyright enforcement appear to be more fundamental. To date, the European Commission has not

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<sup>29</sup> Both through the removal of detailed provisions on online service provider liability and the removal of language in the injunction provisions that might have required injunctions to be available against non-infringing intermediaries in the digital environment.

<sup>30</sup> *Digital Millennium Copyright Act*, 17 U.S.C. §512 (US);

<sup>31</sup> *Directive 2000/31/EC of the European Parliament and of the Council of 8 June 2000 on certain legal aspects of information society services, in particular electronic commerce, in the Internal Market* OJ L 178, 17.7.2000, p. 1–16, Articles 12-14 (Ecommerce Directive).

<sup>32</sup> The US scheme provides intermediaries with protection from full copyright liability provided they comply with regulations requiring, for example, a notice-and-takedown regime and a policy for the termination of repeat infringers in appropriate circumstances. Within the safe harbour, an intermediary can only be subject to certain injunctions: for the termination of a particular account or blocking a particular website. In the EU, the requirements that an intermediary must comply with are less heavily specified, however, the EU has an additional provision that ensures that injunctions may be ordered even against an intermediary that has the benefit of protection from liability: see *Directive 2001/29/EC of the European Parliament and of the Council of 22 May 2001 on the harmonisation of certain aspects of copyright and related rights in the information society*, O.J. L 167, 22/06/2001 P. 0010 – 0019 (Information Society Directive), Article 8(3).

<sup>33</sup> Note however that according to the leaked text from January 2010, Japan too had difficulties with proposed language for intermediary liability, as, unlike the US and EU, Japan does not recognise particular ‘categories’ of internet intermediary, but has a general rule that an ISP will not be liable if it is (a) technically impossible for an ISP to take measures for preventing transmission of the relevant information, or (b) an ISP does not know and does not have a reasonable ground to know that infringing activity is occurring. Canadian draft legislation the subject of consultations at the time of the ACTA negotiations had a different structure of liability again: applying ‘notice and notice’ rather than ‘notice and takedown’, and de-linking infringement liability from separate obligations to take measures to assist rightholders.

proposed any explicit extension of criminal liability that would extend to personal, non-commercial activities,<sup>34</sup> and the European Parliament has affirmatively adopted a position that acts carried out by private users for personal and not-for-profit purposes should be excluded from criminal liability (or at least, excluded from any criminal liability that would be required by inclusion of such acts in a proposed EU Directive on enforcement).<sup>35</sup> On the other hand the US position on criminal enforcement, and the extension of ‘commercial scale’ infringement to cover substantial but non-commercial activities is predicated directly on the perceived need to impose criminal liability on individual users, particularly in the online context where substantial harm to right holders may occur despite the non-commercial nature of an activity, such as file-sharing.<sup>36</sup> Similarly the imposition of liability for even small-scale activity carried out for ‘private financial gain’ in the various US Free Trade Agreements is arguably aimed at the acts of individuals. Criminal enforcement may, it seems, be an area where even the countries more enthusiastically pro-IP and pro-enforcement have real philosophical differences.<sup>37</sup> Differences concerning the appropriateness of applying border measures to patent, and extending enforcement protection for geographical indications (GIs), are also areas of

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<sup>34</sup> *Proposal for a European Parliament and Council Directive on criminal measures aimed at ensuring the enforcement of intellectual property rights* [SEC(2005)848]/\*COM/2005/0276 final – COD 2005/0127\*/. The text of this proposed directive refers only to ‘intentional infringements of an intellectual property right on a commercial scale’. On its face, such language, while broader than TRIPS (because it extends to all IP rights, not just copyright piracy and trade mark counterfeiting) does not seem to cover private non-commercial acts.

<sup>35</sup> Position of the European Parliament adopted at first reading on 25 April 2007 with a view to the adoption of Directive 2007/.../EC of the European Parliament and of the Council on criminal measures aimed at ensuring the enforcement of intellectual property rights (EP-PE\_TC1-COD(2005)0127). For more detail, see the discussion in Kamperman Sanders et al, above n7, 29-30.

<sup>36</sup> The US extension of criminal copyright enforcement to non-commercial activities dates from the 1997 *No Electronic Theft Act*, otherwise known as the *NET Act*, PL 105-147, (codified in scattered sections of 17 USC (1997)). Subsequent to the *NET Act*, criminal liability may arise for willful infringement through the reproduction or distribution, including by electronic means, during any 180-day period, of one or more copies or phonorecords of one or more copyrighted works, which have a total retail value of more than \$1,000: 17 USC §506(a)(1). The Act was a response to *United States v La Macchia* 871 F. Supp. 535 (D Mass 1994), in which the US was unable to prosecute La Macchia for criminal copyright infringement after he facilitated the uploading and downloading of significant quantities of software via an electronic bulletin board, because he received no payment for copies of the software.

<sup>37</sup> Although the final ACTA Article 23(1), which states that commercial scale includes ‘at least those [acts] carried out as commercial activities for direct or indirect economic or commercial advantage’ would, if adopted globally, require China to abandon the numerical minima which were in question in the WTO case brought against China by the US: *China - Measures Affecting the Protection and Enforcement of Intellectual Property Rights - Report of the Panel*, WT/DS362/R, January 26, 2009. As TRIPS presently stands, the WTO Dispute Settlement Body in that case found that China was entitled to maintain these thresholds.

strong difference between the negotiating parties.<sup>38</sup> On the latter, the US remains opposed to extensions to rights in GIs; the EU on the other hand sees GI protection as critical.<sup>39</sup>

What lessons should we draw from the experience of the ACTA negotiations? For present purposes,<sup>40</sup> the most important lesson is that even in the context of ‘North-North’ negotiations on IP and IP enforcement, there remain significant differences in philosophy and approach. One way to see ACTA, then, is as an exemplar of the maximum level of enforcement that will draw support from these important countries, and, hence, as a maximum set of provisions that could conceivably be ‘multilateralised’ in some future global negotiations, even before the interests of large developing countries and the BRIC countries<sup>41</sup> are taken into account. A further lesson from ACTA was that even signing up a number of countries to detailed IP provisions will not guarantee the success of those detailed provisions in later negotiations with a larger group. Although several ACTA parties were signatories to earlier US FTAs (in particular, Singapore, Australia, Morocco and to a lesser extent, Mexico through the North American Free Trade Agreement or NAFTA), other parties in the ACTA negotiations such as Europe and Japan were not, and were clearly not prepared to go along with the US model where it conflicted with their own law.<sup>42</sup>

### **3 The Trans-Pacific Partnership: lessons learned or more mistakes?**

#### **3.1 Introduction to the TPP**

This brings me to current events, or rather, current negotiations, relating to the proposed Trans-Pacific Partnership, or TPP. The question of interest here is whether the lessons of the ACTA negotiation have been learned. Sadly, the answer is no.

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<sup>38</sup> See Weatherall, *Politics, Compromise, Text*, above n 8, 247-248.

<sup>39</sup> See generally Michael Handler, ‘The WTO Geographical Indications Dispute’ (2006) 69 *Modern Law Review* 70; Michael Handler, ‘The EU’s Geographical Indications Agenda and its Potential Impact on Australia’ (2004) 15 *Australian Intellectual Property Journal* 173. As I have pointed out elsewhere, the text on border measures and GIs can only be described as a compromise which enabled both sides to claim victory: Weatherall, *Politics, Compromise, Text*, above n8, 248.

<sup>40</sup> For other lessons from ACTA, see also Weatherall, *Politics, Compromise, Text*, above n 8; see also Kimberlee Weatherall, ‘ACTA as a New Kind of International Lawmaking’ (2011) 26 *American University International Law Review* 838. The latter in particular considers the lessons of ACTA for the ‘one way global IP ratchet’ that has been discussed in the international literature on IP lawmaking.

<sup>41</sup> Brazil, Russia, India and China.

<sup>42</sup> For further discussion of this point, see Weatherall, ‘ACTA as a New Kind of International Lawmaking’, above n40.

The TPP is presently being negotiated between Brunei Darussalam, Chile, New Zealand, Singapore, Australia, Peru, the United States, Vietnam and Malaysia.<sup>43</sup> The genesis of the TPP is in an earlier agreement, the P-4 (Singapore, Chile, New Zealand and Brunei).<sup>44</sup> The P-4 includes an open accession provision,<sup>45</sup> which enabled the US in 2008 to announce its intention to join negotiations; soon after, both Australia and Peru also expressed interest.

The Trans-Pacific Partnership (TPP) is a very different kind of agreement from ACTA. Most obviously, where ACTA only relates to IP rules, the TPP is being negotiated as a comprehensive regional Free Trade Agreement, which will include chapters dealing with a full range of trade issues including market access for both goods and services, rules of origin, government procurement, investment and financial services, telecommunications, and sanitary and phytosanitary Rules; in all 20 chapters are the subject of negotiation.<sup>46</sup> Intellectual property is only one chapter in this negotiation, albeit from a US perspective at least, an important one.

The TPP has been presented as an opportunity to tie together existing trade agreements and hence 'untame the tangle' of existing agreements.<sup>47</sup> But it is also being touted as an opportunity to create a platform for broader regional trade integration. In

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<sup>43</sup> There have been some indications that Japan may be considering joining the negotiations. See Daily Yomiuri Online, 'PM indicates intention to joint TPP talks/Aiming to announce at Nov. Forum', 10 October 2011, available at <http://www.yomiuri.co.jp/dy/national/T111009003175.htm>; Japan Times, 'Noda seeks TPP policy by November Summit', 3 October 2011, available at <http://search.japantimes.co.jp/cgi-bin/nb20111003a1.html>. Commentators note, however, that the power of the agricultural lobby in Japan will make joining difficult: Ann Capling and John Ravenhill, 'Multilateralising Regionalism: What Role for the Trans-Pacific Partnership?' Paper presented at the Australian Political Science Association Conference 2011, available at <http://law.anu.edu.au/COAST/events/APSA/papers/69.pdf>. The Philippines has also been discussed, but more likely as a post-conclusion accession: see Philippine Daily Inquirer, 'US extends assistance for Philippines accession to Trans-Pacific deal', 30 September 2011, available at <http://business.inquirer.net/22231/us-extends-assistance-for-philippines-accession-to-trans-pacific-deal>.

<sup>44</sup> *Trans-Pacific Strategic Economic Partnership Agreement*, text available at [http://www.sice.oas.org/Trade/CHL\\_Asia\\_e/mainAgreemt\\_e.pdf](http://www.sice.oas.org/Trade/CHL_Asia_e/mainAgreemt_e.pdf).

<sup>45</sup> *Trans-Pacific Strategic Economic Partnership Agreement*, Article 20.6.

<sup>46</sup> According to information released by the Australian Department of Foreign Affairs and Trade following the eighth round of negotiations in early September 2011: see <http://www.dfat.gov.au/fta/tpp/110927-tpp-stakeholder-update-8.html>.

<sup>47</sup> Capling and Ravenhill, above n43, 5. As Ravenhill points out, an enlarged TPP including the current negotiating parties would duplicate a number of existing trade agreements: in fact, of the 21 bilateral preferential arrangements that an expanded TPP would create, only 8 are not already covered by some existing agreement: John Ravenhill, 'Extending the TPP: the Political Economy of Multilateralization in Asia', Paper presented to the Asia-Pacific Trade Economists' Conference, *Trade-Led Growth in Times of Crisis*, 2009, available at <http://www.unescap.org/tid/artnet/mtg/2-3John%20Ravenhill.pdf>, 24-25.

other words, the ambition is that other countries will, in the future, also accede to the Agreement, thus over time extending its membership throughout the Asia-Pacific region. In his Ministerial Statement on the TPP in November 2008, Trade Minister Simon Crean reinforced the Australian Government's 'absolutely clear ... commitment to reinforcing the primacy of the multilateral trade system – and ensuring that FTAs support the multilateral trading system.'<sup>48</sup> According to Minister Crean, the Australian government favours 'initiatives that ensure that bilateral and regional trade arrangements are more consistent with the multilateral trading system'. According to Minister Crean, the TPP negotiations are 'perhaps the most important initiative the ... government has taken to fulfil that aim.'<sup>49</sup> The TPPA, he stated, 'has the potential to serve as a viable building block to even greater regional integration in the Asia Pacific'. In a later press release, Minister Crean suggested that the TPP could be a potential building block to a larger Free Trade Area of the Asia Pacific (FTAAP).<sup>50</sup> Australian industry has echoed these goals.<sup>51</sup>

Nor is this hope confined to Australia. The US has long grappled with the need to engage with the Asia-Pacific region.<sup>52</sup> On trade and economic integration in particular, the US has struggled with the Asian countries' apparent preference for voluntarism and non-binding processes, which are largely at odds with the US preference for binding trade liberalisation.<sup>53</sup> The establishment of the Asia Pacific Economic Cooperation forum

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<sup>48</sup> See also the April 2011 statement of Australian Trade Policy, Department of Foreign Affairs and Trade, Commonwealth of Australia, *Trading our way to more jobs and prosperity*, April 2011. In that document, the Australian government clearly states that 'multilateral agreements offer the largest benefits', and, importantly, that 'regional and bilateral agreements must not weaken the multilateral system'. Thus the Australian government 'will pursue high quality, comprehensive regional and bilateral trade deals only where they offer net benefits to Australia and do not impede progress on the multilateral front'.

<sup>49</sup> The Hon. Simon Crean, Minister for Trade, 'Ministerial Statement: The Trans Pacific Partnership: Australia to join efforts to promote free trade in the Asia Pacific', 26 November 2008, available at [http://trademinister.gov.au/speeches/2008/081126\\_tpp.html](http://trademinister.gov.au/speeches/2008/081126_tpp.html) (hereafter Crean, Ministerial Statement).

<sup>50</sup> Minister for Trade the hon. Simon Crean, 'The Trans-Pacific Partnership – Moving Forward', Press Release, 14 November 2009. See also Ian Fergusson and Bruce Vaughn, 'The Trans-Pacific Partnership Agreement', Congressional Research Service Paper R40502, June 25 2010 at 7 (noting that 'many' hold this hope).

<sup>51</sup> Deborah Elms, 'From the P4 to the TPP: Explaining Expansion Interests in the Asia-Pacific', Paper presented to the Asia-Pacific Trade Economists' Conference, *Trade-Led Growth in Times of Crisis*, 2009, available at <http://unescap.org/tid/artnet/mtg/Deborah%20Elms.pdf>, 30-31.

<sup>52</sup> See, eg, Ian Fergusson and Bruce Vaughn, 'The Trans-Pacific Partnership Agreement', Congressional Research Service Paper R40502, June 25 2010, noting that '[i]t is envisaged that the TPP will add members in successive tranches', at 3.

<sup>53</sup> See generally John Ravenhill, *APEC and the Construction of Pacific Rim Regionalism* (Cambridge University Press 2001). Trade and economic integration are, of course, not the only area where the US has grappled with issues in the region; security, too, is an area where US preparedness to engage in

(APEC) in 1989 was one key early step towards engagement with the region, but lost some relevance in the later 1990s as a wave of bilateral trade agreements rose in the region. The US' involvement in bilateral negotiations in the region was limited: while it concluded agreements with Singapore (2003)<sup>54</sup> and Australia (2004),<sup>55</sup> and, later, South Korea,<sup>56</sup> this last, and most significant agreement required renegotiation in light of Congressional opposition, and even then waited Congressional approval for years: only achieving that approval in late 2011. Meanwhile more than a hundred trade negotiations in the Asian region were launched from the late 1990s onward.<sup>57</sup> Beyond the 'noodle bowl' of bilateral arrangements, in the mid-2000s, broader East Asian integration had developed some momentum *without* the US, with China favouring an ASEAN+3 grouping, and Japan favouring a broader grouping to include India, Australia and New Zealand (ASEAN+6).<sup>58</sup> The US decision in 2008 to join negotiations with the P-4 was a response to these other regional moves, and reflects a concern that the US might otherwise be left out of regional groupings.<sup>59</sup> Like Australia, the US sees the TPP as the

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intervention is at odds with the preference of key regional players — such as China — for non-intervention.

<sup>54</sup> *US-Singapore Free Trade Agreement* (signed May 6, 2003; in force January 1, 2004).

<sup>55</sup> *Australia-United States Free Trade Agreement*, signed 18 May 2004 [2005] ATS 1 (in force 1 January 2005) (hereafter 'AUSFTA').

<sup>56</sup> *US-Republic of South Korea Free Trade Agreement* (signed June 30, 2007; further legal texts signed 10 February 2011). As at the time of writing, the agreement was awaiting Korean ratification; assuming this occurs the agreement may come into force in early 2012.

<sup>57</sup> Masahiro Kawai and G. Wignaraja, 'Multilateralizing regional trade agreements in Asia', in R. Baldwin and P. Low (eds) *Multilateralizing Regionalism: Challenges for the Global Trade System* (Cambridge University Press 2009). In 2000, there were only three preferential trade agreements involving countries in the East Asian region; in January 2008, there were 38, with a further 68 under negotiation or consideration.

<sup>58</sup> Mireya Solis, 'Last train for Asia-Pacific Integration? US Objectives in the TPP Negotiations', *Waseda University Organization for Japan-US Studies*, Working Paper No. 201102, July 2011, 7; see also Ian Fergusson and Bruce Vaughn, 'The Trans-Pacific Partnership Agreement', Congressional Research Service Paper R40502, June 25 2010 notes the competing groupings at 6-7; see also Claude Barfield and Philip Levy, 'Tales of the South Pacific: President Obama, The Trans-Pacific Partnership and US leadership in Asia', 28 January 2010, on Vox, <http://www.voxeu.org/index.php?q=node/4533>; Du Lan, 'Comments on US Strategy for Promoting Trans-Pacific Partnership', China Institute of International Studies, August 3 2011, available at [http://www.ciis.org.cn/english/2011-08/03/content\\_4380581.htm](http://www.ciis.org.cn/english/2011-08/03/content_4380581.htm); Meredith Kolsky-Lewis, 'The Trans-Pacific Partnership: New Paradigm or Wolf in Sheep's Clothing?' (2011) 34 *Boston College International and Comparative Law Review* 27, 38, 50 (noting the ASEAN+3 and ASEAN+6 options)

<sup>59</sup> See, for example, the President's 2008 Annual Report on the Trade Agreements Program, which notes that 'US participation in the TPP could position US businesses better to compete in the Asia-Pacific Region, which is seeing a proliferation of preferential trade agreements among US competitors and the development of several competing regional economic integration initiatives that exclude the United States': Office of the United States Trade Representative, *President's 2008 Annual Report on the Trade*

potential basis for broader regional integration.<sup>60</sup> As many commentators have noted, the economic benefits of a TPP confined to the currently-negotiating countries would be limited; only if the membership expands will there be payoff to justify the work presently being done.<sup>61</sup>

If the goal is to provide a platform for broader regional integration, then logically, one would expect this goal to impact on the way the agreement is negotiated and the text proposed and adopted. As the Australian Trade Minister recognised, ‘if we’re to encourage others to dock on to the agreement, we want to make sure we’ve got the foundations right... we ... need to start “knitting together” bilateral trading arrangements if we are to make progress towards our goal of ensuring FTAs are truly consistent with the multilateral system.’<sup>62</sup> Or, as Meredith Kolsky Lewis put it:

*For the TPP to serve as a model for a future FTAAP, it will have to be an agreement that other countries are interested in joining. The TPP agreement is not the only option available for Asia-Pacific regionalism, and if the TPP is not sufficiently attractive, one of the other visions for regional economic integration may instead fill the role as FTAAP model. China would like to see ASEAN+3 serve this function, particularly because it would exclude the United States. Japan prefers ASEAN+6 because it would include more economies to counterbalance China, and would still exclude the United States. The TPP needs to be more attractive to potential partners than ASEAN+3, ASEAN+6, or any other potential regional models.’<sup>63</sup>*

The truth of this comment has only been underlined by the very recent announcement out of ASEAN, that it intends to prepare a framework of general principles to steer the establishment of an Asia-Pacific free trade agreement, labelled the

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*Agreements Program*, at 127. Similar fears have been felt by Australia: Ann Capling, ‘Multilateralising PTAs in the Asia-Pacific Region: A Comparison of the ASEAN-Australia-NZ FTA and the P4 Agreement’, Paper presented to the Asia-Pacific Trade Economists’ Conference, *Trade-Led Growth in Times of Crisis*, 2009, available at <http://www.unescap.org/tid/artnet/mtg/2-2Ann%20Capling.pdf>, 8.

<sup>60</sup> It should be noted that the desire to create a high standard trade agreement that could serve as a model for a broader APEC-wide agreement was already in the ‘DNA’ of the P-4 Agreement: see Meredith Kolsky Lewis, above n58, 33. This is reflected in the open accession provision, *Ibid* Article 20.6.

<sup>61</sup> Solis, above n58, 9-10; Kolsky Lewis, above n58, 35-36; Myron Brilliant, Senior Vice President, International Affairs, US Chamber of Commerce, Oral Testimony to the Trade Policy Staff Committee, Office of the United States Trade Representative, March 4 2009, at 2 (cited in Kolsky Lewis at note 50); Elms, above n51, 4-5.

<sup>62</sup> Crean, Ministerial Statement, above n49.

<sup>63</sup> Kolsky Lewis, above n58, 50-51 (footnotes excluded).

‘ASEAN Framework for a Comprehensive Regional Economic Partnership’.<sup>64</sup> This initiative reflects a deep concern among some member countries that ASEAN could be sidelined by the US-backed Trans-Pacific Partnership.<sup>65</sup> In other words, it is clear that the TPP will continue to have competitors in its quest to provide a framework for regional integration.

Commentators have pointed out a number of issues that may prevent the TPP becoming the attractive framework it needs to be to fulfil its region-building goal. Among these potential barriers are some approaches adopted by the US: for example, the US preference for market access agreements and concessions to remain bilateral in nature under a broader common framework,<sup>66</sup> and the US desire to introduce new disciplines on non-tariff barriers to trade, such as the requirement to create a regulatory coordinating body, and binding obligations on State-Owned Enterprises to curb unfair advantages vis-a-vis private companies.<sup>67</sup> Differences between the East Asian and North American approaches to Rules of Origin (ROOs) are another potential issue.<sup>68</sup> Ravenhill notes the fact that trade agreements in the Asian region have tended not to follow the WTO-plus model utilised by the US in its FTAs — and pushed, it would seem, by the US in the TPP negotiations.<sup>69</sup> Other potential issues include the lack of a business lobby in favour of the agreement and domestic political forces in major countries such as the US and Japan that may stymie attempts to conclude and ratify a comprehensive agreement.<sup>70</sup>

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<sup>64</sup> ‘ASEAN prepares framework of principles for Asia-Pacific wide FTA’, Mainichi Daily News, 18 October 2011, available at <http://mdn.mainichi.jp/mdnnews/business/news/20111017p2g00m0bu069000c.html>.

<sup>65</sup> Ibid.

<sup>66</sup> For a discussion, see Kolsky Lewis, above n 58, 48-50; Solis, above n58, 11-12. In short, the US is proposing that market access concessions remain bilateral, so that market access negotiated in earlier FTAs should remain the same (the US deal with Australia would remain the same, for example, excluding sugar) and new market concession arrangements would be negotiated where they did not already exist (thus New Zealand would negotiate with the US on this point). This approach not only makes the agreement more difficult to negotiate now, and reduces its attractiveness to business groups who would have hoped to gain increased concessions (such as the Australian sugar industry), but it also necessarily decreases the attractiveness of later accession by other countries, in that they would face market access negotiations with each TPP country rather than being able to sign up to a blanket deal: see Solis, above n58.

<sup>67</sup> Solis, above n58, 14.

<sup>68</sup> Capling and Ravenhill, above n43 at 6.

<sup>69</sup> Ravenhill, above n47, 5.

<sup>70</sup> Ravenhill, above n 69; see also Capling and Ravenhill, above n43.

### 3.2 *IP in the TPP*

Relevantly for our purposes, however, it seems that the US approach to IP could also be a significant barrier. The lessons of ACTA have not been learned; the US is still pushing a detailed model that will likely act as a significant barrier to the aspirations for the TPP's regional future.

Like the ACTA negotiations and like many trade negotiations, the TPP negotiations are taking place with a high degree of secrecy surrounding the issues being negotiated and the negotiating text. No text is officially available. To date, the (apparent) negotiating proposals of New Zealand, Chile (both undated, leaked February 2011), and the US (dated February 2011) have been the subject of very public leaks.<sup>71</sup> Assuming these leaked documents are genuine, they demonstrate a divide between the largely TRIPS-consistent, broad and general suggestions of New Zealand and Chile on the one hand,<sup>72</sup> and very detailed US proposals which are not only 'TRIPS-plus', but go further than the chapters included in previous US trade agreements and further, notably, than ACTA.<sup>73</sup> For example, the US draft dating from February 2011 for the IP Chapter of the TPP proposes:

- Limits on parallel importation;<sup>74</sup>
- Extension of the copyright term for films and sound recordings to 95 years;<sup>75</sup>
- A presumption of validity for patents and trade marks;<sup>76</sup> and
- Detailed regulations governing the management of geographical indications and their relationship with trade marks.<sup>77</sup>

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<sup>71</sup> These leaked texts are available online: the New Zealand and Chile proposals at <http://infojustice.org/archives/1428>, and the US proposal at <http://keionline.org/sites/default/files/tpp-10feb2011-us-text-ipr-chapter.pdf>.

<sup>72</sup> The New Zealand proposal (ibid) for example focuses on issues such as cooperation on and transparency of IP systems, capacity building, cooperation on emerging issues, and a small number of substantive provisions on trade mark and copyright enforcement.

<sup>73</sup> For a full analysis of the implications of the leaked TPP draft proposal from the United States for Australian law, in the area of copyright and enforcement mechanisms, see Kimberlee Weatherall, 'An Australian Analysis of the February 2011 Leaked US TPPA IP Chapter Text - copyright and enforcement', unpublished 2011, available at the Selected Works of Kimberlee G Weatherall <http://works.bepress.com/kimweatherall/22>. The following text draws on the analysis in that longer document.

<sup>74</sup> US Draft TPP IP Chapter, above n 71, Article 4.2. No similar limitation presently exists in the AUSFTA (above n 55).

<sup>75</sup> US Draft TPP IP Chapter, above n 71, Article 4.5. In the AUSFTA, the copyright term for these items was extended to 75 years (from a previous 50 years).

<sup>76</sup> US Draft TPP IP Chapter, above n 71, Article 10.2.

<sup>77</sup> US Draft TPP IP Chapter, above n 71, Article 2, especially Article 2.14-2.22.

Critically, the draft includes proposals either not put forward, or rejected, in the context of the ACTA negotiations:

- Statutory damages in copyright and (in a new development) for breaches of the anti-circumvention provisions;<sup>78</sup>
- Mandatory provision for customs authorities to seize allegedly infringing in-transit goods;<sup>79</sup>
- Expansion of criminal liability in copyright to include private, non-commercial activities;<sup>80</sup>
- A level of detail on anti-circumvention law based on past models of US FTAs — detail not included in the ACTA;<sup>81</sup>
- A camcording offence;<sup>82</sup> and
- Detailed online safe harbour provisions.<sup>83</sup>

Further, the TPP draft produced by the US includes none of the safeguards for users and parties to litigation which were negotiated into the ACTA, such as the inclusion of a reference to TRIPS Articles 7 and 8,<sup>84</sup> allowance for the protection of privacy,<sup>85</sup> a requirement that procedures be fair, equitable, and proportionate,<sup>86</sup> and that measures not create barriers to legitimate trade.<sup>87</sup> The draft even includes a provision stating that ‘a decision that a Party makes on the distribution of enforcement resources shall not excuse that Party from complying with this Chapter’ — the exact opposite of the position under ACTA.<sup>88</sup>

On questions relating to the relationship between patents and pharmaceuticals, the TPP seems likely to be particularly controversial. In this area, the information available on the actual text being proposed by the US is more limited, as the US‘ leaked text of February 2011 included only placeholders for the relevant provisions. The most recent information released by the US was in the form of a White Paper entitled *Trans-Pacific*

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<sup>78</sup> US Draft TPP IP Chapter, above n 71, Articles 12.4, 12.2.

<sup>79</sup> US Draft TPP IP Chapter, above n 71, Article 14.4.

<sup>80</sup> US Draft TPP IP Chapter, above n 71, Article 15.1.

<sup>81</sup> US Draft TPP IP Chapter, above n 71, Article 4.9.

<sup>82</sup> US Draft TPP IP Chapter, above n 71, Article 15.3.

<sup>83</sup> US Draft TPP IP Chapter, above n 71, Article 16.3.

<sup>84</sup> ACTA, above n 3, Article 2.3.

<sup>85</sup> ACTA, above n 3, Article 4.

<sup>86</sup> ACTA, above n 3, Article 6.2—6.3.

<sup>87</sup> ACTA, above n 3, Article 6.1.

<sup>88</sup> US Draft TPP IP Chapter, above n 71, Article 10.1. Article 2.2 of ACTA, above n 3, provides that ‘[n]othing in this Agreement creates any obligation with respect to the distribution of resources as between enforcement of intellectual property rights and enforcement of law in general.’

*Partnership Trade Goals to Enhance Access to Medicines*.<sup>89</sup> This document talks in general language about US goals for the TPP, and the US ‘new strategic initiative’, *Trade Enhancing Access to Medicines* (TEAM), which, according to the document, is ‘designed to deploy the tools of trade policy to promote trade in, and reduce obstacles to, access to both innovative and generic medicines, while supporting the innovation and intellectual property protection that is vital to developing new medicines’.

Prior to the release of the White Paper, the US had two approaches on the relationship between patents and pharmaceuticals. The model for *developed* countries, reflected in its most stringent form in the US-Korea Free Trade Agreement,<sup>90</sup> requires patent term adjustments to compensate for unreasonable delays that occur in granting a patent<sup>91</sup> or in obtaining marketing approval for pharmaceutical patents,<sup>92</sup> data exclusivity protecting clinical test data submitted for marketing approval for five years,<sup>93</sup> and an obligation to refuse marketing approval to a company seeking to rely on clinical test data submitted by another without the consent of the previous patent owner during the patent term (known as ‘patent linkage’).<sup>94</sup> For *developing* countries, these stringent obligations were relaxed, pursuant an agreement known as the May 10, 2007 Bipartisan Trade Agreement,<sup>95</sup> negotiated between Democrats and Republicans in order to secure Congressional approval for already-negotiated trade agreements with Panama, Peru, Colombia and Korea.<sup>96</sup> Under that agreement, developing countries were entitled to apply exceptions to protection for clinical test data, protect test data only as long as it was

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<sup>89</sup> The document, released 11 September 2011, is available in a number of places, including <http://www.ustr.gov/about-us/press-office/press-releases/2011/september/trade-enhancing-access-medicines>.

<sup>90</sup> *US-Republic of South Korea Free Trade Agreement* (signed June 30, 2007; further legal texts signed 10 February 2011).

<sup>91</sup> *Ibid* Article 18.8.6(a).

<sup>92</sup> *Ibid* Article 18.8.6(b).

<sup>93</sup> *Ibid* Article 18.9.1(a). In addition the Korean agreement provides for 3 years’ data exclusivity for data relating to a chemical entity previously approved for marketing in another pharmaceutical product.

<sup>94</sup> *Ibid* Article 18.9.5.

<sup>95</sup> The genesis of these provisions is discussed in detail in I. M. Destler, ‘American Trade Politics in 2007: Building Bipartisan Compromise’ (2007), *Peterson Institute for International Economics Policy Brief* Number PB07-5, May 2007. The detail of the Agreement may be found in a document entitled ‘Peru & Panama FTA Changes’, published by the House Ways and Means Committee, and available at <http://waysandmeans.house.gov/Media/pdf/110/05%2014%2007/05%2014%2007.pdf>. A more general introduction may be found in a document issued by the USTR, titled ‘Bipartisan Trade Deal’, May 2007, available at [http://www.ustr.gov/sites/default/files/uploads/factsheets/2007/asset\\_upload\\_file127\\_11319.pdf](http://www.ustr.gov/sites/default/files/uploads/factsheets/2007/asset_upload_file127_11319.pdf).

<sup>96</sup> The IP provisions of the May 10, 2007 Agreement were not applied to Korea, which was considered a developed country less in need of these balancing provisions. Other aspects of the Agreement did apply to Korea.

protected in the US, only optionally provide for patent term extensions to compensate for delays in the patent or marketing approval process, and were not required to ‘link’ drug regulatory agencies approval processes and patent issues.

Under the White Paper approach, it appears that the flexibilities accorded to developing countries under the May 10, 2007 Agreement to deny the various special protections for pharmaceutical patents will no longer apply. Instead, it seems that these ‘pharmaceutical-specific IP protections’ — patent term extensions, data exclusivity and patent linkage — will be available in TPP countries, but conditional on the pharmaceutical patent holder bringing medicine to TPP markets within an agreed window of time (the ‘TPP access window’).<sup>97</sup> Non-government organisations concerned with access to medicines have been critical so far: of the lack of detail in the White Paper, but also the apparent suggestion that flexibilities accorded in the past to developing countries might be abandoned.<sup>98</sup>

In sum, the US is treating neither its existing FTAs which the US has agreed with parties involved in the TPP negotiations,<sup>99</sup> nor its past negotiations with Congress in the form of the May 10, 2007 Agreement, nor ACTA, as a ceiling for the IP provisions it will seek to include in the TPP. Rather, the US appears to be treating past FTAs and ACTA as a starting point on which to build further and stronger IP-related obligations. The wisdom of this approach is questionable, to say the least. I argued above that the ACTA ought to be seen as a ceiling to the kinds of IP enforcement provisions that, at present, could be multilateralised. It is true that the goals of the TPP are confined to the Asian region, whereas the ACTA was designed to establish a standard that could be applied globally. Nevertheless, if, as I have contended, ACTA could be seen as a ceiling to the IP enforcement obligations that are acceptable across a range of (even IP-enthusiastic) countries globally, then it is also, surely, a ceiling where the aspiration is to create an agreement for a region made up of both highly industrialised countries, and developing countries.

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<sup>97</sup> This is coupled too with a series of other proposals relating to medicines: such as the elimination of tariffs on medicines, reducing customs obstacles, taking steps to curb trade in counterfeits, reducing internal barriers to distribution of medicines, and promoting ‘transparency and procedural fairness’ in the operation of government healthcare reimbursement programs: White Paper, above n89.

<sup>98</sup> Tido von Schoen-Angerer, Executive Director of Access to Essential Medicines Campaign, Doctors Without Borders, ‘Shooting itself in the Foot: The Broken Promises of the US Trade Agenda’, Huffington Post, 14 September 2011; Public Citizen, Media Alert, ‘On Access to Medicines, Obama Trade Pact Proposal Appears Set to Undo Bush-Era Improvements’, 13 September 2011.

<sup>99</sup> The US has existing FTAs with three of the TPP negotiating countries: Australia (AUSFTA, above n55), Singapore (above n 54) and Peru (*US-Peru Free Trade Agreement* (signed April 12, 2006; in force February 1, 2009)).

It is difficult indeed to see major powers in the Asian region, such as China or India, as being willing to accept the kinds of proposals presently being made by the US. Indeed, it is worth noting that both countries expressed concern about ACTA as it was being negotiated;<sup>100</sup> in this context ‘ACTA-plus’ would seem unlikely to be wholeheartedly embraced. Even some developing countries might find it difficult to swallow provisions which impacted on their ability to take steps to promote access to medicines. If the US persists in its FTA-plus and ACTA-plus approach, in my view, it is likely to doom any resulting TPP to a minor role in the region, and give up any momentum presently being generated towards economic integration on a US model.

I would not contend that the IP chapter of a TPP would necessarily be a ‘make or break’ factor in any given Asian country’s decision whether or not to join the TPP once negotiated. A decision to join, or not join, any given trade agreement is influenced by many factors, both economic and political. Nevertheless, an overly-stringent IP chapter would be one factor that could impact the attractiveness of the TPP. Nor do I mean to suggest that the US is likely to get all its own way on the content of any IP chapter. I suspect, on the contrary, that it will be difficult for Australia to go further than it went in AUSFTA, especially on medicines and pharmaceutical issues which were highly controversial in the debates that followed Australia’s decision to sign the agreement. According to media reports, the Peruvian Minister of Foreign Commerce and Tourism José Luis Silva has publically stated Peru’s intention to refuse policy proposals on medicines and intellectual property that go beyond the current FTA between Peru and the US.<sup>101</sup> Further, if Japan joins the negotiations, then the history of the ACTA negotiations shows that aspects of the digital enforcement provisions would be difficult to reconcile with Japan’s existing copyright law.

As an aside, a question which arises is why the US would adopt what appears to be a counterproductive negotiating stance? Given the overall goals for the TPP being espoused, why would the US propose text on IP that would render agreement for the negotiating countries difficult and potentially create disincentives for other countries to join at a later point? The US approach is even more mystifying given the real possibility that other institutional frameworks exist or are proposed which could act as an alternative basis for a regional economic integration framework? The short answer is likely to be found in domestic political considerations. As Solis states, the difficulty the US trade negotiators face is ‘[t]he political imperative of negotiating trade agreements that can win

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<sup>100</sup> All three countries made critical statements at the July 2010 meeting of the TRIPS Council. A summary of the meeting and discussion is published on the WTO’s website at [http://www.wto.org/english/news\\_e/news10\\_e/trip\\_08jun10\\_e.htm](http://www.wto.org/english/news_e/news10_e/trip_08jun10_e.htm).

<sup>101</sup> Gestión, ‘Medicinas Pueden subir de precio por propuesta de EE.UU’, available at <http://gestion.pe/noticia/1309598/medicinas-pueden-subir-precio-propuesta-eeuu> (English translation on file with author).

domestic ratification in a climate of increasingly divisive Congressional politics and public skepticism about the benefits of free trade as the economy falters'.<sup>102</sup> The USTR might well take the view that departure from previous strong FTA IP provisions would be seen in a very negative light by important constituencies in the US that are important to obtaining Congressional support for any concluded agreement.<sup>103</sup> USTR sensitivity to the demands of Congress can only have been heightened by the recent October votes on the US Free Trade Agreements with Korea, Colombia, and Panama, which were opposed by a majority of House Democrats.<sup>104</sup> This would not, of course, be the first time that domestic politics stood in the way of good global outcomes in trade. Nevertheless, if such domestic demands cannot be overcome, one could legitimately wonder whether the effort and time being devoted to the negotiation of the TPP is worthwhile.

#### **4 Conclusions**

Together ACTA and the TPP represent an interesting juncture in international IP lawmaking. ACTA revealed, perhaps for the first time, the limits of international consensus on IP enforcement measures among the traditional proponents of strong international IP laws. The TPP shows us the perhaps fatally counterproductive impact of US domestic pressures relating to IP on the achievement of the US' (and other countries') broader trade goals. After all the touted success of the trade-IP linkage, I cannot help but wonder whether we are beginning to see the very real downsides, for trade and trade negotiations in general, of that link. It would be ironic indeed if IP were a factor that dashed US trade aspirations in the Asian region. I await the results of the TPP negotiations with very real interest.

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<sup>102</sup> Solis, above n58, 2.

<sup>103</sup> See also Elms, above n51, at 18 (noting certain US lobby groups who urged attention to IP issues in the context of the TPP).

<sup>104</sup> The Colombia FTA was opposed by 82.3% of House Democrats, the Korea FTA by 67.7% of House Democrats, and the Panama FTA by 64.1% of House Democrats. The agreements were only supported as a result of House Republican votes in favour.

# Chart on TPP Proposed Text - Notes Memo

**From:** [REDACTED]  
**To:** [REDACTED] Brendan Bourke  
<brendan.bourke@ipaaustralia.gov.au>  
**Cc:** [REDACTED]  
**Sent:** 08-11-2011 11:56:07 AM

all redactions s47F

Dear [REDACTED] and Brendan, we hope that this email finds you well.

[REDACTED]

Best!

[REDACTED]

<Attachment: Table-Korea-Peru-TPP w comments.ed.pdf>

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## Documents from [REDACTED] [SEC=UNCLASSIFIED] - Notes Memo

**From:** [REDACTED]  
**To:** "Brendan Bourke (brendan.bourke@ipaaustralia.gov.au)" <brendan.bourke@ipaaustralia.gov.au>  
**Sent:** 11-11-2011 02:39:01 AM

Hi Brendan, these came through from Luigi this morning, and thought you might be interested!

Regards, M.

[REDACTED]

FTA Commitments & Implementation Section

Office of Trade Negotiations

Department of Foreign Affairs & Trade

Tel: [REDACTED]

Fax: 02 6112 3773

Hi [REDACTED] (I forgot to attach the pages from my book in my earlier email-now attached)

all redactions s47F

Many thanks for meeting with [REDACTED] and myself yesterday. As promised, I'm providing a few documents and some information which you and your team might be able to use in the negotiations.

First, is a copy of the E.U. Final Report into two year anti-trust investigation into the pharmaceutical industry.

The Report states:

The denser the web created by the patent clusters and/or the divisionals is, the more difficult it will be for a generic company to bring its generic version of the original pharmaceutical to the market. That is to say, even though the main patent protecting the product, e.g. the basic substance patent, may have expired, the generic version may still infringe one of the multiple patents surrounding the original pharmaceutical. This can occur either because patents cover all economically interesting or viable salt forms, enantiomers or formulations of the compound or all efficient ways of its manufacturing. In other words patent clusters and divisionals seem to be aimed at creating legal uncertainty for generic competitors

As a result of its investigation the European Commission uncovered one example of 100 product-specific patent families that included 1,300 patents related to one medicinal product. There were many more examples, but this was the most extreme.

AusPats (IP Australia's search engine) has very limited capacity to provide patent information relating to any specific product or class of products means that the extent of evergreening is effectively hidden. For generic medicines manufacturers in Australia this is a serious issue.

It is worth noting the comment of one generic manufacturer in Europe cited in the Report.

The entire point of the patenting strategy adopted by many originators is to remove legal certainty. The strategy is to file as many patents as possible on all areas of the drug and create a 'minefield' for the generic to navigate. All generics know that very few patents in that larger group will be valid and infringed by the product they propose to make, but it is impossible to be certain prior to launch that your product will not infringe and you will not be the subject of an interim injunction.

You can access the complete Final Report here:

[http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/staff\\_working\\_paper\\_part1.pdf](http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/staff_working_paper_part1.pdf)

[REDACTED]. I have attached 3 pages from my book, Gene Cartels, which discuss the case concerning the patent battle over Paxil and the consequences on the U.S. health system.

All the best,  
Luigi

all redactions s47F

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Luigi

<Attachment: ANU Academic Signature 11.09ANU Academic Signature 11.09><Attachment:  
ATT00001.htm><Attachment: Paxil\_Gene Cartels\_Palombi.pdf><Attachment:  
ATT00002.htm><Attachment: ANU Academic Signature 11.09><Attachment: ATT00001.htm.001>

was ‘no conflict’ between *Scripps* and *Atlantic*, preferring to lay the blame for the ‘apparent uncertainty [on] the patent community’, Rader believed that there was ‘an apparent conflict’ which needed resolution. The majority of seven judges, however, did not agree, and so leave was refused and these particular proceedings went no further.

The US Supreme Court was eventually brought into the other case in *SmithKline Beecham Corp v Apotex Inc* (2006) 547 US 1218 but, unlike the other proceedings which involved the ‘944 patent, this appeal concerned the validity of the product claim 1 to PHCh in the ‘723 patent.

In this case, the Federal District Court had tried to balance the rights of Apotex (Canadian), SKB (British) and the American public’s need for cheaper drugs by holding the claim to PHCh in the ‘723 patent valid but not infringed. According to the District Court PHC was different from PHCh because the process which Apotex used to make PHC was different from the process claimed in the ‘723 patent. On appeal the CAFC disagreed with the Federal District Court, ruling instead that claim 1 was invalid due to the public use of PHCh (because trace amounts of PHCh were necessarily made during the manufacture of PHC) for more than one year prior to the filing of the patent application. Ironically it was SKB’s own evidence which it tried to use against Apotex in the ‘944 patent case which undermined it in the ‘723 case.

An *en banc* hearing of the CAFC subsequently vacated this first decision and, having directed the CAFC on the law, remanded the appeal back to the CAFC. The CAFC duly delivered a second decision ((2005) 403 F 3d 1331), this time ruling against the validity of claim 1, but for different reasons. In its second attempt to invalidate the patent the CAFC held that claim 1 was invalid because the ‘723 patent was inherently anticipated by the prior art covered by the ‘196 patent’. This, they said, was an example of ‘a prior art reference’ because, even though PHCh was *undisclosed* in the ‘196 patent, it was nonetheless a ‘feature of the claimed invention’. In their opinion, as it was ‘necessarily present, or inherent’ in the production of PHC, it could anticipate. It was irrelevant that in 1977 the inventors of PHC were unaware that PHCh was produced (even in minute amounts) and had therefore failed to disclose it in the ‘196 patent. Citing *Schering Corp v Geneva Pharmaceuticals* (2003) 339 F 3d 1373 with approval, the CAFC reinforced that ‘*inherent anticipation* does not require a person of ordinary skill in the art to recognize the inherent disclosure in the art at the time the prior art is created’.

In what had become a marathon of litigation when it reached the US Supreme Court even the US Solicitor-General (SG) filed a brief as *amicus curiae*, that is as a friend of the Court. This then provided the US Government with an opportunity to make its views publicly known. While

the ultimate legal issue in these proceedings was whether the original patent for PHC granted to Ferrosan AS, which had expired in 1998, anticipated the '723 patent claim to PHCh, the ultimate political issue was the price of medicines for US citizens. In his *amicus curiae* brief, in which the SG agreed with the CAFC, he argued that the US Constitution's grant of power to Congress to promote the progress of science meant that 'patent protection applies only to novel inventions'. He confirmed, "[a] claimed invention may be inherently anticipated by a prior art disclosure if the claimed invention necessarily or inevitably flows from the prior art", see e.g., *Cruciferous Sprout*, 301 F.3d at 1349'.<sup>25</sup> Thus the SG accepted that the production of trace amounts of PHCh was an 'inherent anticipation' because, on the evidence, it was an inevitable by-product of PHC. Describing it as a 'bedrock principle of patent law', he argued: 'if granting patent protection on the disputed claim would allow the patentee to exclude the public from practicing the prior art, then that claim is anticipated, regardless of whether it also covers subject matter not in the prior art'.

For SKB, having lost the '944 patent before the CAFC, this application for leave to appeal to the US Supreme Court was extremely important, given that the market for Paxil was worth billions of dollars. Naturally SKB tried to neutralize the SG's line of reasoning by arguing that such an interpretation of the law posed a general threat to 'the innovation that the patent laws are designed to protect'. The SG countered by pointing out that the more specific and narrower claim to its use as a pharmaceutical to treat anti-depression (claim 5) still provided SKB with patent protection for PHCh as a medicine. 'In this fashion', the SG argued, 'they may retain protection for the actual, practical applications of their new discoveries even if their broader claims to the bare compound are ultimately rejected.' Unfortunately for SKB the US Supreme Court refused leave. That PHC was in the public domain meant that Apotex had every right to manufacture and sell, subject to FDA approval, PHC as a generic medicine. This was good not only for Apotex but also for the American people who needed PHC and would now be able to purchase it at much lower prices.

What is revealing about the history of this litigation is that in 1993 the CAFC had overlooked the SG's reference to the 'bedrock principle' of inherent anticipation in *Bell*, and so upheld as valid a patent over isolated and purified nucleic acid materials which coded for a known protein, whereas in the case of PHCh it applied that very principle to strike down a clearly invalid patent claim which should never have been granted in the first place. Some would argue that the history of the *SKB v Apotex* litigation is a reflection of how well the patent system works, as the invalid patent claim was revoked.

What this case demonstrates instead is just how easy it is for unmeritorious patent claims to be granted, even with extensive pre-grant examination, and how complex, expensive and time-consuming patent litigation is. The irony is that, had it not been for SKB suing Apotex for patent infringement, the validity of these patent claims would not have been scrutinized and probably would have remained on the patents register until their expiry. SKB had enjoyed a lengthy period of patent monopoly protection with PHC and then PHCh, but it sought to use the US patent system to maximize its profits to the detriment of the American people. SKB was not concerned to help those who for many years had been forced to pay a higher than normal price for PHC, and had it not been for the determination of Apotex and its deep pockets it is likely that nothing would have changed. Rather than being an example of how well the US patent system works, this litigation marathon is an example of how inefficient the US patent system is and how the enormous costs of patent litigation (of great benefit only to the patent lawyers involved) is damaging the US economy and is inequitable to the American people.

That, in addition, patents are still being granted for things that are merely isolated versions of naturally existing biological materials is an outcome that must be questioned. Patent law requires more than the mere identification or isolation of a product of nature to qualify as an invention. Given that even the SG accepts that the public domain is the repository of common property that should not be controlled unjustifiably by patents, and that anything inevitably flowing 'from the prior art' is part of the public domain, then it follows that products of nature, even those that are unknown or unappreciated at the time, must be part of the public domain. If patent laws are to be permitted to remove something from the public domain, then there must be some proper basis to justify that removal, even if it be for only a limited period of time and eventually to return to the public domain. That the patent system, despite the law, continues to condone such removal through the administrative actions of patent offices, merely on the basis that isolating a product of nature is an 'invention', means that the patent system is not working as it should and that patent offices are acting *ultra vires*, that is beyond their powers. Even with the pre-grant examination of patents, the patent system remains open to abuse.

The British pharmaceutical company SKB was not in the end deprived entirely of patent protection. Even if the product-by-process claim was invalid, it retained patent protection over the specific process for PHCh production and PHCh as a drug until the '723 patent expired in 2006. In this regard, much like the German patent system which operated between 1877 and 1968, the US patent system seeks to encourage the development of better processes – an incentive that would be removed if a claim over

**FW: Briefing re IP issues [SEC=UNCLASSIFIED] - Notes Memo**

**From:** [REDACTED]  
**To:** "Brendan Bourke (brendan.bourke@ipaaustralia.gov.au)" <brendan.bourke@ipaaustralia.gov.au>  
**Sent:** 20-12-2011 12:39:39 AM

I think you said Con was doing some of this type of work? [REDACTED] has just forwarded this to me from the Public Citizen website, FYI.  
M.

[REDACTED]  
FTA Commitments & Implementation Section  
Office of Trade Negotiations  
Department of Foreign Affairs & Trade  
Tel: [REDACTED]  
Fax: 02 6112 3773

all redactions s47F

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**From:** [REDACTED]  
**Sent:** Tuesday, 20 December 2011 10:41 AM  
**To:** [REDACTED]  
**Subject:** Briefing re IP issues

Dear [REDACTED]  
I realize you may be going on leave, but would like to put in a bid for a telephone briefing on IP issues when you return. Could you please let me know of some possible dates?  
Hope you have a happy Christmas and New year . Also below are details of another Public Citizen chart which may be useful, if you have not already received it.

Thanks  
[REDACTED]  
Public Citizen has produced a chart comparing the pharmaceutical patent and data protection provisions of the following texts:  
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[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]  
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There is also a short form, two-page version for easy reference.  
Both can be found here: <http://www.citizen.org/comparative-chart-trips-tpfta-fta>  
PDF of long form (full provisions) here: <http://www.citizen.org/documents/Comparative-chart-of-TPFTA-TRIPS-FTAs.pdf>  
PDF of short form here: [http://www.citizen.org/documents/Comparative-chart-of-TPFTA-TRIPS-FTAs\(short-form\).pdf](http://www.citizen.org/documents/Comparative-chart-of-TPFTA-TRIPS-FTAs(short-form).pdf)

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# EU Commission Calls for Removal of Linkage between Patents and Generic Medicines Authorization - Notes Memo

**From:** Burcu Kilic <bkilic@citizen.org>  
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**Cc:** [REDACTED]  
**Sent:** 31-01-2012 5:00:04 PM

all redactions s47F

Dear All,  
Hope this mail finds you well and you are enjoying the Beverly Hills sunshine. Weâ€™re writing to share an important piece of information with you. Today, the European Commission issued a formal request to Italy to remove linkage between patents and generic medicines authorization which it says is causing delays in generics reaching the market. The Commission highlighted that patent linkage procedures place generic drugs at a disadvantage on the market.  
The European Commissionâ€™s announcement can be found here: <http://www.egagenerics.com/pr-2012-01-27.html> and the details of the news can be reached from here: [http://www.ip-watch.org/2012/01/31/european-commission-orders-italy-to-drop-patent-linkage-delaying-generics/?utm\\_source=daily&utm\\_medium=email&utm\\_campaign=alerts](http://www.ip-watch.org/2012/01/31/european-commission-orders-italy-to-drop-patent-linkage-delaying-generics/?utm_source=daily&utm_medium=email&utm_campaign=alerts)  
Sharing these concerns, the Director General of the European Generics Medicines Association (EGA) stated, â€œIn this time of severe economic difficulty faced by European citizens and public health authorities, it is of crucial importance that patients can access affordable treatment with no unnecessary delays. Delays in access to generic medicines were deemed unacceptable by the pharmaceutical sector inquiry and the economic crisis makes such blocks as patent linkage totally unjustifiable.â€ See the EGA press release here: <http://www.egagenerics.com/pr-2012-01-27.html>.

[REDACTED]

Please donâ€™t hesitate to contact us with any questions or concerns.

Kind regards,

Dr. Burcu Kilic & Steven Knievel

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## How the Trans-Pacific Partnership Agreement Threatens Access to Medicines

The eighth round of closed-door negotiations for the Trans-Pacific Partnership (TPP) agreement will be held in Chicago from September 6-15, 2011. Negotiations during this round are expected to be substantial, as the current nine negotiating countries, Australia, Brunei, Chile, Malaysia, New Zealand, Peru, Singapore, the United States and Vietnam, plan to present the outlines of an agreement at the Asia Pacific Economic Cooperation (APEC) Leaders' meeting in Honolulu, November 8-13 2011.<sup>1</sup>

According to the United States Trade Representative (USTR), "U.S. involvement in the TPP is predicated on the expansion of the agreement to include more economies across the Asia-Pacific region,"<sup>2</sup> and should "set the standard for 21st-century trade agreements going forward."<sup>3</sup> It is therefore expected that the norms that emerge from these negotiations will serve as a baseline for future trade agreements, potentially impacting a much wider group of countries, including developing countries where MSF has medical operations and beyond. For example, Japan and South Korea are reportedly currently considering joining the TPP.

TPP negotiating parties are under no obligation to subject their negotiating positions to public scrutiny; only the final agreed-upon text will be made publicly available. However, a leaked draft of the U.S. position, now available to the public,<sup>4</sup> indicates that the U.S. is demanding aggressive intellectual property provisions that go beyond what international trade law requires. Furthermore, the U.S. position represents a major retreat from previous U.S. commitments to global health, including the 2007 bipartisan New Trade Policy, in which Congress and the Bush administration agreed to abide by important public health safeguards in future trade agreements.

### 1. INTELLECTUAL PROPERTY AND ACCESS TO MEDICINES

#### Vital Importance of Affordable Medicines

Affordable, quality generic medicines are a critical component of treatment programs. About 80% of the HIV medicines that MSF uses are generics, and MSF routinely relies on generic drugs to treat TB, malaria, and a wide range of infectious diseases. In fact, all the major donors and leading international treatment providers, including the Global Fund to Fight AIDS, Tuberculosis and Malaria, The U.S. President's Emergency Plan for AIDS Relief (PEPFAR), UNITAID and UNICEF, rely on quality affordable generic drugs for the programs they support. PEPFAR, which purchases 80-90 percent of its ARVs drugs from generic suppliers, has reported significant savings through the purchase of generic medicines.<sup>5</sup>

The first generation of HIV drugs have come down in price by 99 percent over the last decade, from U.S.\$10,000 per person per year in 2000 to roughly \$60 today, thanks to generic production in India, Brazil and Thailand, where these drugs were not patented. This dramatic price drop has been instrumental in helping scale up HIV/AIDS treatment for more than six million people in developing countries. About 80 percent of donor-funded anti-AIDS drugs and 92 percent of drugs to treat children with AIDS across the developing world comes from generic manufacturers.

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<sup>1</sup> <http://www.ustr.gov/tpp>

<sup>2</sup> <http://www.ustr.gov/about-us/press-office/press-releases/2010/june/ustr-ron-kirk-comments-trans-pacific-partnership-talk>

<sup>3</sup> <http://www.ustr.gov/about-us/press-office/press-releases/2009/november/ustr-news-kirk-comments-trans-pacific-partnership>

<sup>4</sup> Leaked TPP IPR chapter (<http://keionline.org/sites/default/files/tpp-10feb2011-us-text-ipr-chapter.pdf>)

<sup>5</sup> <http://jama.ama-assn.org/content/304/3/313.short>

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**Public Health Safeguards Threatened**

Since the creation of the World Trade Organization (WTO) and the conclusion of the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) in 1995, the most comprehensive multilateral agreement on intellectual property to date, developing countries have struggled to strike a balance between protecting public health and making their patent laws TRIPS compliant. Patents and other intellectual property (IP) regulations pose significant barriers to access to life-saving medicines, and flexibilities in patent systems are recognized as important public policy tools in the fight to protect public health interests. Even developed countries like the U.S. have utilized TRIPS-compliant legal flexibilities to protect public health and other national interests.

The WTO 2001 Doha Declaration on TRIPS and Public Health was signed to reaffirm that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health, and that it can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all. These commitments were reaffirmed and strengthened in the 2008 World Health Organization (WHO) Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property.

However, over the last decade, many developing countries have come under pressure in trade negotiations not to use TRIPS flexibilities and to implement even tougher rules than those set out in TRIPS – these are known as “TRIPS plus.” The U.S. and the European Union routinely use bilateral and regional trade agreements to limit or circumvent developing countries' abilities to implement the Doha Declaration and safeguard public health. The U.S. and the E.U. both have large pharmaceutical industries lobbying for stricter patent regulations, and these interests not only tip the balance away from public health protections and threaten access to medicines, but also work to counter the efforts of global health programs.

In fact, studies have shown that U.S. bilateral and regional free trade agreements (FTAs) have already undermined access to medicines in developing countries. For example, Oxfam found in a 2007 study<sup>6</sup> that during the five-year period since Jordan implemented TRIPS plus measures included in the U.S.-Jordan FTA, medicines prices rose 20 percent, without any corresponding benefit in terms of domestic innovation or access to new products. In addition, the Center for Policy Analysis on Trade and Health (CPATH) found in a 2009 study<sup>7</sup> that once Guatemala enacted data exclusivity, on the basis of the Dominican Republic-Central America-United States (CAFTA-DR) FTA, prices for some medicines rose significantly – even though just a handful of medicines were under patent protection.

Recognizing the damaging effects that trade agreements have had on public health, the Bush administration and the U.S. Congress signed a bipartisan agreement on May 10th, 2007, known as the 2007 New Trade Policy,<sup>8</sup> to scale-back the harshest IP protections in order to strike a better balance between protection of IP and public health needs. The agreement specifies that the USTR should modify its intellectual property demands in trade agreement negotiations so that important public health safeguards are included. Yet in several meetings with U.S. civil society, the USTR has stated on the record that they are considering options in the TPP that would shift U.S. policy away from the 2007 New Trade Policy.

MSF is concerned that the U.S. demands for the TPP negotiations threaten to roll back vitally important public health safeguards in developing countries, creating a fundamental contradiction between U.S. trade policy and U.S. commitments and priorities on global health.

**Medical Innovation Threatened**

MSF is also concerned about the effects that intellectual property norms have on innovation for essential medical technologies. The USTR presents its efforts to demand stronger regimes for intellectual property protection in developing countries as a tool to protect innovation. MSF recognizes the importance of innovation

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<sup>6</sup> [http://www.oxfam.org/en/policy/bp102\\_jordan\\_us\\_fta](http://www.oxfam.org/en/policy/bp102_jordan_us_fta)

<sup>7</sup> <http://www.cpath.org/sitebuildercontent/sitebuilderfiles/cpathhaonline8-25-09.pdf>

<sup>8</sup> <http://waysandmeans.house.gov/media/enewsletter/5-11-07/07%2005%2010%20New%20Trade%20Policy%20Outline.pdf>

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and the need to finance research and development. We are a humanitarian medical organization that needs and welcomes biomedical innovation to better treat our patients. However, the reality is that intellectual property protection in the medical field keeps prices high and limits access to treatment, and furthermore does not stimulate innovation for many of the diseases affecting people in developing countries, where patients have limited purchasing power. By seeking greater and higher intellectual property norms in developing countries, the U.S. government is perpetuating a failed business model that links innovation costs to high prices, and does not address the innovation needs of developing countries.

## **2. THE TRANS-PACIFIC PARTNERSHIP AND ACCESS TO MEDICINES**

The TPP negotiations are being conducted in secret, so MSF other interested stakeholders don't have access to the U.S. or other countries' demands. However, according to a leaked draft of the U.S. position, now available to the public at <http://keionline.org/node/1091>, as well as correspondence and discussions between Congress and the USTR, the U.S. is expected to demand the following TRIPS plus measures to be included in the Intellectual Property Chapter of the TPP:

### **a) Broadening the scope of patentability: the U.S. wants to make it easier to patent new forms of old medicines that offer no added therapeutic efficacy for patients**

The TRIPS agreement includes important flexibilities for governments to decide what type of "innovation" deserves to be protected by patents in a given country. Essential terms such as 'novelty,' 'inventive step,' and 'industrial applicability' are left undefined as standards to be best determined by individual governments within the context of existing national legislation and circumstances.

However, the U.S. is seeking to erode this flexibility by requesting that TPP partners introduce new rules that would severely limit the ability of each country to define what is 'patentable.'

For example, the U.S. proposal for the TPP requests the patenting of a "new form, use, or method of using" an existing product - even if there is no increase in efficacy.<sup>9</sup> This technique, known as "evergreening," allows pharmaceutical companies to obtain or extend monopoly protection for old drugs simply by making minor modifications to existing formulas. Evergreening significantly delays the arrival of more affordable generic medicines onto the market.

Novartis has been battling the Indian government on its implementation of this flexibility since 2006, when its patent for the cancer drug imatinib mesylate (Gleevec) was rejected on the grounds it was based on a drug compound that already existed. Having lost its case in 2007 and the patent appeal in 2009, Novartis is now attempting to ensure the words 'therapeutic efficacy' are interpreted in a way that allows even small changes to an old medicine - such as imatinib mesylate - to be patentable<sup>10</sup>.

Additionally, the US seeks to require that parties make patents available on plants and animals, as well as diagnostic, therapeutic and surgical methods for the treatment of humans or animals despite the fact that Article 27 of the TRIPS Agreement explicitly allows for the exclusion of these inventions from patent protection<sup>11</sup>. Aside from the serious ethical concerns for surgeons performing procedures on patients, this text is not even compatible with the U.S. policy not to enforce patents against medical professionals.<sup>12</sup>

### **b) Restrictions on pre-grant patent oppositions: the U.S. wants to make it harder to challenge unjustified patents**

The TRIPS agreement allows countries and third parties (including generic companies and civil society organizations such as patient groups) to file an opposition to the granting of a patent - either before it has been

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<sup>9</sup> Article 8.1, Leaked TPP IPR chapter (<http://keionline.org/sites/default/files/tpp-10feb2011-us-text-ipr-chapter.pdf>)

<sup>10</sup> <http://www.msfaaccess.org/about-us/media-room/press-releases/drug-company-novartis-tries-weaken-indian-patent-law-protects>

<sup>11</sup> Article 8.2, Leaked TPP IPR chapter (<http://keionline.org/sites/default/files/tpp-10feb2011-us-text-ipr-chapter.pdf>)

<sup>12</sup> <http://keionline.org/node/1216>

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granted (pre-grant opposition) or after (post-grant opposition). Patent opposition procedures have been successfully used in several countries to prevent patents being granted undeservedly.

For example, in June 2008 the Indian patent office rejected a patent for the hemihydrate (syrup) form of Nevirapine (NVP), a widely-used antiretroviral (ARV) treatment, based on pre-grant oppositions by civil society groups. The price of NVP has decreased dramatically over the past years as a result of generic competition. Similarly, the Indian patent office rejected the patent application for Tenofovir Disoproxil Fumarate (TDF), an important HIV drug highly recommended by the World Health Organization (WHO), and Darunavir (DRV), a third-line ARV, based on pre-grant oppositions.

Patent oppositions are an essential public health safeguard that can accelerate the entry of generic competition, improve the patent system through public participation, and help reduce over-patenting.

However, the U.S. government is now seeking to clamp down on this flexibility and prevent pre-grant oppositions in TPP partner countries,<sup>13</sup> making it more costly and cumbersome to oppose a patent. In addition, patent offices will not have the benefit of the expertise of opponents/competitors to the applicant who may be able to identify inaccuracies in the application before a patent is approved.

**c) Imposing new forms of IP enforcement: the U.S. wants to allow customs officials to seize shipments of drugs on mere suspicion of IP infringement and to increase damages for IP infringement**

The TRIPS agreement allows for governments to have a great amount of flexibility when designing the mechanisms that the country will allow for the enforcement of IP rights. However, the U.S., through the TPP and other tools (e.g. ACTA<sup>14</sup>), is demanding that countries enforce IP rights with new forms of enforcement beyond what TRIPS requires.

For example, the U.S. is requesting that TPP countries grant customs officials the ex officio right to detain shipments of medicines at the border, even in transit, if the goods are suspected of being counterfeits or if they are considered “confusingly similar” to trademarked goods.<sup>15</sup>

Under TRIPS, “counterfeit” products are defined as those resulting from criminal – and not civil – trademark infringement, which occurs knowingly and on a commercial scale.<sup>16</sup> The U.S.’s proposed TPP IP chapter allows border officials to rely on a different, more lenient standard – “confusingly similar” – in order to seize consignments. This standard conflates pure commercial trademark disputes, which do not represent a threat to public health or patent rights, with criminal offenses, such as production of counterfeit, falsified or substandard medicines.<sup>17</sup>

In fact, customs and border officials are often not fully trained or equipped to make accurate assessments with regard to intellectual property infringement and may be overzealous in the protection of brand name companies. For example, during 2008 and 2009, at least 19 shipments of generic medicines from India to other countries were impounded while in transit in Europe on grounds that the shipments were suspected of infringing patent rights.<sup>18</sup> In one instance, German customs authorities wrongfully seized a drug shipment of “Amoxicillin” on the suspicion that it infringed the brand name “Amoxil” – the cargo was detained for four weeks while further investigation took place, eventually revealing that there was no trademark infringement.<sup>19</sup> In another instance, the Dutch customs authorities seized a shipment of the AIDS drug abacavir sulfate while it was en route (via Europe) from India to a Clinton Foundation project in Nigeria.<sup>20</sup>

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<sup>13</sup> Article 8.7, Leaked TPP IPR chapter (<http://keionline.org/sites/default/files/tpp-10feb2011-us-text-ipr-chapter.pdf>)

<sup>14</sup> The Anti-Counterfeiting Trade Agreement (ACTA) would impose limits on price-reducing generic competition and jeopardize the free flow of legitimate medicines across borders.

<sup>15</sup> Article 14.4, Leaked TPP IPR chapter (<http://keionline.org/sites/default/files/tpp-10feb2011-us-text-ipr-chapter.pdf>)

<sup>16</sup> [http://www.doctorswithoutborders.org/publications/reports/2011/2011Special301MSF\\_Final.pdf](http://www.doctorswithoutborders.org/publications/reports/2011/2011Special301MSF_Final.pdf)

<sup>17</sup> [http://www.doctorswithoutborders.org/publications/reports/2011/2011Special301MSF\\_Final.pdf](http://www.doctorswithoutborders.org/publications/reports/2011/2011Special301MSF_Final.pdf)

<sup>18</sup> <http://www.bmj.com/content/340/bmj.c2672.extract>

<sup>19</sup> <http://www.twinside.org.sg/title2/IPR/pdf/ipr13.pdf>

<sup>20</sup> <http://www.safemedicines.org/nigeriabound-hivaids-drugs-seized-in-netherlands.html>

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In addition, under the U.S.'s proposed TPP regulations, shipments that are legitimate in the country of origin and the country of ultimate destination would still be subject to detention in the transit country. Unwarranted interception of legitimate in-transit pharmaceutical supplies can undermine legitimate trade in generic medicines.

Furthermore, the U.S. is requesting TPP countries to mandate that judicial authorities consider valuing damages based on "the suggested retail price or other legitimate measure of value submitted by the right holder" in cases of infringement of intellectual property rights,<sup>21</sup> a mechanism that strongly favors the rights holder and increases damage amounts. Each country should have the flexibility to individually determine the appropriate measure for damages for IP infringement.

**d) Expanding data exclusivity: the U.S. is seeking to expand a backdoor way to grant monopoly status**

Data exclusivity is a TRIPS plus provision that restricts access to essential clinical trial data pertaining to the safety and efficacy of drugs. Data exclusivity measures prevent generic manufacturers from using existing clinical research to gain regulatory approval of their medicines, forcing them to perform duplicate clinical trials or wait for the "data monopoly" period to end.

In the absence of data exclusivity measures, when a generic manufacturer applies to register and sell a version of a previously-registered medicine, they only have to provide data showing that their product is equivalent to the original.<sup>22</sup> The drug regulatory authority relies on the clinical trial data provided by the original manufacturer to evaluate the safety and efficacy of the generic drug.

The introduction of data exclusivity provisions essentially creates a new system for granting monopolies by blocking registration of generic medicines until the data exclusivity period ends, even if the patent monopoly has already ended or been overcome, for example with the use of a compulsory license. Under these terms, generic competition is stifled not only for old medicines no longer under patent protection, but also for new medicines that don't warrant patent protection.

Data exclusivity prevents the registration of generic versions of a medicine for many years (the U.S. is asking for up to 12 years of data exclusivity for some classes of drugs), unless the generic manufacturer repeats the necessary clinical trials. This is not only extremely costly, but also arguably unethical, as it forces duplication of clinical trials for patients and animals in order to prove something that is already known.

In addition, while there are clear methods and procedures by which patents can be challenged and overcome – such as patent oppositions and compulsory licenses – rules governing data exclusivity for pharmaceutical test data do not always provide the same public health safeguards.

Although it is not yet clear what the U.S. demands for data exclusivity will be for the TPP, the U.S. has traditionally pressed for a minimum term of five years, similar to U.S. law for certain products. However, Pharmaceutical Research and Manufacturers of America (PhRMA) has been aggressively lobbying for the TPP to require 12 years of data exclusivity for a subset of pharmaceutical drugs, called biologic (also called biosimilar or biopharmaceutical) drugs.<sup>23</sup> In August 2011, several members of the House of Representatives, led by Rep. Henry Waxman, urged president Obama to refrain from negotiating any provisions on exclusivity for biologics in the TPP, noting that a 12-year exclusivity period would impede the ability of Congress to achieve the administration's proposal that the exclusivity period for biologics be reduced to seven years, as reflected in the FY2012 budget proposal, without running afoul of U.S. trade obligations.<sup>24</sup> It is also unclear if the U.S will allow the public health safeguards for data exclusivity specified in the 2007 New Trade Policy.

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<sup>21</sup> Article 12.3 (b), Leaked TPP IPR chapter (<http://keionline.org/sites/default/files/tpp-10feb2011-us-text-ipr-chapter.pdf>)

<sup>22</sup> [http://www.who.int/medicines/services/expertcommittees/pharmprep/QAS04\\_093Rev4\\_final.pdf](http://www.who.int/medicines/services/expertcommittees/pharmprep/QAS04_093Rev4_final.pdf)

<sup>23</sup> <http://www.pharmalot.com/2011/05/phrma-wants-12-years-data-protection-in-tpp-talks>

<sup>24</sup> [http://www.waxman.house.gov/UploadedFiles/TPP\\_Biologics\\_Letter\\_08-04-11.pdf](http://www.waxman.house.gov/UploadedFiles/TPP_Biologics_Letter_08-04-11.pdf)

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**e) Requesting patent term extensions: the U.S. is seeking to keep generic competitors out of the market, for longer**

The TRIPS Agreement requires patents to last 20 years. Although it is not yet clear what the U.S. demands for patent term extensions in the TPP will be, the U.S. is expected to seek to extend the monopoly patent period in order to compensate for administrative delays in the regulatory process, even though the 2007 New Trade Policy made patent extensions optional for countries negotiating trade agreements with the U.S. Such extensions delay the entry of generic medicines, punishing patients for bureaucratic delays.

**f) Requesting patent linkage: the U.S. is seeking to turn drug regulatory authorities into ‘patent police’**

Patent linkage provisions prevent drug regulatory authorities from approving new drugs if they could potentially infringe existing patents. Such provisions effectively require drug regulatory authorities, which are responsible for evaluating the safety, quality, and efficacy of medicines, to take on the responsibility of policing patents, an area normally under the purview of separate patent authorities. Linking drug registration and patent status can delay generic entry into the market and is an aggressive TRIPS plus measure.

The 2007 New Trade Policy made patent linkage optional for countries negotiating trade agreements with the U.S. Most countries in Europe do not impose linkage between patent status and drug registration. If a linkage obligation is included in the TPP, it will impose on developing countries more restrictive conditions for the registration of generic medicines than are found in Europe

**3. OBAMA ADMINISTRATION BACKTRACKING ON U.S. COMMITMENTS TO ACCESS TO MEDICINES**

The TPP is the first trade agreement negotiated under the Obama administration. Leaked U.S. positions and correspondence and discussions between Congress and the USTR indicate that the U.S. is prepared to walk away from its previous public health commitments, including the 2007 New Trade Policy.

The bipartisan May 10th, 2007 New Trade Policy,<sup>25</sup> signed by the Bush administration and U.S. Congress, specified that the USTR should modify its intellectual property demands in trade agreement negotiations so that important public health safeguards are included. The 2007 New Trade Policy aims to scale-back the harshest IP protections for developing countries in order to strike a better balance between protection of IP and public health needs. Although it did not go far enough, it was a step in the right direction. In particular:<sup>26</sup>

- Patent linkage provisions were made voluntary (whereas they had been mandatory in previous US trade agreements).
- Patent term extension provisions were made voluntary (whereas they had been mandatory in previous US trade agreements).
- Data exclusivity was limited to five years for new chemical entities; concurrent periods of exclusivity were mandated, and public health exceptions were allowed to ensure governments could still implement public health safeguards such as compulsory licenses.

When the 2007 New Trade Policy was announced, the House Ways and Means Committee called it “a fundamental shift in U.S. trade policy.”<sup>27</sup> However, the U.S. pharmaceutical industry has been aggressively lobbying against the 2007 New Trade Policy being applied to the TPP negotiation countries. USTR has stated that they are considering options in the TPP that would shift U.S. policy away from the 2007 New Trade Policy and toward greater protection of intellectual property rights for brand-name pharmaceutical companies in the

<sup>25</sup> <http://waysandmeans.house.gov/media/enewsletter/5-11-07/07%2005%2010%20New%20Trade%20Policy%20Outline.pdf>

<sup>26</sup> For an analysis of the May 10 agreement, see: Fabiana Jorge. New U.S. trade policy: A turning point?. *Journal of Generic Medicines* (2007) 5, 5–8. doi:10.1057/palgrave.jgm.4950093. Available at: <http://www.palgrave-journals.com/jgm/journal/v5/n1/abs/4950093a.html>

<sup>27</sup> <http://waysandmeans.house.gov/media/enewsletter/5-11-07/07%2005%2010%20New%20Trade%20Policy%20Outline.pdf>

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developing world. Several Members of US Congress have also warned against this possibility and written to the Obama administration to demand that it uphold the 2007 New Trade Policy<sup>28</sup>.

#### **4. RECOMMENDATIONS**

The U.S. government should:

- a) **Withdraw TRIPS plus requests:** The U.S. should not seek to impose TRIPS plus provisions (e.g. broader scope of patentability, limits on patent oppositions, new forms of enforcement, data exclusivity, patent extensions and patent linkage) on TPP partners. At a minimum, the Obama administration should not walk away from public health protections agreed between Congress and the Bush administration in the 2007 New Trade Policy.
- b) **Increase transparency:** The TPP is being negotiated entirely in secret. Trade agreement negotiations that affect public health must be conducted with adequate levels of transparency and public scrutiny, both with respect to the actual negotiating texts under discussion and the relevant negotiating position and demands of each country.
- c) **Recognize previous commitments to access to medicines and innovation:** The U.S. should ensure that the final text of the TPP agreement is aligned with the US global health priorities and specifically mentions and honors the commitments made in the 2001 WTO Doha Declaration on TRIPS and Public Health, the 2008 WHO Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property and its own 2007 New Trade Policy.

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<sup>28</sup> <http://democrats.waysandmeans.house.gov/press/PRArticle.aspx?NewsID=11756>

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**APPENDIX: Summary of TRIPS, 2007 New Trade Policy and TRIPS plus policies**

<b>Policy</b>	<b>TRIPS flexibilities for public health</b>	<b>2007 New Trade Policy</b>	<b>U.S. “TRIPS plus” proposals for TPP</b>
<b>Scope of patentability</b>	Countries have the right to define patentability criteria; for example, to only grant patents for truly innovative products and to exclude certain products from patentability	No mention	USTR leaked position expands scope of patentability to include: <ul style="list-style-type: none"> <li>– New forms &amp; uses, even if no increase in efficacy</li> <li>– “Evergreening” of old drugs</li> <li>– Patenting of plants &amp; animals, and diagnostic, therapeutic &amp; surgical methods</li> </ul>
<b>Patent challenges</b>	Countries have the right to create patent challenge mechanisms. The TRIPS agreement contains no limits on the possibility of pre- or post-grant patent challenges	No mention	USTR leaked position does not allow pre-grant patent oppositions
<b>Enforcement</b>	Countries can define intellectual property enforcement mechanisms within broad confines of TRIPS agreement	No mention	USTR leaked position imposes new mechanisms of enforcement: <ul style="list-style-type: none"> <li>– More lenient standards for seizures</li> <li>– Allows seizures in transit countries even if products are legal in origin &amp; destination countries</li> <li>– Defines IP damages based on retail price of drugs</li> <li>– Patent validity presumed until proven otherwise</li> </ul>
<b>Data exclusivity</b>	Countries have the right to define data protection provisions that do not grant market exclusivity or monopolies; data exclusivity is not included in the TRIPS agreement	Mandated, but for a maximum of five years; exceptions allowed for public health, including the granting of patent compulsory licenses	<ul style="list-style-type: none"> <li>- USTR position not public but the U.S. will reportedly require data exclusivity and extension of term to 12 years for biologic products</li> <li>- Unclear if public health exceptions will be allowed</li> <li>- Prevents generic drug registration during period of data exclusivity unless generic firm conducts duplicate clinical trials (expensive, unethical)</li> </ul>
<b>Patent Term Extensions</b>	TRIPS agreement only requires 20-year patent terms; term extensions beyond 20 years are not in the TRIPS agreement	Term extensions for regulatory delays are optional	USTR position not public but the U.S. will reportedly require countries to extend 20-year patents to compensate for regulatory delays
<b>Patent Linkage</b>	Countries have the right to grant regulatory approval of generic medicines independent from patent status; patent linkage is not in the TRIPS agreement	The implementation of patent-linkage optional	USTR position not public the U.S. will reportedly require countries to implement patent linkage
<b>Compulsory Licenses</b>	Countries can issue compulsory licenses and can authorize the use of a patented product without the authorization of the patent holder for a variety of reasons, including public health	Recognizing that data exclusivity can eliminate effectiveness of compulsory licenses by delaying entry of generics, a public health exception to data exclusivity is allowed (see Data exclusivity)	No mention in leaked USTR position
<b>Parallel Importation</b>	Countries have the right to define their patent exhaustion regime and to allow for parallel importation of cheaper medicines	No mention	No mention in leaked USTR position



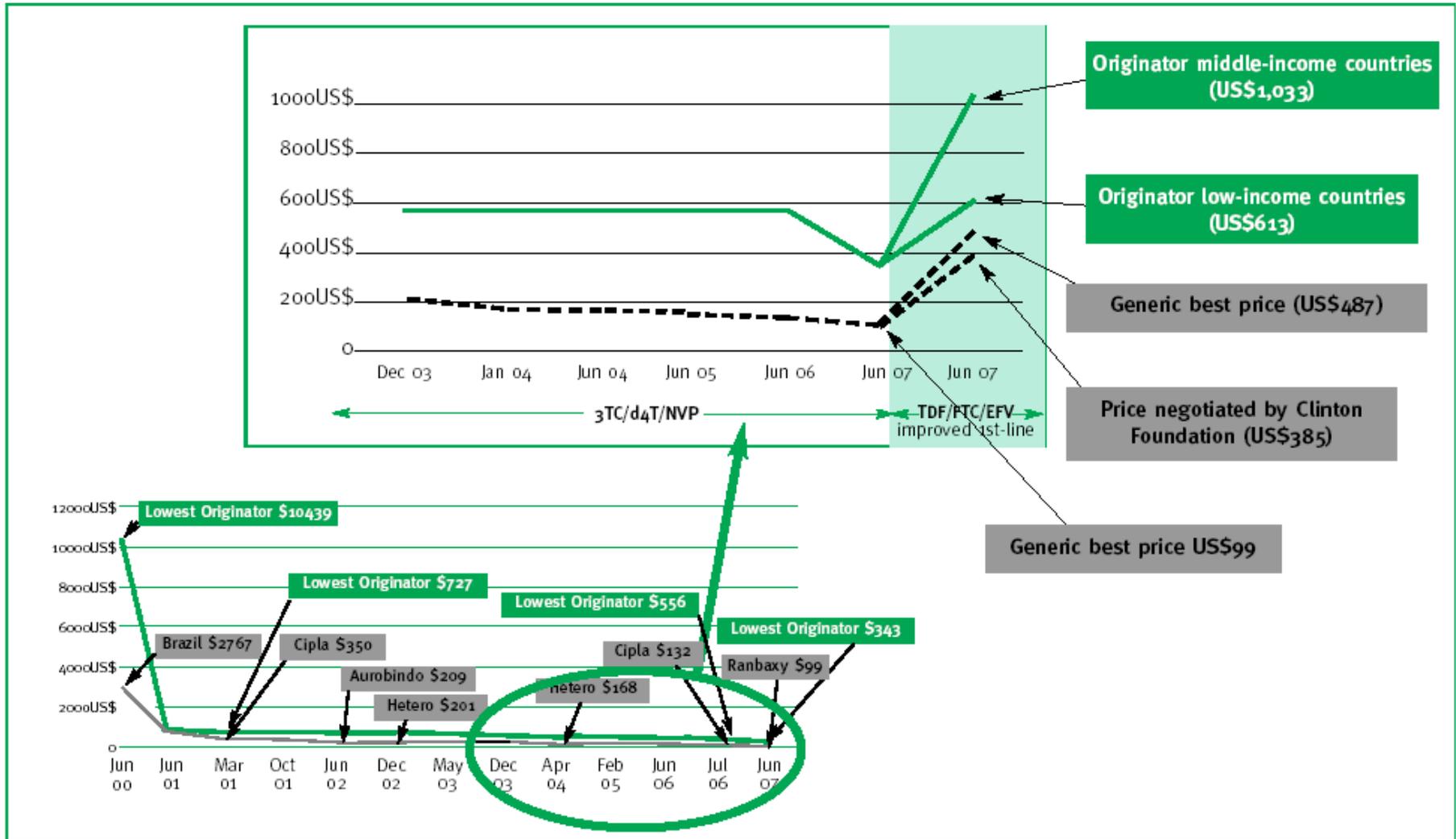
# Access to affordable medicines under threat by **TPPA**

Judit Rius Sanjuan

**Doctors Without Borders/ Médecins Sans  
Frontières (MSF) - Access Campaign**

# Doctors Without Borders (MSF)

- International medical humanitarian organisation, founded in 1971
- Field operations in nearly 70 countries. In 2009:
  - 7.5 million outpatient consultations
  - 292,000 hospital admission
  - 7.9 million vaccinated during meningitis outbreaks
  - 1.1 million confirmed malaria cases
  - 162,000 people on HIV anti-retroviral treatment
- 1999 Launch of the Access Campaign
  - to improve access to existing medical tools that are unaffordable
  - to stimulate the development of urgently needed better tools



Sample of ARV triple-combination: stavudine (d4T) + lamivudine (3TC) + nevirapine (NVP). Lowest prices per patient per year. Improved first line: tenofovir (TDF) + emtricitabine (FTC) + efavirenz (EFV)

# Goals of IP chapter

- I. Extend patent monopolies
- II. Limit rights to use TRIPS flexibilities
- III. Create new monopolies

# I. Extend Patent Monopolies

- Term beyond 20 years - Patent term extension
- New forms of IPR enforcement:
  - Transform IP from a private to public right - Patent - Registration Linkage
  - Reduce countries' flexibilities on enforcement: Injunctions / damages/ border measures

## II. Limit right to use TRIPS Flexibilities

- Eliminating pre-grant patent opposition
  - Examples: TDF, Nevirapine, Kaletra,
- Patentability Criteria - lower the bar for granting patents
  - Section 3 (d) of Indian law & Novartis case
  - Example:  
<http://utw.msfacecess.org/drugs/abacavir>
- Restricting compulsory licensing

### III. Create new monopolies

- Data Exclusivity on clinical data – additional and automatic barrier to generic entry
- TRIPS Plus - 2007 New Trade Policy - Public health exception and important flexibilities
- US going further for first time – expansion for biologics - 12 years? still under discussion in the US!

# WHO / UNAIDS on TRIPS Plus

- **WHO:** “From the perspective of public health and access to medicines, it is preferable not to grant data exclusivity. Moreover, there is no requirement under international law that countries grant data exclusivity; countries only have to provide for data protection” .... “TRIPS plus’ requirements have at times been incorporated in bilateral or regional free trade negotiations, in bilateral investment agreements and in other international agreements and treaties. From the perspective of access to medicines, this is a worrying trend; countries should therefore be vigilant and should not ‘trade away’ their people’s right to have access to medicines”. (*Briefing Note Access to Medicines, WHO, March 2006*)
- **UNAIDS:** “In this current economic climate, resources for AIDS have already flattened and need for treatment continues to outstrip supply. Trade agreements that place additional burdens on the manufacture, import or export lifesaving medicines—so-called ‘TRIPS plus’ measures such as ‘data exclusivity—and incorrect interpretations of the term ‘counterfeit’ should be avoided.” (UNAIDS Press Statement “Trade agreements should not hinder efforts towards universal access to HIV prevention, treatment, care and support” December 2010)

# Why US proposal will not work

- Doha language – good BUT limited to 3 diseases/ only in emergencies and urgency/ only for certain flexibilities
- TEAM proposal – high prices and longer monopolies for developing countries (registration by reference) in exchange of nothing – it will not work and it will make things worse

# TRIPS Plus - Who is going to be affected?

- Patients
- Treatment providers like MSF
- Countries that pay for treatment: donors and developing countries
- Countries/companies that produce generics or that want to develop local manufacturing capacity

# **A better agenda on Innovation + Access to Medicines?**

**WTO Doha Declaration on the TRIPS agreement and Public Health**

**+**

**WHO Global Strategy & Plan of Action on public health, innovation and intellectual property (resolution WHA 61.21)**

Open licensing, De-linkage and Biomedical R&D treaty



# Thank You!

Judit Rius Sanjuan

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More Information:

<http://www.msfacecess.org>

<http://www.doctorswithoutborders.org>



## OXFAM AMERICA ANALYSIS OF THE USTR TRADE ENHANCING ACCESS TO MEDICINES (TEAM) WHITE PAPER

### I. Overview

The Office of the United States Trade Representative (“USTR”) has released a White Paper outlining the Administration’s plans to harmonize trade and intellectual property (“IP”) policies with trading partners in order to protect and promote access to medicines.<sup>1</sup> According to the White Paper, the ongoing Trans-Pacific Partnership Agreement (“TPPA”) negotiations provide a key opportunity for implementation by USTR of a new initiative – Trade Enhancing Access to Medicines (“TEAM”) – which will “deploy the tools of trade policy in order to promote trade in, and reduce obstacles to, access to both innovative and generic medicines.”

Oxfam has reviewed the USTR White Paper describing TEAM. We believe that TEAM is not an appropriate mechanism to improve access to medicines in low- and middle-income countries, and that it will in fact be harmful to access and public health.

TEAM brings nothing new to the table, as there are already mechanisms in place for addressing the nexus between trade rules and public health. Specifically, under the TRIPS Agreement and the Doha Declaration on TRIPS and Public Health, the US Government has already committed to prioritizing the promotion of public health over the protection of intellectual property for pharmaceuticals.<sup>2</sup> Moreover, under the May 10<sup>th</sup> 2007 Agreement, the United States re-negotiated intellectual property standards under free trade agreements (“FTA”) with Peru, Panama, and Colombia, to ensure that public health was not undermined by those FTAs.

TEAM’s approach is fundamentally flawed because it relies on a trade-oriented approach to address public health problems. Also, TEAM does not capture the important distinctions between availability and affordability of medicines in developing versus developed countries. And it fails to take into account fundamental differences in how originator and generic medicines are developed and commercialized, which illustrates the crucial role of generic competition in lowering prices and improving access to treatment. TEAM consists of little more than a repackaging of the demands and preferences of multinational pharmaceutical companies as pro-health policies.

Oxfam welcomes USTR’s acknowledgement that intellectual property rules, together with rules affecting negotiation of pharmaceutical prices, have a direct negative impact upon the affordability of medicines and access to health care in developing countries. Oxfam also supports efforts to reduce tariffs, internal taxes, and excessive mark-ups of medicines in the

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<sup>1</sup> See: [http://www.ustr.gov/webfm\\_send/3059](http://www.ustr.gov/webfm_send/3059)

<sup>2</sup> See: [http://www.wto.org/english/thewto\\_e/minist\\_e/min01\\_e/mindecl\\_trips\\_e.htm](http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm)

supply chain; appropriately, such efforts are being led by health experts at the World Health Organization (“WHO”) rather than by US trade negotiators.

Oxfam believes that because it exacerbates rather than improves access to medicines in low- and middle-income countries, TEAM should be rejected as a new approach. This memo identifies some of the misconceptions underlying the USTR TEAM White Paper, and reviews concepts that are central to promotion of access to medicines.

## **II. How best to ensure access to affordable medicines**

Medicines play a critical role in public health systems. In the last decades, the public health problems facing developing countries have expanded beyond infectious diseases. In large part due to changing lifestyles, a broad range of non-communicable diseases (“NCDs”) are now *the* critical public health problem in developing countries. The WHO estimates that 80 per cent of all deaths from NCDs occur in low- and middle-income countries. Treatment of NCDs, such as diabetes and heart disease, relies upon long-term use of medicines. In the developing countries negotiating the Trans-Pacific Partnership Agreement – Peru, Chile, Vietnam, and Malaysia – there is a high burden of both non-communicable and infectious diseases.

Due to inadequate financial resources in the public and private sector, affordable prices for medicines are vital to ensure that governments can progressively realize universal access to health care. In particular, low-cost, quality generic medicines have played – and continue to play – a critical role in public health systems. Generics cost a fraction of originator medicine prices, and the presence of multiple generic competitors has reduced the price of treatment by as much as 80 per cent. Access to quality generic treatment is particularly important for households that lack health insurance and must therefore pay for medicines out-of-pocket. When poor households lack access to affordable generics, they must forego treatment, sell precious assets, or make difficult choices between paying for medicines and other basic necessities, such as school fees or food.

Ultimately, policies that strengthen or extend patent monopolies, which subsequently delay generic competition and the associated drop in prices, have negative impacts upon access to affordable medicines. Originator companies often note that the vast majority of medicines currently on the WHO Essential Medicines List (“EML”) are off-patent, citing this as evidence that patents do not block access. However, this actually reflects the relative unaffordability of patented medicines – not the irrelevance of patent protection. The WHO EML does not include products that are too expensive, with the sole exception of medicines to treat HIV and AIDS. Otherwise, patented medicines are left off of the list due to their high price.

Data regarding the registration of medicines must also be interpreted with caution. While the registration of new branded medicines in developing countries theoretically should result in “availability” of new medicines in that market, it is essential to consider what portion of the population can actually obtain them. When a patent monopoly is in place, the high cost of new medicines often prevents access to those medicines except for a tiny elite that can afford them.

Thus, registration of new medicines is not a significant indicator of access. In contrast, registration of high-priced medicines may foster inequality; in many places, only a few individuals can access high-priced medicines, therefore obtaining better treatment outcomes, while the vast majority of people receive no or sub-optimal treatment. Improving the availability of, and access to, quality, low-cost generics is essential to advancing public health, particularly in developing countries.

### **III. Transparency in TPPA negotiations must be improved**

Oxfam has been highly disappointed with this Administration's lack of commitment to transparency in the TPPA negotiations. The TPPA will have a tremendous impact upon access to health care for patients in all countries negotiating the Agreement. Nevertheless, TPPA negotiating proposals and draft negotiating texts have not been shared publicly. In the United States, they have only been made available to a limited set of stakeholders that represent narrow commercial interests – including the multinational pharmaceutical industry.

The White Paper is not an adequate substitute for release by the Administration of all of its negotiating proposals and of the current TPPA negotiating text. In lieu of resolving civil society concerns with transparency, the White Paper actually perpetuates suspicion that the United States is not upholding commitments, under either the Doha Declaration or the May 10<sup>th</sup> 2007 Agreement, to prioritize and promote access to medicines and to modify FTA proposals to support access and public health in developing countries. The White Paper should have included complete information about USTR proposals for the intellectual property and pharmaceuticals chapters of the TPPA. Instead, USTR kept its negotiating proposals secret and attempted to divert attention from the probable harmful impact of its proposals.

### **IV. Analysis of the USTR White Paper**

The White Paper states that TEAM is “about working with trading partners to develop strong and common standards to help drive access [...]”.<sup>3</sup> Yet Oxfam's assessment is that TEAM entails, first, abandonment by USTR of important prior commitments to support access to medicines, including the May 10<sup>th</sup> 2007 Agreement, and, second, the introduction of new measures that will restrict access to treatment and harm public health. This section reviews the most worrisome aspects of the TEAM proposal.

#### **A. The TPP “Access Window”**

Under the TPPA, it appears the US Government will abandon the commitments to improving access to medicines made under the May 10<sup>th</sup> 2007 Agreement, which aimed to limit the harmful impact of data exclusivity on developing countries and which made patent linkage and patent term extensions voluntary rather than mandatory. Setting aside this agreement, under TEAM, the US Government plans instead to provide a generous window for the introduction by multinational drug companies of high-cost patented medicines in developing country markets.

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<sup>3</sup> See FN 1.

In exchange for registering new products in developing countries during the access window, originator drug companies will benefit from several years of TRIPS-plus patent protections including data exclusivity, patent linkage, and patent term extensions. While the exact duration of the window is unknown, it is believed the window could be from two to six years. According to the White Paper, this approach aims to stimulate the entry and commercialization of originator drugs in TPPA countries, which USTR alleges will enhance access to medicines in those markets.

Oxfam disagrees with this USTR assessment and believes that the “access window” approach will actually undermine access to medicines. Irrespective of when launched, originator medicines are unaffordable for the governments of and nearly all households in low- and middle-income countries. Only generic competition, coupled with effective price negotiation by governments (when generics are not available), has been proven to lower prices thus enabling access to medicines. Yet generic competition is delayed under the USTR proposal, granting extensive TRIPS-plus patent protections in exchange for registration within the window. This proposal, together with the proposed chapter on pharmaceutical pricing (described below) would actually prevent governments in low- and middle-income countries from taking the necessary steps to ensure that patients can obtain needed medicines.

The “access window” is based upon faulty logic including:

- *The premise that registration of originator medicines in a market translates into access.* In reality, registration does not guarantee that the medicines are available, accessible, or affordable to patients other than a tiny wealthy elite. In a previous study issued by Oxfam, the registration of 26 new medicines in Jordan, following the signature of a free trade agreement with high-levels of IP protection, resulted in nearly no sales of the medicine in the public and private sector.<sup>4</sup> As is often the case, high prices meant that the medicines were not accessible through the public sector or for purchase out-of-pocket by the vast majority of people. For example, Fludara, a medicine used to treat chronic myeloid leukemia, would have required a civil servant in Jordan to work 244 days to afford one unit of the medicine. Unsurprisingly, though this medicine was registered, 0 units were sold in Jordan between 2002 and 2006.<sup>5</sup>
- *The belief that stricter intellectual property rules will encourage companies to launch their medicines earlier in the patent term in developing countries.* In addition to effectively rewarding companies for having failed in the past to register their products in low- and middle-income countries, this approach ignores market realities. Multinational drug companies do not launch medicines in developing countries for a range of reasons that are unrelated to the level of IP protection. For example, a company may delay the launch of a medicine because it does not want to market the medicine at a low price in an emerging market, which could lead wealthier countries to demand lower prices. In

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<sup>4</sup> See: [http://www.oxfam.org/en/policy/bp102\\_jordan\\_us\\_fta](http://www.oxfam.org/en/policy/bp102_jordan_us_fta)

<sup>5</sup> Ibid.

the case of biologics, a company may decide not to launch the product in a market due to lack of demand, including inability to pay, or due to insufficient expertise or facilities to administer such medicines.

#### **B. Restrictions on Pharmaceutical Pricing and Reimbursement**

Based on the USTR White Paper, TEAM would address the need for better “procedural fairness” and “transparency” in the functioning of national healthcare reimbursement schemes. This is also the focus of the recently tabled US proposal for a pharmaceutical pricing chapter in the TPPA. Experts have warned that the proposed chapter, which sets forth obligations that far exceed “transparency”, would tie the hands of governments – including the US Government - seeking to manage the cost of reimbursing expensive new medicines through public health programs. Where generic substitutes are not available (for instance due to patent protection), governments must effectively negotiate affordable reimbursement prices for originator drugs to avoid breaking the budget. This is especially important for developing countries, given their relative lack of resources.

#### **C. Focus on Counterfeit Products**

TEAM proposes to enhance access to medicines by fighting counterfeits. For obvious reasons, Oxfam does not support trade in counterfeit medicines, which may be of compromised quality, safety, and efficacy. However, anti-counterfeit initiatives address only a subset of the broader problem of substandard medicines because they focus only on certain trademark-infringing products. Oxfam recommends that, instead, resources be dedicated to upgrading Drug Regulatory Authorities (“DRAs”) so they can effectively monitor the quality, safety, and efficacy of all medicines on the market. DRAs remove counterfeits, together with other undesirable products, through their normal registration and market surveillance activities.

Importantly, Oxfam is concerned that the United States and other countries have initiated a number of international anti-counterfeit actions that harm public health by curbing the availability of generics. Such initiatives, which use an expansive definition of “counterfeits”, have resulted in the targeting of legitimate, quality generic medicines beyond products that are intended to deceive consumers. Many anti-counterfeit initiatives are fundamentally flawed in their attempt to use a trade and intellectual property framework to address a public health problem – which is also the case with TEAM.<sup>6</sup>

#### **D. Additional Elements of USTR Proposal Harm Access**

Throughout its White Paper, USTR promotes policies that have long been advocated by the originator pharmaceutical industry while mischaracterizing them – together with provisions in its TPPA IP proposal – as pro-access. At the same time, in its White Paper and elsewhere, USTR has failed to acknowledge that other provisions that it is seeking in the TPPA would undermine access to medicines. For instance:

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<sup>6</sup> See: <http://www.oxfam.org/en/policy/eye-ball>

- In its February 2011 negotiating proposal, the United States requested that developing countries introduce new rules that would severely limit the ability of each country to define what is patentable, that is deserving of monopoly protection. In particular, the proposal would allow for the patenting of a “new form, use, or method of using” an existing product even if there is no increase in efficacy. This TRIPS-plus provision allows companies to extend the term of patent protection for existing medicines that have already received a full term of patent protection. This technique, known as “ever-greening”, delays generic entry onto the market for lengthy period of times.
- In TPPA talks, USTR also seeks to eliminate pre-grant opposition, an important safeguard against undeserved patents. In many countries, including TPPA negotiating countries such as Vietnam, Australia, and New Zealand, third parties can oppose the granting of patents, a process that improves patent quality and helps to prevent abuse of the IP system. Elimination of this mechanism could facilitate use of ever-greening, which would delay generic competition.

#### **V. PEPFAR, the Global Health Initiative, and the Medicines Patent Pool**

Oxfam acknowledges the numerous measures put in place by the United States to improve access to medicines, including PEPFAR, the Global Health Initiative, and, more recently, political support for the Medicines Patent Pool.

Yet instead of building upon these measures, by ensuring that trade policies do not undermine these and other pro-health initiatives of the US Government, USTR cites these measures in its White Paper in order to justify a trade policy that will undermine access to treatment in developing countries. This is a classic case of giving with one hand while taking with the other. Oxfam believes that, instead, each successful initiative should encourage the US Government to do more to improve access to medicines.

The President’s Emergency Plan for AIDS Relief relies almost exclusively on generic medicines. At present, over 90 per cent of all medicines used under PEPFAR are generic anti-retroviral medicines manufactured in India. Without the use of generics, the US Government would not have been able to provide treatment to over 3 million people with HIV and AIDS. Yet the TPPA would undermine the effectiveness of PEPFAR by extending patent monopolies and delaying the availability of generic medicines. Vietnam, which is negotiating the TPPA with the United States, is one of the recipient countries under PEPFAR. Between 2004 and 2009, Vietnam received USD 323.6 million for HIV/AIDS prevention, treatment, and care programs. A significant portion of that money has been spent to purchase antiretroviral medicines and medicines for opportunistic infections. Although in 2005, no generics were available to Vietnam under PEPFAR, by 2008, generics comprised 97 per cent of medicines purchased by Vietnam using PEPFAR funds. This shift to generics under PEPFAR (undertaken not only by Vietnam, but also fifteen other PEPFAR countries) is calculated to have saved USD 323 million between 2005 and 2008, plus another USD 380 million in 2010.

The Global Health Initiative is one part of the Administration’s broader Global Development Policy. As part of the Global Development Policy, the Administration promised to ensure

greater coherence between aid policies and other policies that impact developing countries. However, USTR negotiating proposals in the TPPA, which would introduce strict levels of IP protection and place restrictions on pharmaceutical price negotiations, contradict the objectives of the Global Health Initiative. The US Government appears to be unable or unwilling to ensure coherence between its trade and aid policies.

Oxfam, alongside many other civil society organizations, welcomed the commitment by the United States to support the Medicines Patent Pool. The Medicines Patent Pool was conceived as an effort to ensure that the unaffordable costs of new anti-retroviral medicines could be sustainably reduced, while also ensuring that new forms of innovation could be promoted, particularly new fixed-dose combinations. The underlying theory of the Medicines Patent Pool is that flexible intellectual property systems can best improve affordability and innovation. In TPPA talks, USTR has shirked this approach and instead introduced new, strict IP rules that will both undermine access to medicines and discourage innovation, since the proposed new rules would enable pharmaceutical companies to pursue additional patent protection through ever-greening.

## **VI. Conclusion and Recommendations**

The TEAM initiative will not improve access to affordable medicines in developing countries. Its implementation would constitute a giant step backwards after a slow but positive evolution in US trade policy in recent years. In lieu of searching for an appropriate balance between the protection of intellectual property and the promotion of public health, TEAM repackages the stringent IP protections and other policies long sought by the originator pharmaceutical industry, marketing them as pro-health. If accepted by US trading partners, this approach – particularly the proposal for an “access window” – will drastically undermine access to medicines in developing countries while doing little to stimulate innovation. Together with US IP and pharmaceutical pricing proposals for TPPA, TEAM should be rejected by trading partners.

In addition, Oxfam believes the following elements must be included in the TPPA IP chapter to mitigate its probable negative impact on access to medicines and public health:

- In line with public health concerns, and the May 10<sup>th</sup> 2007 Agreement, any provisions providing for patent linkage and patent extension should be voluntary for developing countries;
- Data exclusivity provisions should include public health-related flexibilities;
- Provisions setting out an expanded scope of patentability should be voluntary for developing countries;
- There should be no TRIPS-plus IP enforcement provisions in the TPPA;
- There should be no pharmaceuticals chapter in the TPPA; and
- The TPPA negotiations should be conducted with full transparency.

(untitled) - Notes Memo

**From:** [REDACTED]  
**To:** <Brendan.Bourke@ipaustralia.gov.au>  
**Sent:** 11-04-2012 08:16:22 AM

all redactions s47F

Please find enclosed two documents I may get a chance to refer to at our lunch briefing today. The enclosed chart focuses on the enforcement provisions of the [REDACTED] proposal and shows where they go beyond TRIPS and ACTA. It is a work in progress and does not contain every section yet. Below is a link from a letter from nearly 70 international academics and experts to Colombia on the FTA implementation bill before their Congress yesterday. It highlights many of the specific problems with negotiating and implementing unbalanced FTA agreements that export only one side [REDACTED]  
<http://infojustice.org/wp-content/uploads/2012/04/Colombia-Sign-On-Letter-with-Signatures-April-2012.pdf>

With kind regards,  
[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]

[www.pijip.org](http://www.pijip.org)  
[www.infojustice.org](http://www.infojustice.org)

<Attachment: TPP trips chart .3>

File C2012/12282 FOI 285  
**TPP-ACTA Comparison Table, v. 1**

PIJIP Fellows, March 2012  
 please send comments to pijip@wcl.american.edu

**General Provisions**

TPP	TRIPS	ACTA	Comparison/Analysis
<p>Art. 1.2: Further to Article 1, the Parties affirm their existing rights and obligations with respect to each other under the TRIPS Agreement.</p> <p>3. Each Party shall ratify or accede to the following agreements by the date of entry into force of this Agreement:</p> <p>(a) Patent Cooperation Treaty (1970), as amended in 1979;</p> <p>(b) Paris Convention for the Protection of Industrial Property (1967);</p> <p>(c) Berne Convention for the Protection of Literary and Artistic Works (1971);</p> <p>(d) Convention Relating to the Distribution of Programme-Carrying Signals Transmitted by Satellite (1974);</p> <p>(e) Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks (1989);</p> <p>(f) Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure (1977), as amended in 1980;</p> <p>(g) International Convention for the Protection of New Varieties of Plants (1991) (UPOV Convention);</p> <p>(h) Singapore Treaty on the Law of Trademarks (2006);</p>	<p>Art. 2. Intellectual Property Conventions.</p> <p>1. In respect of Parts II, III and IV of this Agreement, Members shall comply with Articles 1 through 12, and Article 19, of the Paris Convention (1967).</p> <p>2. Nothing in Parts I to IV of this Agreement shall derogate from existing obligations that Members may have to each other under the Paris Convention, the Berne Convention, the Rome Convention and the Treaty on Intellectual Property in Respect of Integrated Circuits.</p>	<p>Art. 1: Nothing in this Agreement shall derogate from any obligation of a Party with respect to any other Party under existing agreements, including the TRIPS Agreement.</p>	<p>ACTA merely avoids interfering with other agreements, while TPP requires countries to join in to a long list of treaties, conventions, and protocols. TRIPS demands compliance with certain Paris Convention provisions and avoids interfering with Paris, Berne, Rome and the Treaty on Intellectual Property in Respect of Integrated Circuits.</p>

<p>(i) WIPO Copyright Treaty (1996); and          (j) WIPO Performances and Phonograms Treaty (1996).          4. Each Party shall notify the WTO of its acceptance of the Protocol amending the TRIPS Agreement done at Geneva on December 6, 2005.          5. Each Party shall make all reasonable efforts ratify or accede to the following agreements by the date of entry into force of the Agreement:          (a) Patent Law Treaty (2000); and          (b) Hague Agreement Concerning the International Registration of Industrial Designs (1999).</p>			
<p>Art. 1.13: Further to Article ____ (Publication), and with the object of making the protection and enforcement of intellectual property rights transparent, each Party shall ensure that all laws, regulations, and publicly available procedures concerning the protection and enforcement of intellectual property rights are in writing and are published,<sup>3</sup> or where publication is not practicable, made publicly available, in a national language in such a manner as to enable governments and right holders to become acquainted with them.</p> <p><sup>3</sup> A Party may satisfy requirement for publication by making the law, regulation, or procedure available to the public on the Internet.</p>		<p>Art. 30: To promote transparency in the administration of its intellectual property rights enforcement system, each Party shall take appropriate measures, pursuant to its law and policies, to publish or otherwise make available to the public information on:          (a) procedures available under its law for enforcing intellectual property rights, its competent authorities responsible for such enforcement, and contact points available for assistance;          (b) relevant laws, regulations, final judicial decisions, and administrative rulings of general application pertaining to the enforcement of intellectual property rights; and          (c) its efforts to ensure an effective system of enforcement and protection of intellectual property rights.</p>	<p>Essentially identical, although TPP explicitly mentions internet publication as an option.</p>

<p>Art. 10.1</p>	<p>Art. 41.5. It is understood that this Part does not create any obligation to put in place a judicial system for the enforcement of intellectual property rights distinct from that for the enforcement of law in general, nor does it affect the capacity of Members to enforce their law in general. Nothing in this Part creates any obligation with respect to the distribution of resources as between enforcement of intellectual property rights and the enforcement of law in general.</p>		
<p>Art. 10.2</p>	<p>Berne Art. (15?)</p>		
<p>Art. 11.1: Each Party shall provide that final judicial decisions and administrative rulings of general application pertaining to the enforcement of intellectual property rights shall be in writing and shall state any relevant findings of fact and the reasoning or the legal basis on which the decisions and rulings are based. Each Party shall also provide that such decisions and rulings shall be published<sup>16</sup> or, where publication is not practicable, otherwise made available to the public, in its national language in such a manner as to enable governments and right holders to become acquainted with them.</p> <p><sup>16</sup> A Party may satisfy the requirement for publication by making the decision or ruling available to the public on the Internet.</p>	<p>Art. 41.3. Decisions on the merits of a case shall preferably be in writing and reasoned. They shall be made available at least to the parties to the proceeding without undue delay. Decisions on the merits of a case shall be based only on evidence in respect of which parties were offered the opportunity to be heard.</p>	<p>Art. 30: To promote transparency in the administration of its intellectual property rights enforcement system, each Party shall take appropriate measures, pursuant to its law and policies, to publish or otherwise make available to the public information on: ... (b) relevant laws, regulations, final judicial decisions, and administrative rulings of general application pertaining to the enforcement of intellectual property rights</p>	<p>Both ACTA and TPP require rulings to be made available to the public. Only TPP gives requirements for the form and content of decisions and rulings. TRIPS does not provide for making the decisions available to the public (although it remains open to it). Both TRIPS and TPP call for decisions to include the reasoning behind them</p>

Art. 11.2: Each Party shall promote the collection and analysis of statistical data and other relevant information concerning intellectual property rights infringements as well as the collection of information on best practices to prevent and combat infringements.	NA	Art. 28.2: Each Party shall promote the collection and analysis of statistical data and other relevant information concerning intellectual property rights infringements as well as the collection of information on best practices to prevent and combat infringements.	Identical. May divert scarce analysis resources toward purposes that are less serving of a country's needs.
Art. 11.3:	NA		May divert scarce analysis resources toward purposes that are less serving of a country's needs.
Art. 11.4			

**Scope**

<b>TPP</b>	<b>TRIPS</b>	<b>ACTA</b>	<b>Comparison/Analysis</b>
Art. 1.6: A Party may provide more extensive protection for, and enforcement of, intellectual property rights under its law than this Chapter requires, provided that the more extensive protection does not contravene this Chapter.	Art. 1. Nature and Scope of Obligations 1. Members shall give effect to the provisions of this Agreement. Members may, but shall not be obliged to, implement in their law more extensive protection than is required by this Agreement, provided that such protection does not contravene the provisions of this Agreement. Members shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice.	Art. 2.1: Each Party shall give effect to the provisions of this Agreement. A Party may implement in its law more extensive enforcement of intellectual property rights than is required by this Agreement, provided that such enforcement does not contravene the provisions of this Agreement. Each Party shall be free to determine the appropriate method of implementing the provisions of this Agreement within its own legal system and practice.	Essentially identical, though ACTA and TRIPS give some additional deference to the sovereignty of its signatories.
Art. 1.7: In respect of all categories of intellectual property covered in this Chapter, each Party shall accord to nationals of the other Parties treatment no less favorable than it accords to its own nationals	Art. 3. National Treatment 1. Each Member shall accord to the nationals of other Members treatment no less favourable than that it accords to its own nationals with regard to the		ACTA does not have an equivalent section. TRIPS includes more details than TPP regarding exceptions to IP provision in Paris, Berne, Rome

<p>with regard to the protection and enjoyment of such intellectual property rights and any benefits derived from such rights.</p> <p>8. A Party may derogate from paragraph [7] in relation to its judicial and administrative procedures, including requiring a national of the other Party to designate an address for service of process in its territory, or to appoint an agent in its territory, provided that such derogation is:</p> <p>(a) necessary to secure compliance with laws and regulations that are not inconsistent with this Chapter; and</p> <p>(b) not applied in a manner that would constitute a disguised restriction on trade.</p> <p>9. Paragraph [7] does not apply to procedures provided in multilateral agreements to which any Party is a party and which were concluded under the auspices of the World Intellectual Property Organization (WIPO) in relation to the acquisition or maintenance of intellectual property rights.</p>	<p>protection<sup>1</sup> of intellectual property, subject to the exceptions already provided in, respectively, the Paris Convention (1967), the Berne Convention (1971), the Rome Convention or the Treaty on Intellectual Property in Respect of Integrated Circuits. In respect of performers, producers of phonograms and broadcasting organizations, this obligation only applies in respect of the rights provided under this Agreement. Any Member availing itself of the possibilities provided in Article 6 of the Berne Convention (1971) or paragraph 1(b) of Article 16 of the Rome Convention shall make a notification as foreseen in those provisions to the Council for TRIPS.</p> <p>2. Members may avail themselves of the exceptions permitted under paragraph 1 in relation to judicial and administrative procedures, including the designation of an address for service or the appointment of an agent within the jurisdiction of a Member, only where such exceptions are necessary to secure compliance with laws and regulations which are not inconsistent with the provisions of this Agreement and where such practices are not applied in a manner which would constitute a disguised restriction on trade.</p>		
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<sup>1</sup> For the purposes of Articles 3 and 4, "protection" shall include matters affecting the availability, acquisition, scope, maintenance and enforcement of intellectual property rights as well as those matters affecting the use of intellectual property rights specifically addressed in this Agreement.

<p>Art. 1.10: Except as it otherwise provides, including in Article ___ (Berne 18/TRIPS 14.6), this Chapter gives rise to obligations in respect of all subject matter existing at the date of entry into force of this Agreement that is protected on that date in the territory of the Party where protection is claimed, or that meets or comes subsequently to meet the criteria for protection under this Chapter.</p>	<p>Art 1.2. For the purposes of this Agreement, the term "intellectual property" refers to all categories of intellectual property that are the subject of Sections 1 through 7 of Part II.</p>	<p>Art. 2.1: Each Party shall give effect to the provisions of this Agreement.</p> <p>Art. 5: (h) intellectual property refers to all categories of intellectual property that are the subject of Sections 1 through 7 of Part II of the TRIPS Agreement</p>	<p>Although likely functionally the same, TPP is explicitly applied to all existing protected intellectual property, while ACTA is not.</p>
<p>Art. 1.11: Except as otherwise provided in this Chapter, including Article ___ (Berne 18/TRIPS 14.6), a Party shall not be required to restore protection to subject matter that on the date of entry into force of this Agreement has fallen into the public domain in its territory.</p>	<p>Art. 70. Protection of Existing Subject Matter</p> <p>1. This Agreement does not give rise to obligations in respect of acts which occurred before the date of application of the Agreement for the Member in question.</p> <p>2. Except as otherwise provided for in this Agreement, this Agreement gives rise to obligations in respect of all subject matter existing at the date of application of this Agreement for the Member in question, and which is protected in that Member on the said date, or which meets or comes subsequently to meet the criteria for protection under the terms of this Agreement. In respect of this paragraph and paragraphs 3 and 4, copyright obligations with respect to existing works shall be solely determined under Article 18 of the Berne Convention (1971), and obligations with respect to the rights of producers of phonograms and performers in existing phonograms shall be determined solely under Article 18 of the Berne</p>	<p>Art. 3.2: This Agreement does not create any obligation on a Party to apply measures where a right in intellectual property is not protected under its laws and regulations.</p>	<p>Neither ACTA nor TPP nor TRIPS requires a country to restore copyright protection to a work that is in the public domain in that country.</p>

Convention (1971) as made applicable under paragraph 6 of Article 14 of this Agreement.

3. There shall be no obligation to restore protection to subject matter which on the date of application of this Agreement for the Member in question has fallen into the public domain.

4. In respect of any acts in respect of specific objects embodying protected subject matter which become infringing under the terms of legislation in conformity with this Agreement, and which were commenced, or in respect of which a significant investment was made, before the date of acceptance of the WTO Agreement by that Member, any Member may provide for a limitation of the remedies available to the right holder as to the continued performance of such acts after the date of application of this Agreement for that Member. In such cases the Member shall, however, at least provide for the payment of equitable remuneration.

5. A Member is not obliged to apply the provisions of Article 11 and of paragraph 4 of Article 14 with respect to originals or copies purchased prior to the date of application of this Agreement for that Member.

6. Members shall not be

required to apply Article 31, or the requirement in paragraph 1 of Article 27 that patent rights shall be enjoyable without discrimination as to the field of technology, to use without the authorization of the right holder where authorization for such use was granted by the government before the date this Agreement became known.

7. In the case of intellectual property rights for which protection is conditional upon registration, applications for protection which are pending on the date of application of this Agreement for the Member in question shall be permitted to be amended to claim any enhanced protection provided under the provisions of this Agreement. Such amendments shall not include new matter.

8. Where a Member does not make available as of the date of entry into force of the WTO Agreement patent protection for pharmaceutical and agricultural chemical products commensurate with its obligations under Article 27, that Member shall:

(a) notwithstanding the provisions of Part VI, provide as from the date of entry into force of the WTO Agreement a means by which applications for patents for such inventions can be filed;

(b) apply to these

<p>applications, as of the date of application of this Agreement, the criteria for patentability as laid down in this Agreement as if those criteria were being applied on the date of filing in that Member or, where priority is available and claimed, the priority date of the application; and</p> <p>(c) provide patent protection in accordance with this Agreement as from the grant of the patent and for the remainder of the patent term, counted from the filing date in accordance with Article 33 of this Agreement, for those of these applications that meet the criteria for protection referred to in subparagraph (b).</p> <p>9. Where a product is the subject of a patent application in a Member in accordance with paragraph 8(a), exclusive marketing rights shall be granted, notwithstanding the provisions of Part VI, for a period of five years after obtaining marketing approval in that Member or until a product patent is granted or rejected in that Member, whichever period is shorter, provided that, subsequent to the entry into force of the WTO Agreement, a patent application has been filed and a patent granted for that product in another Member and marketing approval obtained in such other Member.</p>		
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TPP	TRIPS	ACTA	Comparison/Analysis
<p>Art. 3.1: In order to address the problem of trademark cyber-piracy, each Party shall require that the management of its country-code top-level domain (ccTLD) provide an appropriate procedure for the settlement of disputes, based on the principles established in the Uniform Domain-Name Dispute-Resolution Policy.</p>			<p>ACTA does not have an equivalent section.</p>
<p>Art. 3.2: Each Party shall require that the management of its ccTLD provide online public access to a reliable and accurate database of contact information concerning domain-name registrants.</p>			<p>ACTA does not have an equivalent section.</p>
<p>Art. 16.1: Each Party shall ensure that enforcement procedures, to the extent set forth in the civil and criminal enforcement sections of this Chapter, are available under its law so as to permit effective action against an act of trademark, copyright or related rights infringement which takes place in the digital environment, including expeditious remedies to prevent infringement and remedies which constitute a deterrent to further infringement.</p>		<p>Art. 27.1: Each Party shall ensure that enforcement procedures, to the extent set forth in Sections 2 (Civil Enforcement) and 4 (Criminal Enforcement), are available under its law so as to permit effective action against an act of infringement of intellectual property rights which takes place in the digital environment, including expeditious remedies to prevent infringement and remedies which constitute a deterrent to further infringements.</p>	<p>TPP specifically deals with “act of trademark, copyright or related rights infringement” while ACTA deals with “act of infringement of intellectual property rights”. Otherwise, the two provisions are essentially identical.</p>
<p>Art. 16.3(a): [E]ach Party shall provide, consistent with the framework set out in this Article: (a) legal incentives for service providers to cooperate with copyright owners in deterring the unauthorized storage and transmission of copyrighted materials; and</p>		<p>Art. 27.3: Each Party shall endeavour to promote cooperative efforts within the business community to effectively address trademark and copyright or related rights infringement while preserving legitimate competition and, consistent with that Party’s law, preserving fundamental principles such as freedom of expression, fair process, and privacy.</p>	<p>TPP specifically deals with cooperation between “service providers” and “copyright owners” while ACTA deals with “cooperative efforts within the business community”.</p>

<p>Art. 16.3(b)(v): With respect to functions referred to in clauses (i)(C) and (D) [safe harbor for content providers], the limitations shall be conditioned on the service provider:</p> <p>...</p> <p>(B) expeditiously removing or disabling access to the material residing on its system or network on obtaining actual knowledge of the infringement or becoming aware of facts or circumstances from which the infringement was apparent, such as through effective notifications of claimed infringement in accordance with clause (ix); and</p> <p>(C) publicly designating a representative to receive such notifications.</p>			<p>ACTA does not have an equivalent section. See entries on Side Letter 1, below.</p>
<p>Art. 16.3(b)(ix): For purposes of the notice and take down process for the functions referred to in clauses (i)(C) and (D), each Party shall establish appropriate procedures in its law or in regulations for effective notifications of claimed infringement, and effective counter-notifications by those whose material is removed or disabled through mistake or misidentification. Each Party shall also provide for monetary remedies against any person who makes a knowing material misrepresentation in a notification or counter-notification that causes injury to any interested party as a result of a service provider relying on the misrepresentation.</p>			<p>ACTA does not have an equivalent section. See entries on Side Letter 1, below.</p>
<p>Art. 16.3(b)(x) If the service provider removes or disables access to material in good faith based on claimed or apparent infringement, each Party shall provide that the</p>			<p>ACTA does not have an equivalent section. See entries on Side Letter 1, below.</p>

<p>service provider shall be exempted from liability for any resulting claims, provided that, in the case of material residing on its system or network, it takes reasonable steps promptly to notify the person making the material available on its system or network that it has done so and, if such person makes an effective counter-notification and is subject to jurisdiction in an infringement suit, to restore the material online unless the person giving the original effective notification seeks judicial relief within a reasonable time.</p>			
<p>Side letter 1: In meeting the obligations of Article 16.3(ix), the United States shall apply the pertinent provisions of its law and [x Party] shall adopt requirements for: (a) effective written notice to service providers with respect to materials that are claimed to be infringing, and (b) effective written counter-notification by those whose material is removed or disabled and who claim that it was disabled through mistake or misidentification, as set forth in this letter. Effective written notice means notice that substantially complies with the elements listed in section (a) of this letter, and effective written counter-notification means counter-notification that substantially complies with the elements listed in section (b) of this letter.</p>			<p>TPP contains detailed notification and counter-notification procedures for rightholders, ISPs and subscribers. ACTA does not have an equivalent section.</p>

<p>Side letter 1 (a) Effective Written Notice, by a Copyright Owner or Person Authorized to Act on Behalf of an Owner of an Exclusive Right, to a Service Provider's Publicly Designated Representative In order for a notice to a service provider to comply with the relevant requirements set out in Article 16.3(ix), that notice must be a written communication, which may be provided electronically, that includes substantially the following: 1. the identity, address, telephone number, and electronic mail address of the complaining party (or its authorized agent);</p>			<p>ACTA does not have an equivalent section. However, the DMCA contains similar requirements:</p> <p>(c)(3) ELEMENTS OF NOTIFICATION.— (A) To be effective under this subsection, a notification of claimed infringement must be a written communication provided to the designated agent of a service provider that includes substantially the following: ... (iv) Information reasonably sufficient to permit the service provider to contact the complaining party, such as an address, telephone number, and, if available, an electronic mail address at which the complaining party may be contacted.</p>
<p>Side letter 1 (a) 2. information reasonably sufficient to enable the service provider to identify the copyrighted work(s) claimed to have been infringed;</p>			<p>ACTA does not have an equivalent section. However, the DMCA contains similar requirements:</p> <p>(c)(3)(A)(ii) Identification of the copyrighted work claimed to have been infringed, or, if multiple copyrighted works at a single online site are covered by a single notification, a representative list of such works at that site.</p>
<p>Side letter 1 (a) 3. information reasonably sufficient to permit the service provider to identify and locate the material residing on a system or network controlled or operated by it or for it that is claimed to be infringing, or to be the subject of infringing activity, and that is to be removed, or access to which is to be disabled;</p>			<p>ACTA does not have an equivalent section. However, the DMCA contains similar requirements:</p> <p>(c)(3)(A)(iii) Identification of the material that is claimed to be infringing or to be the subject of infringing activity and that is to be removed or access to which is to be disabled, and information reasonably sufficient to permit the service provider to locate the material.</p>

<p>Side letter 1 (a) 4. a statement that the complaining party has a good faith belief that use of the material in themanner complained of is not authorized by the copyright owner, its agent, or the law;</p>			<p>ACTA does not have an equivalent section. However, the DMCA contains similar requirements:</p> <p>(c)(3)(A)(v) A statement that the complaining party has a good faith belief that use of the material in themanner complained of is not authorized by the copyrightowner, its agent, or the law.</p>
<p>Side letter 1 (a) 5. a statement that the information in the notice is accurate;</p>			<p>ACTA does not have an equivalent section. However, the DMCA contains similar requirements:</p> <p>(c)(3)(A) (vi) A statement that the information in thenotification is accurate, and under penalty of perjury, that the complaining party is authorized to act onbehalf of the owner of an exclusive right that is allegedlyinfringed.</p>
<p>Side letter 1 (a) 6. a statement with sufficient indicia of reliability (such as a statement under penalty of perjury orequivalent legal sanctions) that the complaining party is the holder of an exclusive right that is allegedlyinfringed, or is authorized to act on the owner's behalf; and</p>			<p>ACTA does not have an equivalent section. However, the DMCA contains similar requirements:</p> <p>(c)(3)(A) (vi) A statement that the information in thenotification is accurate, and under penalty of perjury, that the complaining party is authorized to act onbehalf of the owner of an exclusive right that is allegedlyinfringed.</p>
<p>Side letter 1 (a) 7. the signature of the person giving notice.</p>			<p>ACTA does not have an equivalent section. However, the DMCA contains similar requirements:</p> <p>(c)(3)(A) (i) A physical or electronic signature of a person authorized to act on behalf of the owner of an exclusiveright that is allegedly infringed.</p>

<p>Side letter 1 (b) Effective Written Counter-Notification by a Subscriber Whose Material Was Removed or Disabled as a Result of Mistake or Misidentification of Material</p> <p>In order for a counter-notification to a service provider to comply with the relevant requirements set out in Article 16.3(ix), that counter-notification must be a written communication, which may be provided electronically, that includes substantially the following:</p> <p>1. the identity, address, and telephone number of the subscriber;</p>			<p>ACTA does not have an equivalent section. However, the DMCA contains similar requirements:</p> <p>(g)(3) CONTENTS OF COUNTER NOTIFICATION.—To be effective under this subsection, a counter notification must be a written communication provided to the service provider’s designated agent that includes substantially the following: ...</p> <p>(D) The subscriber’s name, address, and telephone number, and a statement that the subscriber consents to the jurisdiction of Federal District Court for the judicial district in which the address is located, or if the subscriber’s address is outside of the United States, for any judicial district in which the service provider may be found, and that the subscriber will accept service of process from the person who provided notification under subsection (c)(1)(C) or an agent of such person.</p>
<p>Side letter 1 (b) 2. the identity of the material that has been removed or to which access has been disabled;</p>			<p>ACTA does not have an equivalent section. However, the DMCA contains similar requirements:</p> <p>(g)(3)(B) Identification of the material that has been removed or to which access has been disabled and the location at which the material appeared before it was removed or access to it was disabled.</p>
<p>Side letter 1 (b) 3. the location at which the material appeared before it was removed or access to it was disabled;</p>			<p>ACTA does not have an equivalent section. However, the DMCA contains similar requirements:</p> <p>(g)(3)(B) Identification of the material that has been removed or to which access has been disabled and the location at which the material appeared before it was removed or</p>

			<p>access to it was disabled.</p>
<p>Side letter 1 (b)4. a statement with sufficient indicia of reliability (such as a statement under penalty of perjury or equivalent legal sanctions) that the subscriber has a good faith belief that the material was removed or disabled as a result of mistake or misidentification of the material;</p>			<p>ACTA does not have an equivalent section. However, the DMCA contains similar requirements:</p> <p>(g)(3)(C) A statement under penalty of perjury that the subscriber has a good faith belief that the material was removed or disabled as a result of mistake or misidentification of the material to be removed or disabled.</p>
<p>Side letter 1 (b)5. a statement that the subscriber agrees to be subject to orders of any court that has jurisdiction over the place where the subscriber's address is located, or, if that address is located outside the Party's territory, any other court with jurisdiction over any place in the Party's territory where the service provider may be found, and in which a copyright infringement suit could be brought with respect to the alleged infringement;</p>			<p>ACTA does not have an equivalent section. However, the DMCA contains similar requirements:</p> <p>(g)(3) (D) The subscriber's name, address, and telephone number, and a statement that the subscriber consents to the jurisdiction of Federal District Court for the judicial district in which the address is located, or if the subscriber's address is outside of the United States, for any judicial district in which the service provider may be found, and that the subscriber will accept service of process from the person who provided notification under subsection (c)(1)(C) or an agent of such person.</p>

<p>Side letter 1 (b)6. a statement that the subscriber will accept service of process in any such suit; and</p>			<p>ACTA does not have an equivalent section. However, the DMCA contains similar requirements:</p> <p>(g)(3)(D) The subscriber's name, address, and telephonenumber, and a statement that the subscriber consents to the jurisdiction of Federal District Court for the judicialdistrict in which the address is located, or if the subscriber's address is outside of the United States, for any judicialdistrict in which the service provider may be found, and that the subscriber will accept service of process from the person who provided notification under subsection (c)(1)(C) or an agent of such person.</p>
<p>Side letter 1 (b)7. the signature of the subscriber.</p>			<p>ACTA does not have an equivalent section. However, the DMCA contains similar requirements:</p> <p>(g)(3) (A) A physical or electronic signature of the subscriber.</p>

**Technological Protection Measures**

TPP	TRIPS	ACTA	Chile FTA	Comparison/Analysis
<p>Art. 4.9(a): In order to provide adequate legal protection and effective legal remedies against the circumvention of effective technological measures that authors, performers, and producers of phonograms use in connection with the exercise of their rights and that restrict unauthorized acts in respect of their works, performances, and phonograms, each Party shall provide that any person who:</p>	<p>N/A</p>	<p>Art. 27.5: Each Party shall provide adequate legal protection and effective legal remedies against the circumvention of effective technological measures that are used by authors, performers or producers of phonograms in connection with the exercise of their rights in, and that restrict acts in respect of, their works, performances, and phonograms, which are not authorized by the authors, the performers or the</p>		<p>Essentially identical.</p>

		producers of phonograms concerned or permitted by law.		
Art. 4.9(a)(i): circumvents without authority any effective technological measure that controls access to a protected work, performance, phonogram, or other subject matter; or	N/A	Art. 27.6(a)(i): In order to provide the adequate legal protection and effective legal remedies referred to in paragraph 5, each Party shall provide protection at least against: (a) to the extent provided by its law: (i) the unauthorized circumvention of an effective technological measure carried out knowingly or with reasonable grounds to know		Unlike ACTA, the TPP does not require that unauthorized circumvention be carried out knowingly or with reasonable grounds to know.
Art. 4.9(a)(ii): manufactures, imports, distributes, offers to the public, provides, or otherwise traffics in devices, products, or components, or offers to the public or provides services, that: (A) are promoted, advertised, or marketed by that person, or by another person acting in concert with that person and with that person's knowledge, for the purpose of circumvention of any effective technological measure, (B) have only a limited commercially significant purpose or use other than to circumvent any effective technological measure, or (C) are primarily designed, produced, or performed for the purpose of enabling or facilitating the circumvention of any effective technological measure, shall be liable and subject to the	N/A	Art. 27.6(a)(ii), (b)(i), (b)(ii): In order to provide the adequate legal protection and effective legal remedies referred to in paragraph 5, each Party shall provide protection at least against: (a) to the extent provided by its law: (ii) the offering to the public by marketing of a device or product, including computer programs, or a service, as a means of circumventing an effective technological measure; and (b) the manufacture, importation, or distribution of a device or product, including computer programs, or provision of a service that: (i) is primarily designed or produced for the purpose of circumventing an effective technological measure; or (ii) has only a limited		Unlike ACTA, TPP adds components to the list of banned circumvention products. Also unlike ACTA, TPP requires criminal penalties for anyone other than nonprofit libraries, archives, educational institutions, and noncommercial broadcasters who, for profit, willfully circumvents TPM or provides products or services for circumvention of TPM, or is an accomplice of someone providing such products or services.

<p>remedies set out in Article [12.12]. Each Party shall provide for criminal procedures and penalties to be applied when any person, other than a nonprofit library, archive, educational institution, or public noncommercial broadcasting entity, is found to have engaged willfully and for purposes of commercial advantage or private financial gain in any of the foregoing activities. Such criminal procedures and penalties shall include the application to such activities of the remedies and authorities listed in subparagraphs (a), (b), and (f) of Article [15.5] as applicable to infringements, mutatis mutandis.</p>		<p>commercially significant purpose other than circumventing an effective technological measure.</p>		
<p>Art. 4.9(b) In implementing subparagraph (a), no Party shall be obligated to require that the design of, or the design and selection of parts and components for, a consumer electronics, telecommunications, or computing product provide for a response to any particular technological measure, so long as the product does not otherwise violate any measures implementing subparagraph (a).</p>	<p>N/A</p>			<p>ACTA does not have an equivalent section.</p>
<p>Art. 4.9(c) Each Party shall provide that a violation of a measure implementing this paragraph is a separate cause of action, independent of any infringement that might occur under the Party's law on copyright and related rights.</p>	<p>N/A</p>	<p>Art. 27.8: ...The obligations set forth in paragraphs 5, 6, and 7 are without prejudice to the rights, limitations, exceptions, or defences to copyright or related rights infringement under a Party's law.</p>		<p>Both ACTA and TPP make circumvention a distinct cause of action, independent of infringement.</p>
<p>Art. 4.9(d) Each Party shall confine exceptions and limitations to measures implementing subparagraph (a) to the following activities, which shall be applied to relevant measures in accordance with subparagraph (e): (i) noninfringing reverse</p>	<p>N/A</p>	<p>Art. 27.8: In providing adequate legal protection and effective legal remedies pursuant to the provisions of paragraphs 5 and 7, a Party may adopt or maintain appropriate limitations or exceptions to measures implementing the provisions of</p>		<p>ACTA gives a country free reign to create exceptions it finds reasonable, while TPP explicitly limits the possible exceptions.</p>

<p>engineering activities with regard to a lawfully obtained copy of a computer program, carried out in good faith with respect to particular elements of that computer program that have not been readily available to the person engaged in those activities, for the sole purpose of achieving interoperability of an independently created computer program with other programs;</p> <p>(ii) noninfringing good faith activities, carried out by an appropriately qualified researcher who has lawfully obtained a copy, unfixed performance, or display of a work, performance, or phonogram and who has made a good faith effort to obtain authorization for such activities, to the extent necessary for the sole purpose of research consisting of identifying and analyzing flaws and vulnerabilities of technologies for scrambling and descrambling of information;</p> <p>(iii) the inclusion of a component or part for the sole purpose of preventing the access of minors to inappropriate online content in a technology, product, service, or device that itself is not prohibited under the measures implementing subparagraph (a)(ii);</p> <p>(iv) noninfringing good faith activities that are authorized by the owner of a computer, computer system, or computer network for the sole purpose of testing, investigating, or correcting the security of that computer, computer system, or computer network;</p> <p>(v) noninfringing activities for the sole purpose of identifying and disabling a capability to carry out undisclosed collection or</p>		<p>paragraphs 5, 6, and 7.</p>		
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<p>dissemination of personally identifying information reflecting the online activities of a natural person in a way that has no other effect on the ability of any person to gain access to any work;  (vi) lawfully authorized activities carried out by government employees, agents, or contractors for the purpose of law enforcement, intelligence, essential security, or similar governmental purposes;  (vii) access by a nonprofit library, archive, or educational institution to a work, performance, or phonogram not otherwise available to it, for the sole purpose of making acquisition decisions; and  (viii) noninfringing uses of a work, performance, or phonogram in a particular class of works, performances, or phonograms when an actual or likely adverse impact on those noninfringing uses is demonstrated in a legislative or administrative proceeding by substantial evidence; provided that any limitation or exception adopted in reliance upon this clause shall have effect for a renewable period of not more than three years from the date of conclusion of such proceeding.</p>				
<p>(e) The exceptions and limitations to measures implementing subparagraph (a) for the activities set forth in subparagraph [4.9(d)] may only be applied as follows, and only to the extent that they do not impair the adequacy of legal protection or the effectiveness of legal remedies against the circumvention of effective technological measures:  (i) Measures implementing subparagraph (a)(i) may be subject</p>	<p>N/A</p>	<p>Art. 27.8: In providing adequate legal protection and effective legal remedies pursuant to the provisions of paragraphs 5 and 7, a Party may adopt or maintain appropriate limitations or exceptions to measures implementing the provisions of paragraphs 5, 6, and 7.</p>		<p>ACTA gives a country free reign to create exceptions it finds reasonable, while TPP explicitly limits the possible exceptions.</p>

<p>to exceptions and limitations with respect to each activity set forth in subparagraph (d).  (ii) Measures implementing subparagraph (a)(ii), as they apply to effective technological measures that control access to a work, performance, or phonogram, may be subject to exceptions and limitations with respect to activities set forth in subparagraph (d)(i), (ii), (iii), (iv), and (vi).  (iii) Measures implementing subparagraph (a)(ii), as they apply to effective technological measures that protect any copyright or any rights related to copyright, may be subject to exceptions and limitations with respect to activities set forth in subparagraph (d)(i) and (vi).</p>				
<p>(f) Effective technological measure means any technology, device, or component that, in the normal course of its operation, controls access to a protected work, performance, phonogram, or other protected subject matter, or protects any copyright or any rights related to copyright.</p>	<p>N/A</p>	<p>Art. 27.5, footnote 14: For the purposes of this Article, technological measures means any technology, device, or component that, in the normal course of its operation, is designed to prevent or restrict acts, in respect of works, performances, or phonograms, which are not authorized by authors, performers or producers of phonograms, as provided for by a Party's law. Without prejudice to the scope of copyright or related rights contained in a Party's law, technological measures shall be deemed effective where the use of protected works, performances, or phonograms is controlled by authors, performers or producers of phonograms through the application of a relevant access control or protection process, such as encryption or scrambling, or a copy control mechanism, which achieves the objective of</p>		<p>Essentially identical, although ACTA provides examples of TPM while TPP does not, and ACTA defines technical measures separately from what makes them effective while TPP only defines effective technological measures.</p>

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**Criminal Enforcement**

TPP	TRIPS	ACTA	Chile FTA	Comparison/Analysis
<p>Art. 15.1: Each Party shall provide for criminal procedures and penalties to be applied at least in cases of willful trademark counterfeiting or copyright or related rights piracy on a commercial scale. Willful copyright or related rights piracy on a commercial scale includes: (a) significant willful copyright or related rights infringements that have no direct or indirect motivation of financial gain; and (b) willful infringements for purposes of commercial advantage or private financial gain. Each Party shall treat willful importation or exportation of counterfeit or pirated goods as unlawful activities subject to criminal penalties.</p>	<p>Art. 61 Members shall provide for criminal procedures and penalties to be applied at least in cases of willful trademark counterfeiting or copyright piracy on a commercial scale. Remedies available shall include imprisonment and/or monetary fines sufficient to provide a deterrent, consistently with the level of penalties applied for crimes of a corresponding gravity. In appropriate cases, remedies available shall also include the seizure, forfeiture and destruction of the infringing goods and of any materials and implements the predominant use of which has been in the commission of the offence. Members may provide for criminal procedures and penalties to be applied in other cases of infringement of intellectual property rights, in particular where they are committed willfully and on a commercial scale.</p>	<p>Art. 23.1: Each Party shall provide for criminal procedures and penalties to be applied at least in cases of willful trademark counterfeiting or copyright or related rights piracy on a commercial scale. For the purposes of this Section, acts carried out on a commercial scale include at least those carried out as commercial activities for direct or indirect economic or commercial advantage.</p>		<p>ACTA defines piracy on a commercial scale to include “commercial activities for direct or indirect economic or commercial advantage”. TPP, on the other hand, defines piracy on a commercial scale to include infringement with no financial motivations as well as commercial infringement for financial gain. TRIPS does not define piracy and takes a broader approach to include ‘other cases of infringement of IPR’. TPP and TRIPS also include willful trade of counterfeit or pirated goods as a criminal activity, while ACTA does not do so explicitly. TRIPS provides for specific criminal remedies consistent with level of penalties applied for crimes of corresponding gravity.</p>

<p>Art. 15.2: Each Party shall also provide for criminal procedures and penalties to be applied, even absent willful trademark counterfeiting or copyright or related rights piracy, at least in cases of knowing trafficking in: (a) labels or packaging, of any type or nature, to which a counterfeit trademark has been applied, the use of which is likely to cause confusion, to cause mistake, or to deceive; and (b) counterfeit or illicit labels affixed to, enclosing, or accompanying, or designed to be affixed to, enclose, or accompany the following: (i) a phonogram, (ii) a copy of a computer program or a literary work, (iii) a copy of a motion picture or other audiovisual work, (iv) documentation or packaging for such items; and (c) counterfeit documentation or packaging for items of the type described in subparagraph (b).</p>		<p>Art. 23.2: Each Party shall provide for criminal procedures and penalties to be applied in cases of wilful importation and domestic use, in the course of trade and on a commercial scale, of labels or packaging: (a) to which a mark has been applied without authorization which is identical to, or cannot be distinguished from, a trademark registered in its territory; and (b) which are intended to be used in the course of trade on goods or in relation to services which are identical to goods or services for which such trademark is registered.</p>		<p>First, ACTA's standard for criminal procedures and penalties in cases of infringement of labels or packaging is "wilful importation and domestic use, in the course of trade and on a commercial scale" while TPP's is "knowing trafficking in". Second, ACTA's threshold for infringement is authorized use of identical/undistinguishable trademark, while TPP's is use of a trademark "which is likely to cause confusion, to cause mistake, or to deceive". Third, TPP does not require the use of the 'confusing' label "on goods or in relation to services which are identical to goods or services for which such trademark is registered". Finally, TPP explicitly protects against counterfeit or illicit labels affixed to, enclosed in, or accompanying a phonogram, a computer program, a copy of a movie, documentation or packaging for such items.</p>
<p>Art. 15.3: Each Party shall also provide for criminal procedures and penalties to be applied against any person who, without authorization of the holder of copyright or related rights in a motion picture or other audiovisual work, knowingly uses or attempts to use an audiovisual recording device to transmit or make a copy of a motion picture or other audiovisual work, or any part thereof, from a performance of such work in a public motion picture exhibition facility.</p>		<p>Art. 23.3: A Party may provide criminal procedures and penalties in appropriate cases for the unauthorized copying of cinematographic works from a performance in a motion picture exhibition facility generally open to the public.</p>		<p>TPP prohibits unauthorized transmission or copying of a "motion picture or other audiovisual work" while ACTA prohibits "unauthorized copying of cinematographic works".</p>

<p>Art. 15.4: With respect to the offenses for which this Article requires the Parties to provide for criminal procedures and penalties, Parties shall ensure that criminal liability for aiding and abetting is available under its law.</p>		<p>Art. 23.4: With respect to the offences specified in this Article for which a Party provides criminal procedures and penalties, that Party shall ensure that criminal liability for aiding and abetting is available under its law.</p>		<p>Essentially identical.</p>
<p>Art. 15.5(a): With respect to the offences described in Article 15.[1]-[4] above, each Party shall provide: (a) penalties that include sentences of imprisonment as well as monetary fines sufficiently high to provide a deterrent to future infringements, consistent with a policy of removing the infringer’s monetary incentive. Each Party shall further establish policies or guidelines that encourage judicial authorities to impose those penalties at levels sufficient to provide a deterrent to future infringements, including the imposition of actual terms of imprisonment when criminal infringement is undertaken for commercial advantage or private financial gain;</p>		<p>Art. 24: For offences specified in paragraphs 1, 2, and 4 of Article 23 (Criminal Offences), each Party shall provide penalties that include imprisonment as well as monetary fines<sup>12</sup> sufficiently high to provide a deterrent to future acts of infringement, consistently with the level of penalties applied for crimes of a corresponding gravity.</p>		<p>Both TPP and ACTA prescribe both “imprisonment and monetary fines sufficiently high to provide a deterrent to future” infringements. (Note, however, TPP also adds that such penalties should be “consistent with a policy of removing the infringer’s monetary incentive”.) However, TPP omits ACTA’s safeguard that such penalties shall be consistent with “the level of penalties applied for crimes of a corresponding gravity”. Furthermore, TPP requires party members to establish policies or guidelines to “encourage judicial authorities to [actually] impose those penalties”.</p>
<p>Art. 15.5(b): that its judicial authorities shall have the authority to order the seizure of suspected counterfeit or pirated goods, any related materials and implements used in the commission of the offense, any assets traceable to the infringing activity, and any documentary evidence relevant to the offense. Each Party shall provide that items that are subject to seizure pursuant to any such judicial order need not be individually identified so long as they fall within general categories specified in the order;</p>		<p>Art. 25.1: With respect to the offences specified in paragraphs 1, 2, 3, and 4 of Article 23 (Criminal Offences) for which a Party provides criminal procedures and penalties, that Party shall provide that its competent authorities have the authority to order the seizure of suspected counterfeit trademark goods or pirated copyright goods, any related materials and implements used in the commission of the alleged offence, documentary evidence relevant to the alleged offence, and the assets derived from, or obtained directly or indirectly through, the alleged</p>		<p>TPP requires seizure of “any assets traceable to the infringing activity” while ACCTA requires seizure of “assets derived from, or obtained directly or indirectly through the alleged infringing activity”. Traceable may be a broader standard. Additionally, TPP allows seizure of such items without individual identification “so long as they fall within general categories specified in the order”.</p>

		infringing activity.		
Art. 15.5(c): that its judicial authorities shall have the authority to order, among other measures, the forfeiture of any assets traceable to the infringing activity, and shall order such forfeiture at least in cases of trademark counterfeiting;		Art. 25.1: With respect to the offences specified in paragraphs 1, 2, 3, and 4 of Article 23 (Criminal Offences) for which a Party provides criminal procedures and penalties, that Party shall provide that its competent authorities have the authority to order the seizure of suspected counterfeit trademark goods or pirated copyright goods, any related materials and implements used in the commission of the alleged offence, documentary evidence relevant to the alleged offence, and the assets derived from, or obtained directly or indirectly through, the alleged infringing activity.		TPP requires forfeiture of “any assets traceable to the infringing activity” while ACTA requires seizure of “assets derived from, or obtained directly or indirectly through, the alleged infringing activity”.
Art. 15.5(d)(i): that its judicial authorities shall, except in exceptional cases, order (i) the forfeiture and destruction of all counterfeit or pirated goods, and any articles consisting of a counterfeit mark; and		Art. 25.3: With respect to the offences specified in paragraphs 1, 2, 3, and 4 of Article 23 (Criminal Offences) for which a Party provides criminal procedures and penalties, that Party shall provide that its competent authorities have the authority to order the forfeiture or destruction of all counterfeit trademark goods or pirated copyright goods. In cases where counterfeit trademark goods and pirated copyright goods are not destroyed, the competent authorities shall ensure that, except in exceptional circumstances, such goods shall be disposed of outside the channels of commerce in such a manner as to avoid causing any harm to the right holder. Each Party shall ensure that the forfeiture or destruction of such goods shall occur without compensation of any sort to the		TPP requires forfeiture AND destruction of all counterfeit or pirated goods while ACTA requires forfeiture OR destruction. While both TPP and ACTA allow for an exception, unlike ACTA, TPP does not explicitly allow goods to be “disposed of outside the channels of commerce”.

		infringer.		
<p>Art. 15.5(d)(ii): the forfeiture or destruction of materials and implements that have been used in the creation of pirated or counterfeit goods.</p> <p>Each Party shall further provide that forfeiture and destruction under this subparagraph and subparagraph (c) shall occur without compensation of any kind to the defendant;</p>		<p>Art. 25.4: With respect to the offences specified in paragraphs 1, 2, 3, and 4 of Article 23 (Criminal Offences) for which a Party provides criminal procedures and penalties, that Party shall provide that its competent authorities have the authority to order the forfeiture or destruction of materials and implements predominantly used in the creation of counterfeit trademark goods or pirated copyright goods and, at least for serious offences, of the assets derived from, or obtained directly or indirectly through, the infringing activity. Each Party shall ensure that the forfeiture or destruction of such materials, implements, or assets shall occur without compensation of any sort to the infringer.</p>		<p>Essentially identical. ACTA further provides that for serious offences, competent authorities shall order the forfeiture or destruction of “assets derived from, or obtained directly or indirectly through the infringing activity”.</p>
<p>Art. 15.5(e): that its judicial authorities have the authority to order the seizure or forfeiture of assets the value of which corresponds to that of the assets derived from, or obtained directly or indirectly through, the infringing activity.</p>		<p>Art. 25.5.(b): With respect to the offences specified in paragraphs 1, 2, 3, and 4 of Article 23 (Criminal Offences) for which a Party provides criminal procedures and penalties, that Party may provide that its judicial authorities have the authority to order:</p> <p>(b) the forfeiture of assets the value of which corresponds to that of the assets derived from, or obtained directly or indirectly through, the infringing activity.</p>		<p>TPP allows seizure OR forfeiture while ACTA only allows forfeiture.</p>
<p>Art. 15.5(g): that its authorities may initiate legal action <i>ex officio</i> with respect to the offenses described in this Chapter, without the need for a formal complaint by a private party or right holder.</p>		<p>Art. 26: Each Party shall provide that, in appropriate cases, its competent authorities may act upon their own initiative to initiate investigation or legal action with respect to the criminal offences specified in paragraphs 1, 2, 3, and 4 of Article 23 (Criminal</p>		<p>Essentially identical.</p>

		Offences) for which that Party provides criminal procedures and penalties.		
Art. 16.3(b)(xi): Each Party shall establish an administrative or judicial procedure enabling copyright owners who have given effective notification of claimed infringement to obtain expeditiously from a service provider information in its possession identifying the alleged infringer.		Art. 27.4 A Party may provide, in accordance with its laws and regulations, its competent authorities with the authority to order an online service provider to disclose expeditiously to a right holder information sufficient to identify a subscriber whose account was allegedly used for infringement, where that right holder has filed a legally sufficient claim of trademark or copyright or related rights infringement, and where such information is being sought for the purpose of protecting or enforcing those rights. These procedures shall be implemented in a manner that avoids the creation of barriers to legitimate activity, including electronic commerce, and, consistent with that Party's law, preserves fundamental principles such as freedom of expression, fair process, and privacy.		TPP lacks ACTA's requirements that: (i) there be a sufficient claim of infringement; (ii) the information be sought for the purpose of protecting or enforcing a copyright; and (iii) the procedures shall be implemented in a manner that avoids the creation of barriers to legitimate activity.

**Provisional Measures**

<b>TPP</b>	<b>TRIPS</b>	<b>ACTA</b>	<b>Comparison/Analysis</b>
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<p>Art. 13.1: Each Party shall act on requests for provisional relief <i>inaudita altera parte</i> expeditiously, and shall, except in exceptional cases, generally execute such requests within ten days.</p>	<p>Art. 50.2 The judicial authorities shall have the authority to adopt provisional measures <i>inaudita altera parte</i> where appropriate, in particular where any delay is likely to cause irreparable harm to the right holder, or where there is a demonstrable risk of evidence being destroyed.</p> <p>Art. 50.4 Where provisional measures have been adopted <i>inaudita altera parte</i>, the parties affected shall be given notice, without delay after the execution of the measures at the latest. A review, including a right to be heard, shall take place upon request of the defendant with a view to deciding, within a reasonable period after the notification of the measures, whether these measures shall be modified, revoked or confirmed</p>	<p>Art. 12.2: Each Party shall provide that its judicial authorities have the authority to adopt provisional measures <i>inaudita altera parte</i> where appropriate, in particular where any delay is likely to cause irreparable harm to the right holder, or where there is a demonstrable risk of evidence being destroyed. In proceedings conducted <i>inaudita altera parte</i>, each Party shall provide its judicial authorities with the authority to act expeditiously on requests for provisional measures and to make a decision without undue delay.</p>	<p>ACTA and TRIPS allows authorities to adopt provisional measures <i>inaudita altera parte</i> where appropriate, giving examples where delay is likely to cause harm. TPP requires such actions, and gives a timeframe of ten days, except in exceptional cases. TRIPS requires notification to the parties affected.</p>
<p>Art. 13.2: Each Party shall provide that its judicial authorities have the authority to require the applicant, with respect to provisional measures, to provide any reasonably available evidence in order to satisfy themselves with a sufficient degree of certainty that the applicant's right is being infringed or that such infringement is imminent, and to order the applicant to provide a reasonable security or equivalent assurance set at a level sufficient to protect the defendant and to prevent abuse, and so as not to unreasonably deter recourse to such procedures.</p>	<p>Art. 50.3. The judicial authorities shall have the authority to require the applicant to provide any reasonably available evidence in order to satisfy themselves with a sufficient degree of certainty that the applicant is the right holder and that the applicant's right is being infringed or that such infringement is imminent, and to order the applicant to provide a security or equivalent assurance sufficient to protect the defendant and to prevent abuse.</p>	<p>Art. 12.4: Each Party shall provide that its authorities have the authority to require the applicant, with respect to provisional measures, to provide any reasonably available evidence in order to satisfy themselves with a sufficient degree of certainty that the applicant's right is being infringed or that such infringement is imminent, and to order the applicant to provide a security or equivalent assurance sufficient to protect the defendant and to prevent abuse. Such security or equivalent assurance shall not unreasonably deter recourse to procedures for such provisional measures.</p>	<p>Essentially identical.</p>

	<p>Article 50</p> <p>1. The judicial authorities shall have the authority to order prompt and effective provisional measures:</p> <p>(a) to prevent an infringement of any intellectual property right from occurring, and in particular to prevent the entry into the channels of commerce in their jurisdiction of goods, including imported goods immediately after customs clearance;</p> <p>(b) to preserve relevant evidence in regard to the alleged infringement.</p> <p>2. The judicial authorities shall have the authority to adopt provisional measures <i>inaudita altera parte</i> where appropriate, in particular where any delay is likely to cause irreparable harm to the right holder, or where there is a demonstrable risk of evidence being destroyed.</p> <p>3. The judicial authorities shall have the authority to require the applicant to provide any reasonably available evidence in order to satisfy themselves with a sufficient degree of certainty that the applicant is the right holder and that the applicant's right is being infringed or that such infringement is imminent, and to order the applicant to provide a security or equivalent assurance sufficient to protect the defendant and to prevent abuse.</p> <p>4. Where provisional measures have been adopted <i>inaudita altera parte</i>, the parties affected shall be given notice, without delay after the execution of the measures at the latest. A review, including a right to be heard, shall take place upon request of the defendant with a view to deciding, within a reasonable period after the notification of the measures, whether these measures shall be modified, revoked or confirmed.</p> <p>5. The applicant may be required to supply other information necessary for the identification of the goods concerned by the authority that will execute the</p>		<p>Overall, TRIPS Art. 50 is more comprehensive on the matter of provisional measures.</p>
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	<p>provisional measures.</p> <p>6. Without prejudice to paragraph 4, provisional measures taken on the basis of paragraphs 1 and 2 shall, upon request by the defendant, be revoked or otherwise cease to have effect, if proceedings leading to a decision on the merits of the case are not initiated within a reasonable period, to be determined by the judicial authority ordering the measures where a Member's law so permits or, in the absence of such a determination, not to exceed 20 working days or 31 calendar days, whichever is the longer.</p> <p>7. Where the provisional measures are revoked or where they lapse due to any act or omission by the applicant, or where it is subsequently found that there has been no infringement or threat of infringement of an intellectual property right, the judicial authorities shall have the authority to order the applicant, upon request of the defendant, to provide the defendant appropriate compensation for any injury caused by these measures.</p> <p>8. To the extent that any provisional measure can be ordered as a result of administrative procedures, such procedures shall conform to principles equivalent in substance to those set forth in this Section.</p>		
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**Civil and Administrative Procedures and Remedies**

TPP	TRIPS	ACTA	Chile FTA	Comparison/Analysis
<p>Art. 10.2: In civil, administrative, and criminal proceedings involving copyright or related rights, each Party shall provide for a presumption that, in the absence of proof to the contrary, the person whose name is indicated in the usual manner as the author, producer, performer, or publisher of the work, performance, or phonogram is the designated right holder in such work, performance, or phonogram. Each Party shall also provide for a presumption that, in the absence of proof to the contrary, the copyright or related right subsists in such subject matter. In civil, administrative, and criminal proceedings involving trademarks, each Party shall provide for a rebuttable presumption that a registered trademark is valid. In civil and administrative proceedings involving patents, each Party shall provide for a rebuttable presumption that a patent is valid, and shall provide that each claim of a patent is presumed valid independently of the validity of the other claims.</p>	<p>Berne Art (15?)</p>			<p>ACTA does not have an equivalent section. Neither does TRIPS</p>
<p>Art 11.1</p>	<p>Art 41.3. Decisions on the merits of a case shall preferably be in writing and reasoned. They shall be made available at least to the parties to the proceeding without undue delay. Decisions on the merits of a case shall be based only on evidence in respect of which parties were offered the opportunity to be heard.</p>			

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11.2				TRIPS does not have a similar section (closest would be Art 69 on Intl Cooperation)
11.3				TRIPS does not have a similar section (closest would be Art 69 on Intl Cooperation)
11.4				TRIPS does not have a similar section (closest would be Art 69 on Intl Cooperation)
12.1	42			Deletes defendant rights.
Fn 17	Fn 11			
Art. 12.2: Each Party shall provide for injunctive relief consistent with Article 44 of the TRIPS Agreement, and shall also make injunctions available to prevent the exportation of infringing goods.	42	Art. 8.1: Each Party shall provide that, in civil judicial proceedings concerning the enforcement of intellectual property rights, its judicial authorities have the authority to issue an order against a party to desist from an infringement, and inter alia, an order to that party or, where appropriate, to a third party over whom the relevant judicial authority exercises jurisdiction, to prevent goods that involve the infringement of an intellectual property right from entering into the channels of commerce.		Unlike ACTA, the injunctive relief under TPP is not explicitly applied to third parties.

<p>Art. 12.3(a)(i) Each Party shall provide that:                  (a) in civil judicial proceedings, its judicial authorities shall have the authority to order the infringer to pay the right holder:                  (i) damages adequate to compensate for the injury the right holder has suffered as a result of the infringement, and</p>	<p>45</p>	<p>Art. 9.1: Each Party shall provide that, in civil judicial proceedings concerning the enforcement of intellectual property rights, its judicial authorities have the authority to order the infringer who, knowingly or with reasonable grounds to know, engaged in infringing activity to pay the right holder damages adequate to compensate for the injury the right holder has suffered as a result of the infringement. In determining the amount of damages for infringement of intellectual property rights, a Party's judicial authorities shall have the authority to consider, inter alia, any legitimate measure of value the right holder submits, which may include lost profits, the value of the infringed goods or services measured by the market price, or the suggested retail price.</p>		<p>Unlike ACTA, TPP does not require the infringer to have “knowingly or with reasonable grounds to know, engaged in infringing activity”. However, both TPP and ACTA require the infringer to “pay damages adequate to compensate for the injury”.                  For the part on determining the amount of damages, please see <i>infra</i> TPP art. 12.3(b)/ACTA art. 9.1</p>
<p>Art. 12.3(a)(ii): at least in the case of copyright or related rights infringement and trademark counterfeiting, the profits of the infringer that are attributable to the infringement and that are not taken into account in computing the amount of the damages referred to in clause (i).</p>		<p>Art. 9.2: At least in cases of copyright or related rights infringement and trademark counterfeiting, each Party shall provide that, in civil judicial proceedings, its judicial authorities have the authority to order the infringer to pay the right holder the infringer's profits that are attributable to the infringement. A Party may presume those profits to be the amount of damages referred to in paragraph 1.</p>		<p>ACTA allows judicial authorities to base damages on the infringer's profits; TPP does not. However, both allow the judicial authorities to order the infringer to pay the profits to the rights holder.</p>

<p>Art. 12.3(b): in determining damages for infringement of intellectual property rights, its judicial authorities shall consider, inter alia, the value of the infringed good or service, measured by the suggested retail price or other legitimate measure of value submitted by the right holder.</p>	<p>?</p>	<p>Art. 9.1: Each Party shall provide that, in civil judicial proceedings concerning the enforcement of intellectual property rights, its judicial authorities have the authority to order the infringer who, knowingly or with reasonable grounds to know, engaged in infringing activity to pay the right holder damages adequate to compensate for the injury the right holder has suffered as a result of the infringement. In determining the amount of damages for infringement of intellectual property rights, a Party's judicial authorities shall have the authority to consider, inter alia, any legitimate measure of value the right holder submits, which may include lost profits, the value of the infringed goods or services measured by the market price, or the suggested retail price.</p>		<p>Both TPP and ACTA allow computation of damages by using any "legitimate measure of value" submitted by the right holder. However, TPP does not explicitly list lost profits or market price as means of measurement.</p>
<p>Art. 12.4: In civil judicial proceedings, each Party shall, at least with respect to works, phonograms, and performances protected by copyright or related rights, and in cases of trademark counterfeiting, establish or maintain a system that provides for pre-established damages, which shall be available upon the election of the right holder. Pre-established damages shall be in an amount sufficiently high to constitute a deterrent to future infringements and to compensate fully the right holder for the harm caused by the infringement. In civil judicial proceedings concerning patent infringement, each Party shall provide that its judicial authorities shall have the authority to increase damages to an amount that is up to</p>	<p>?</p>	<p>Art. 9.3: At least with respect to infringement of copyright or related rights protecting works, phonograms, and performances, and in cases of trademark counterfeiting, each Party shall also establish or maintain a system that provides for one or more of the following:          (a) pre-established damages; or          (b) presumptions for determining the amount of damages sufficient to compensate the right holder for the harm caused by the infringement; or          (c) at least for copyright, additional damages.</p>		<p>Although both TPP and ACTA require pre-established damages sufficient to compensate the right holder for the harm caused by the infringement, TPP also requires the amount to be "sufficiently high to constitute a deterrent to future infringement". Additionally, unlike ACTA, TPP provides that in patent infringement cases, the damages may be increased up to three times the injury.</p>

three times the amount of the injury found or assessed.				
Art. 12.5: Each Party shall provide that its judicial authorities, except in exceptional circumstances, have the authority to order, at the conclusion of civil judicial proceedings concerning copyright or related rights infringement, trademark infringement, or patent infringement, that the prevailing party shall be awarded payment by the losing party of court costs or fees and, at least in proceedings concerning copyright or related rights infringement or willful trademark counterfeiting, reasonable attorney's fees. Further, each Party shall provide that its judicial authorities, at least in exceptional circumstances, shall have the authority to order, at the conclusion of civil judicial proceedings concerning patent infringement, that the prevailing party shall be awarded payment by the losing party of reasonable attorneys' fees.	45(2)	Art. 9.5: Each Party shall provide that its judicial authorities, where appropriate, have the authority to order, at the conclusion of civil judicial proceedings concerning infringement of at least copyright or related rights, or trademarks, that the prevailing party be awarded payment by the losing party of court costs or fees and appropriate attorney's fees, or any other expenses as provided for under that Party's law.		Unlike ACTA, under TPP the losing party may be required to pay for court costs and attorney's fees in cases concerning patent infringement (in addition to copyright and trademark infringement cases).
12.6	Criminal only – art 61			
Art. 12.7(a): Each Party shall provide that in civil judicial proceedings: (a) at the right holder's request, goods that have been found to be pirated or counterfeit shall be destroyed, except in exceptional circumstances;	46	Art. 10.1: At least with respect to pirated copyright goods and counterfeit trademark goods, each Party shall provide that, in civil judicial proceedings, at the right holder's request, its judicial authorities have the authority to order that such infringing goods be destroyed, except in exceptional circumstances, without compensation of any sort.		Although both TPP and ACTA require the destruction of pirated or counterfeit goods at the request of the right holder, unlike ACTA, TPP does not require the destruction of the goods to be carried out without compensation of any sort (but does make this requirement for criminal sanctions, see Art. 15.5(d)(ii) below).

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<p>Art. 12.7(b): its judicial authorities shall have the authority to order that materials and implements that have been used in the manufacture or creation of such pirated or counterfeit goods be, without compensation of any sort, promptly destroyed or, in exceptional circumstances, without compensation of any sort, disposed of outside the channels of commerce in such a manner as to minimize the risks of further infringements; and</p>	<p>46</p>	<p>Art. 10.2: Each Party shall further provide that its judicial authorities have the authority to order that materials and implements, the predominant use of which has been in the manufacture or creation of such infringing goods, be, without undue delay and without compensation of any sort, destroyed or disposed of outside the channels of commerce in such a manner as to minimize the risks of further infringements.</p>		<p>TPP allows the destruction of materials and implements that merely have been used in manufacture or creation of infringing goods, while ACTA requires that such goods have been <b>predominantly</b> so used. Also unlike ACTA, TPP allows disposal of infringing goods outside the channels of commerce as an alternative to the destruction of the goods in exceptional circumstances.</p>
<p>Art. 12.7(c): in regard to counterfeit trademarked goods, the simple removal of the trademark unlawfully affixed shall not be sufficient to permit the release of goods into the channels of commerce.</p>	<p>46</p>	<p>Art. 20.2: In regard to counterfeit trademark goods, the simple removal of the trademark unlawfully affixed shall not be sufficient, other than in exceptional cases, to permit release of the goods into the channels of commerce.</p>		<p>Unlike ACTA, TPP does not provide an exception in exceptional cases to allow the removal of the trademark to permit the release of counterfeit trademarked goods.</p>
<p>Art. 12.8: Each Party shall provide that in civil judicial proceedings concerning the enforcement of intellectual property rights, its judicial authorities shall have the authority to order the infringer to provide any information that the infringer possesses or controls regarding any persons or entities involved in any aspect of the infringement and regarding the means of production or distribution channel of such goods or services, including the identification of third persons involved in the production and distribution of the infringing goods or services or in their channels of distribution, and to provide this information to the right holder.</p>	<p>47, “may”</p>	<p>Art. 11: Without prejudice to its law governing privilege, the protection of confidentiality of information sources, or the processing of personal data, each Party shall provide that, in civil judicial proceedings concerning the enforcement of intellectual property rights, its judicial authorities have the authority, upon a justified request of the right holder, to order the infringer or, in the alternative, the alleged infringer, to provide to the right holder or to the judicial authorities, at least for the purpose of collecting evidence, relevant information as provided for in its applicable laws and regulations that the infringer or alleged infringer possesses or controls. Such information may include information regarding any person involved in any aspect of the</p>		<p>Unlike ACTA, TPP does not contain the safeguards providing that access to information shall be “without prejudice to [each country’s] law governing privilege, the protection of confidentiality of information sources, or the processing of personal data . . . .” Additionally, TPP does not require the access to such information to be conditional “upon a justified request of the right holder”. Finally, TPP omits the word “alleged” and instead, simply refers to “infringement” and “infringer”. Other than that, TPP closely follows the language of ACTA.</p>

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		infringement or alleged infringement and regarding the means of production or the channels of distribution of the infringing or allegedly infringing goods or services, including the identification of third persons alleged to be involved in the production and distribution of such goods or services and of their channels of distribution.		
Art. 12.9: Each Party shall provide that its judicial authorities have the authority to: (a) fine or imprison, in appropriate cases, a party to a civil judicial proceeding who fails to abide by valid orders issued by such authorities; and (b) impose sanctions on parties to a civil judicial proceeding their counsel, experts, or other persons subject to the court's jurisdiction, for violation of judicial orders regarding the protection of confidential information produced or exchanged in a proceeding.	?			TPP interferes with the sovereignty of signatories by mandating judicial procedures. ACTA does not have an equivalent section.
Art. 12.10: To the extent that any civil remedy can be ordered as a result of administrative procedures on the merits of a case, each Party shall provide that such procedures conform to principles equivalent in substance to those set out in this Chapter.	?	Art. 7.2: To the extent that any civil remedy can be ordered as a result of administrative procedures on the merits of a case, each Party shall provide that such procedures shall conform to principles equivalent in substance to those set forth in this Section.		Identical.

<p>Art. 12.12: In civil judicial proceedings concerning the acts described in Article 4.[9] (TPMs) and Article 4.[10] (RMI), each Party shall provide that its judicial authorities shall, at the least, have the authority to:</p> <p>(a) impose provisional measures, including seizure of devices and products suspected of being involved in the prohibited activity;</p> <p>(b) provide an opportunity for the right holder to elect between actual damages it suffered (plus any profits attributable to the prohibited activity not taken into account in computing those damages) or pre-established damages;</p> <p>(c) order payment to the prevailing right holder at the conclusion of civil judicial proceedings of court costs and fees, and reasonable attorney's fees, by the party engaged in the prohibited conduct; and</p> <p>(d) order the destruction of devices and products found to be involved in the prohibited activity.</p> <p>No Party shall make damages available under this paragraph against a nonprofit library, archives, educational institution, or public noncommercial broadcasting entity that sustains the burden of proving that such entity was not aware and had no reason to believe that its acts constituted a prohibited activity.</p>	<p>?</p>	<p>Art. 27.8: In providing adequate legal protection and effective legal remedies pursuant to the provisions of paragraphs 5 and 7, a Party may adopt or maintain appropriate limitations or exceptions to measures implementing the provisions of paragraphs 5, 6, and 7. The obligations set forth in paragraphs 5, 6, and 7 are without prejudice to the rights, limitations, exceptions, or defences to copyright or related rights infringement under a Party's law.</p>		<p>ACTA does not provide specific minimum remedies, while TPP does. TPP requires an exception for nonprofit educational use, while ACTA only allows it. ACTA also explicitly does not interfere with a country's existing copyright law.</p> <p>Check against US law</p>
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**Special Requirements Related to Border Enforcement**

TPP	TRIPS	ACTA	Comparison/Analysis
<p>Art. 14.1: Each Party shall provide that any right holder initiating procedures for its competent authorities to suspend release of suspected counterfeit or confusingly similar trademark goods, or pirated copyright goods into free circulation is required to provide adequate evidence to satisfy the competent authorities that, under the laws of the country of importation, there is <i>prima facie</i> an infringement of the right holder's intellectual property right and to supply sufficient information that may reasonably be expected to be within the right holder's knowledge to make the suspected goods reasonably recognizable by its competent authorities. The requirement to provide sufficient information shall not unreasonably deter recourse to these procedures. Each Party shall provide that the application to suspend the release of goods apply to all points of entry to its territory and remain in force for a period of not less than one year from the date of application, or the period that the good is protected by copyright or the relevant trademark registration is valid, whichever is shorter.</p>	<p>Art. 51. Suspension of Release by Customs Authorities. Members shall, in conformity with the provisions set out below, adopt procedures (13) to enable a right holder, who has valid grounds for suspecting that the importation of counterfeit trademark or pirated copyright goods (14) may take place, to lodge an application in writing with competent authorities, administrative or judicial, for the suspension by the customs authorities of the release into free circulation of such goods. Members may enable such an application to be made in respect of goods which involve other infringements of intellectual property rights, provided that the requirements of this Section are met. Members may also provide for corresponding procedures concerning the suspension by the customs authorities of the release of infringing goods destined for exportation from their territories.</p> <p>Art. 52. Application. Any right holder initiating the procedures under Article 51 shall be required to provide adequate evidence to satisfy the competent authorities that, under the laws of the country of importation, there is <i>prima facie</i> an infringement of the right holder's intellectual property right and to supply a sufficiently detailed description of the goods to make them readily recognizable by the customs authorities. The competent authorities shall inform the applicant within a reasonable period whether they have accepted the application and, where determined by the competent authorities, the period for which the customs authorities will take action.</p>	<p>Art. 17.1: Each Party shall provide that its competent authorities require a right holder that requests the procedures described in subparagraphs 1(b) and 2(b) of Article 16 (Border Measures) to provide adequate evidence to satisfy the competent authorities that, under the law of the Party providing the procedures, there is <i>prima facie</i> an infringement of the right holder's intellectual property right, and to supply sufficient information that may reasonably be expected to be within the right holder's knowledge to make the suspect goods reasonably recognizable by the competent authorities. The requirement to provide sufficient information shall not unreasonably deter recourse to the procedures described in subparagraphs 1(b) and 2(b) of Article 16 (Border Measures).</p>	<p>TPP, TRIPS and ACTA provisions similarly require a <i>prima facie</i> showing of infringement and sufficient evidence to make the suspected goods reasonably recognizable. However, TPP goes further than ACTA by requiring that "application to suspend the release of goods apply to all points of entry to its territory and remain in force for a period of not less than one year from the date of application, or the period that the good is protected by copyright or the relevant trademark registration is valid, whichever is shorter." TRIPS establishes a shorter period of suspension if proceedings are not initiated (10 days).</p>

Art. 55. Duration of Suspension. If, within a period not exceeding 10 working days after the applicant has been served notice of the suspension, the customs authorities have not been informed that proceedings leading to a decision on the merits of the case have been initiated by a party other than the defendant, or that the duly empowered authority has taken provisional measures prolonging the suspension of the release of the goods, the goods shall be released, provided that all other conditions for importation or exportation have been complied with; in appropriate cases, this time-limit may be extended by another 10 working days. If proceedings leading to a decision on the merits of the case have been initiated, a review, including a right to be heard, shall take place upon request of the defendant with a view to deciding, within a reasonable period, whether these measures shall be modified, revoked or confirmed. Notwithstanding the above, where the suspension of the release of goods is carried out or continued in accordance with a provisional judicial measure, the provisions of paragraph 6 of Article 50 shall apply.

[Art. 50.6. Without prejudice to paragraph 4, provisional measures taken on the basis of paragraphs 1 and 2 shall, upon request by the defendant, be revoked or otherwise cease to have effect, if proceedings leading to a decision on the merits of the case are not initiated within a reasonable period, to be determined by the judicial authority ordering the measures where a Member's law so permits or, in the absence of such a determination, not to exceed 20 working days or 31 calendar days, whichever is the longer].

<p>FN 20: For purposes of Article 14:                  (a) <b>counterfeit trademark goods</b> means any goods, including packaging, bearing without authorization a trademark that is identical to the trademark validly registered in respect of such goods, or that cannot be distinguished in its essential aspects from such a trademark, and that thereby infringes the rights of the owner of the trademark in question under the law of the country of importation; and                  (b) <b>pirated copyright goods</b> means any goods that are copies made without the consent of the right holder or person duly authorized by the right holder in the country of production and that are made directly or indirectly from an article where the making of that copy would have constituted an infringement of a copyright or a related right under the law of the country of importation.</p>	<p>For Article 51                  FN13: It is understood that there shall be no obligation to apply such procedures to imports of goods put on the market in another country by or with the consent of the right holder, or to goods in transit.                  FN14: For the purposes of this Agreement:                  (a)"counterfeit trademark goods" shall mean any goods, including packaging, bearing without authorization a trademark which is identical to the trademark validly registered in respect of such goods, or which cannot be distinguished in its essential aspects from such a trademark, and which thereby infringes the rights of the owner of the trademark in question under the law of the country of importation;                  (b)"pirated copyright goods" shall mean any goods which are copies made without the consent of the right holder or person duly authorized by the right holder in the country of production and which are made directly or indirectly from an article where the making of that copy would have constituted an infringement of a copyright or a related right under the law of the country of importation.</p>	<p>Arts. 5(d), (k): ... (d) counterfeit trademark goods means any goods, including packaging, bearing without authorization a trademark which is identical to the trademark validly registered in respect of such goods, or which cannot be distinguished in its essential aspects from such a trademark, and which thereby infringes the rights of the owner of the trademark in question under the law of the country in which the procedures set forth in Chapter II (Legal Framework for Enforcement of Intellectual Property Rights) are invoked;                  ... (k) pirated copyright goods means any goods which are copies made without the consent of the right holder or person duly authorized by the right holder in the country of production and which are made directly or indirectly from an article where the making of that copy would have constituted an infringement of a copyright or a related right under the law of the country in which the procedures set forth in Chapter II (Legal Framework for Enforcement of Intellectual Property Rights) are invoked;</p>	<p>TPP and TRIPS base their definitions on whether there is infringement in the country of importation, while ACTA bases its definitions on whether there is infringement in the country where ACTA procedures are invoked.</p>
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<p>Art. 14.2: Each Party shall provide that its competent authorities shall have the authority to require a right holder initiating procedures to suspend the release of suspected counterfeit or confusingly similar trademark goods, or pirated copyright goods, to provide a reasonable security or equivalent assurance sufficient to protect the defendant and the competent authorities and to prevent abuse. Each Party shall provide that such security or equivalent assurance shall not unreasonably deter recourse to these procedures. A Party may provide that such security may be in the form of a bond conditioned to hold the importer or owner of the imported merchandise harmless from any loss or damage resulting from any suspension of the release of goods in the event the competent authorities determine that the article is not an infringing good.</p>	<p>Art. 53: Security or Equivalent Assurance.</p> <p>1. The competent authorities shall have the authority to require an applicant to provide a security or equivalent assurance sufficient to protect the defendant and the competent authorities and to prevent abuse. Such security or equivalent assurance shall not unreasonably deter recourse to these procedures.</p> <p>2. Where pursuant to an application under this Section the release of goods involving industrial designs, patents, layout-designs or undisclosed information into free circulation has been suspended by customs authorities on the basis of a decision other than by a judicial or other independent authority, and the period provided for in Article 55 has expired without the granting of provisional relief by the duly empowered authority, and provided that all other conditions for importation have been complied with, the owner, importer, or consignee of such goods shall be entitled to their release on the posting of a security in an amount sufficient to protect the right holder for any infringement. Payment of such security shall not prejudice any other remedy available to the right holder, it being understood that the security shall be released if the right holder fails to pursue the right of action within a reasonable period of time.</p> <p>Art. 56. Indemnification of the Importer and of the Owner of the Goods. Relevant authorities shall have the authority to order the applicant to pay the importer, the consignee and the owner of the goods appropriate compensation for any injury caused to them through the wrongful detention of goods or through the detention of goods released pursuant to Article 55.</p>	<p>Art. 18: Each Party shall provide that its competent authorities have the authority to require a right holder that requests the procedures described in subparagraphs 1(b) and 2(b) of Article 16 (Border Measures) to provide a reasonable security or equivalent assurance sufficient to protect the defendant and the competent authorities and to prevent abuse. Each Party shall provide that such security or equivalent assurance shall not unreasonably deter recourse to these procedures. A Party may provide that such security may be in the form of a bond conditioned to hold the defendant harmless from any loss or damage resulting from any suspension of the release of, or detention of, the goods in the event the competent authorities determine that the goods are not infringing. A Party may, only in exceptional circumstances or pursuant to a judicial order, permit the defendant to obtain possession of suspect goods by posting a bond or other security.</p>	<p>TPP and ACTA are essentially identical. TRIPS contains the same provision but goes further by establishing that the importer must provide a security to cover for the potential loss of the right holder when the goods are released if (1) a decision on the merits of an application is pending, (2) all other importation conditions have been complied with and (3) the 10 day period has expired.</p> <p>TRIPS also expressly provides for the indemnification of the importer by the applicant in case the importer suffers an injury by the detention of goods.</p>
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<p>Art. 14.3: Where its competent authorities have seized goods that are counterfeit or pirated, a Party shall provide that its competent authorities have the authority to inform the right holder within 30-days<sup>21</sup> of the seizure of the names and addresses of the consignor, exporter, consignee, or importer, a description of the merchandise, quantity of the merchandise, and, if known, the country of origin of the merchandise.</p>	<p>Art. 54. Notice of Suspension. The importer and the applicant shall be promptly notified of the suspension of the release of goods according to Article 51.</p> <p>Art. 57. Right of Inspection and Information. Without prejudice to the protection of confidential information, Members shall provide the competent authorities the authority to give the right holder sufficient opportunity to have any goods detained by the customs authorities inspected in order to substantiate the right holder's claims. The competent authorities shall also have authority to give the importer an equivalent opportunity to have any such goods inspected. Where a positive determination has been made on the merits of a case, Members may provide the competent authorities the authority to inform the right holder of the names and addresses of the consignor, the importer and the consignee and of the quantity of the goods in question.</p>	<p>Art. 22: Without prejudice to a Party's laws pertaining to the privacy or confidentiality of information:</p> <p>(a) a Party may authorize its competent authorities to provide a right holder with information about specific shipments of goods, including the description and quantity of the goods, to assist in the detection of infringing goods;</p> <p>(b) a Party may authorize its competent authorities to provide a right holder with information about goods, including, but not limited to, the description and quantity of the goods, the name and address of the consignor, importer, exporter, or consignee, and, if known, the country of origin of the goods, and the name and address of the manufacturer of the goods, to assist in the determination referred to in Article 19 (Determination as to Infringement);</p> <p>(c) unless a Party has provided its competent authorities with the authority described in subparagraph (b), at least in cases of imported goods, where its competent authorities have seized suspect goods or, in the alternative, made a determination referred to in Article 19 (Determination as to Infringement) that the goods are infringing, the Party shall authorize its competent authorities to provide a right holder, within thirty days<sup>[8]</sup> of the seizure or determination, with information about such goods, including, but not limited to, the description and quantity of the goods, the name and address of the consignor, importer, exporter, or consignee, and, if known, the country of origin of the goods, and the name and address of the manufacturer of the goods.</p>	<p>TPP does not provide any protections for privacy or confidentiality of information. TRIPS and ACTA are similar but TRIPS does not specify the period by which authorities have to notify the importer or the applicant of the suspension of the release of the goods.</p>
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<p>Art. 14.4: Each Party shall provide that its competent authorities may initiate border measures <i>ex officio</i> with respect to imported, exported, or in-transit merchandise, or merchandise in free trade zones, that is suspected of being counterfeit or confusingly similar trademark goods, or pirated copyright goods.</p>	<p>Art. 58. Ex Officio Action. Where Members require competent authorities to act upon their own initiative and to suspend the release of goods in respect of which they have acquired prima facie evidence that an intellectual property right is being infringed:                  (a) the competent authorities may at any time seek from the right holder any information that may assist them to exercise these powers;                  (b) the importer and the right holder shall be promptly notified of the suspension. Where the importer has lodged an appeal against the suspension with the competent authorities, the suspension shall be subject to the conditions, mutatis mutandis, set out at Article 55;                  (c) Members shall only exempt both public authorities and officials from liability to appropriate remedial measures where actions are taken or intended in good faith.</p>	<p>Art. 16: 1. Each Party shall adopt or maintain procedures with respect to import and export shipments under which:                  (a) its customs authorities may act upon their own initiative to suspend the release of suspect goods; and                  (b) where appropriate, a right holder may request its competent authorities to suspend the release of suspect goods.                  2. A Party may adopt or maintain procedures with respect to suspect in-transit goods or in other situations where the goods are under customs control under which:                  (a) its customs authorities may act upon their own initiative to suspend the release of, or to detain, suspect goods; and                  (b) where appropriate, a right holder may request its competent authorities to suspend the release of, or to detain, suspect goods.</p>	<p>TPP broadly allows initiation of “Border Measures,” while ACTA lists specific procedures. Additionally, TPP concerns not only suspected counterfeit goods but also “confusingly similar trademark goods”. TRIPS is broader in the sense that it concerns the infringement of an intellectual property right. However, TRIPS seems to have a higher standard as it requires the authorities to ‘acquire prima facie evidence’, whereas TPP just requires authorities to ‘suspect’ a good is counterfeit or confusingly similar or pirated copyright.</p>
<p>Art. 14.5: Each Party shall adopt or maintain a procedure by which its competent authorities shall determine, within a reasonable period of time after the initiation of the procedures described under Article 14.1 whether the suspect goods infringe an intellectual property right. Where a Party provides administrative procedures for the determination of an infringement, it shall also provide its authorities with the authority to impose administrative penalties following a determination that the goods are infringing.</p>	<p>Art. 51. Suspension of Release by Customs Authorities. Members shall, in conformity with the provisions set out below, adopt procedures (13) to enable a right holder, who has valid grounds for suspecting that the importation of counterfeit trademark or pirated copyright goods (14) may take place, to lodge an application in writing with competent authorities, administrative or judicial, for the suspension by the customs authorities of the release into free circulation of such goods. Members may enable such an application to be made in respect of goods which involve other infringements of intellectual property rights, provided that the requirements of this Section are met. Members may also provide for corresponding procedures concerning the suspension by the customs authorities of</p>	<p>Art. 19: Each Party shall adopt or maintain procedures by which its competent authorities may determine, within a reasonable period after the initiation of the procedures described in Article 16 (Border Measures), whether the suspect goods infringe an intellectual property right.</p>	<p>The first sentence of TPP is essentially identical to ACTA. However, TPP further adds that “Where a Party provides administrative procedures for the determination of an infringement, it shall also provide its authorities with the authority to impose administrative penalties following a determination that the goods are infringing”. TRIPS, as ACTA, does not talk about providing authorities with the authority to impose admin penalties.</p>

	the release of infringing goods destined for exportation from their territories.		
Art. 14.6: Each Party shall provide that goods that have been determined by its competent authorities to be pirated or counterfeit shall be destroyed, except in exceptional circumstances. In regard to counterfeit trademark goods, the simple removal of the trademark unlawfully affixed shall not be sufficient to permit the release of the goods into the channels of commerce. In no event shall the competent authorities be authorized, except in exceptional circumstances, to permit the exportation of counterfeit or pirated goods or to permit such goods to be subject to other customs procedures.	Article 59. Remedies. Without prejudice to other rights of action open to the right holder and subject to the right of the defendant to seek review by a judicial authority, competent authorities shall have the authority to order the destruction or disposal of infringing goods in accordance with the principles set out in Article 46. In regard to counterfeit trademark goods, the authorities shall not allow the re-exportation of the infringing goods in an unaltered state or subject them to a different customs procedure, other than in exceptional circumstances.	Arts. 20.1, 20.2: 1. Each Party shall provide that its competent authorities have the authority to order the destruction of goods following a determination referred to in Article 19 (Determination as to Infringement) that the goods are infringing. In cases where such goods are not destroyed, each Party shall ensure that, except in exceptional circumstances, such goods are disposed of outside the channels of commerce in such a manner as to avoid any harm to the right holder. 2. In regard to counterfeit trademark goods, the simple removal of the trademark unlawfully affixed shall not be sufficient, other than in exceptional cases, to permit release of the goods into the channels of commerce.	Although both TPP and ACTA provide for an exception to destruction of the infringing goods as a form of remedy, TPP does not explicitly allow for disposal of such goods outside the channels of commerce. TRIPS does allow for disposal of the goods outside the channels of commerce (Art. 46). Additionally unlike ACTA, TPP and TRIPS further note that, except in exceptional cases, in no event shall the counterfeit or pirated goods be permitted to be exported or to be subject to other customs procedures. TRIPS also expressly prohibits the re-exportation of the infringing good in an unaltered state.
Art. 14.7: Where an application fee, merchandise storage fee, or destruction fee is assessed in connection with border measures to enforce an intellectual property right, each Party shall provide that such fee shall not be set at an amount that unreasonably deters recourse to these measures.		Art. 21: Each Party shall provide that any application fee, storage fee, or destruction fee to be assessed by its competent authorities in connection with the procedures described in this Section shall not be used to unreasonably deter recourse to these procedures.	Essentially identical. TRIPS has no equivalent provision.
Art. 14.8: A Party may exclude from the application of this Article (border measures), small quantities of goods of a non-commercial nature contained in traveler's personal luggage.	Article 60. De Minimis Imports. Members may exclude from the application of the above provisions small quantities of goods of a non-commercial nature contained in travellers' personal luggage or sent in small consignments.	Art. 14: 1. Each Party shall include in the application of this Section goods of a commercial nature sent in small consignments. 2. A Party may exclude from the application of this Section small quantities of goods of a non-commercial nature contained in travelers' personal luggage.	Essentially identical for personal luggage exclusion. ACTA explicitly includes small consignments of commercial goods. TRIPS refers to small consignments but this may be non-commercial.

**Rights Management Provisions**

TPP	ACTA	Comparison/Analysis
Art. 4.10(a): each Party shall provide that any person who without authority, and knowing, or, with respect to civil remedies, having reasonable grounds to	To protect electronic rights management information, each Party shall provide adequate legal protection and effective legal remedies against any person	ACTA only requires adequate legal protection and remedies, while TPP requires criminal penalties when infringement is for profit.

<p>know, that it would induce, enable, facilitate, or conceal an infringement of any copyright or related right,                  (i) knowingly removes or alters any rights management information;                  (ii) distributes or imports for distribution rights management information knowing that the rights management information has been removed or altered without authority; or                  (iii) distributes, imports for distribution, broadcasts, communicates or makes available to the public copies of works, performances, or phonograms, knowing that rights management information has been removed or altered without authority,                  shall be liable and subject to the remedies set out in Article [12.12 Each Party shall provide for criminal procedures and penalties to be applied when any person, other than a nonprofit library, archive, educational institution, or public noncommercial broadcasting entity, is found to have engaged willfully and for purposes of commercial advantage or private financial gain in any of the foregoing activities. Such criminal procedures and penalties shall include the application to such activities of the remedies and authorities listed in subparagraphs (a), (b) and (f) of Article [15.5] as applicable to infringements, mutatis mutandis.</p>	<p>knowingly performing without authority any of the following acts knowing, or with respect to civil remedies, having reasonable grounds to know, that it will induce, enable, facilitate, or conceal an infringement of any copyright or related rights:                  (a) to remove or alter any electronic rights management information;                  (b) to distribute, import for distribution, broadcast, communicate, or make available to the public copies of works, performances, or phonograms, knowing that electronic rights management information has been removed or altered without authority.</p>	
<p>Art. 4.10(b) each Party shall confine exceptions and limitations to measures implementing subparagraph (a) to lawfully authorized activities carried out by government employees, agents, or contractors for the purpose of law enforcement, intelligence, essential security, or similar governmental purposes.</p>	<p>Art. 27.8: In providing adequate legal protection and effective legal remedies pursuant to the provisions of paragraphs 5 and 7, a Party may adopt or maintain appropriate limitations or exceptions to measures implementing the provisions of paragraphs 5, 6, and 7. The obligations set forth in paragraphs 5, 6, and 7 are without prejudice to the rights, limitations, exceptions, or defences to copyright or related rights infringement under a Party's law.</p>	<p>TPP limits exceptions to those carried out by people working for the government for law-enforcement-related government purposes.</p>

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<p>Art. 4.10(c) Rights management information means:          (i) information that identifies a work, performance, or phonogram; the author of the work, the performer of the performance, or the producer of the phonogram; or the owner of any right in the work, performance, or phonogram;          (ii) information about the terms and conditions of the use of the work, performance, or phonogram; or          (iii) any numbers or codes that represent such information, when any of these items is attached to a copy of the work, performance, or phonogram or appears in connection with the communication or making available of a work, performance or phonogram, to the public.</p>	<p>Art. 27 footnote 16: For the purposes of this Article, rights management information means: (a) information that identifies the work, the performance, or the phonogram; the author of the work, the performer of the performance, or the producer of the phonogram; or the owner of any right in the work, performance, or phonogram; (b) information about the terms and conditions of use of the work, performance, or phonogram; or (c) any numbers or codes that represent the information described in (a) and (b) above; when any of these items of information is attached to a copy of a work, performance, or phonogram, or appears in connection with the communication or making available of a work, performance, or phonogram to the public.</p>	<p>Essentially identical</p>
<p>Art. 4.10(d) For greater certainty, nothing in this paragraph shall obligate a Party to require the owner of any right in the work, performance, or phonogram to attach rights management information to copies of the work, performance, or phonogram, or to cause rights management information to appear in connection with a communication of the work, performance, or phonogram to the public.</p>		<p>ACTA does not have an equivalent section.</p>

**RE: Increased medicines cost due to TRIPS+ clauses in FTAs  
[SEC=UNCLASSIFIED] - Notes Memo**

**From:** [redacted]  
**To:** [redacted]  
**Cc:** "Brendan.Bourke@ipaustrialia.gov.au" <Brendan.Bourke@ipaustrialia.gov.au>,  
[redacted]

all redactions s47F

**Sent:** 16-07-2012 08:11:03 AM

Dear [redacted]

Many thanks for sharing your research. We appreciate your efforts in pulling this together and will read with interest. Any other information you would like to provide would be welcome.

All the best at the International AIDS Conference

Kind regards

[redacted]

[redacted]  
Executive Officer  
International Intellectual Property Section  
Office of Trade Negotiations  
Australian Department of Foreign Affairs & Trade

Tel: [redacted]  
Fax: +61 2 6112 2347

-----Original Message-----

**From:** [redacted]  
**Sent:** Tuesday, 10 July 2012 2:45 PM  
**To:** [redacted]  
**Subject:** Increased medicines cost due to TRIPS+ clauses in FTAs

[redacted] on the telephone call a week or so ago, [redacted]  
[redacted]

[redacted]

The attached is what I have come up with so far.

[redacted]

[redacted]

will meet some of the people who have been collecting this information at the International AIDS Conference in Washington later this month.

=====  
Email scanned by PC Tools - No viruses or spyware found.  
(Email Guard: 9.0.0.909, Virus/Spyware Database: 6.20100) <http://www.pctools.com/>  
=====

<Attachment: ImpactOnMedicinePrices&AustralianStudy-1.doc>

## Likely impact of TRIPS-plus provisions on medicines

The World Trade Organization requires its Members to comply with the standards of intellectual property protection set out in the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). However, developed countries often require developing countries to agree in free trade agreements (FTAs) to stronger intellectual property protection than the minimum required by TRIPS. This is known as TRIPS-plus. This note examines the data on the impact of TRIPS-plus provisions on medicine prices and consumption.

Patented medicines are much more expensive than their generic equivalents. For example, the patented version of medicines to treat AIDS cost US\$15,000 per patient per year, but the generic version only costs US\$67 per patient per year.<sup>1</sup> Provisions in these North-South FTAs such as requirements to comply with or join the Patent Cooperation Treaty are likely to mean that more medicines are patented.<sup>2</sup>

The price of patented medicines in Malaysia are already high enough to be of concern. For example a 2005 study using WHO methodology found that for a family of three receiving the lowest level of Malaysian civil servant salary, it would take two-months' salary to pay for one month of patented medicines.<sup>3</sup> Similarly, an article by Azmi and Alavi found that patented medicines can be 1,044% more expensive than their generic equivalents in Malaysia.<sup>4</sup>

The World Health Organization (WHO) has an economic model of the impact of these TRIPS-plus provisions on medicine consumption and a country's generic medicine manufacturers. The model predicts that the full impact of medicine price rises will not be felt until about 15 years after the USFTA begins because the stronger IP protection only applies to each new medicine after the FTA starts so it will not affect all medicines in a country and the overall medicine price until about 15 years has passed.

When the WHO model was applied to Colombia, it found that the effect of most of these TRIPS-plus provisions is that Colombia would require an extra US\$1.5billion to be spent on medicines every year by 2030.<sup>5</sup> If this were not spent, Colombians will have to reduce their medicine consumption by 44% by 2030.<sup>6</sup>

A study of the impact thus far of the TRIPS-plus provisions of the Jordan-USFTA found that: one hospital alone has increased its medicine spending six-fold, medicine prices in Jordan have already increased 20% since 2001 when the FTA began, over 25% of the Ministry of Health's budget is now spent on buying medicines, data exclusivity has delayed the introduction of cheaper generic versions of 79% of medicines launched by 21 multinational companies between 2002 and mid-2006 and ultimately the higher medicine prices are threatening the financial sustainability of government public

<sup>1</sup> [http://www.doctorswithoutborders.org/publications/reports/2011/MSF\\_Access\\_Report\\_13th\\_edition.pdf](http://www.doctorswithoutborders.org/publications/reports/2011/MSF_Access_Report_13th_edition.pdf) and [http://www.msf.org/msfinternational/invoke.cfm?objectid=63C0C1F1-E018-0C72-093AB3D906C4C469&component=toolkit.article&method=full\\_html](http://www.msf.org/msfinternational/invoke.cfm?objectid=63C0C1F1-E018-0C72-093AB3D906C4C469&component=toolkit.article&method=full_html).

<sup>2</sup> Based on data from the World Intellectual Property Organization.

<sup>3</sup> Members of the hypothetical family suffered depression, peptic ulcers, a viral infection and asthma. 'A Survey of Medicine Prices, Availability, Affordability and Price Components in Malaysia using the WHO/HAI methodology: Research Report', Babar, Ibrahim, Singh, Bukhari, University College Sedaya Interntional and Universiti Sains Malaysia in collaboration with the World Health Organization and Health Action International, Malaysia, October 2005.

<sup>4</sup> 'TRIPS, Patents, Technology Transfer, Foreign Direct Investment and the Pharmaceutical Industry in Malaysia', Ida Madieha Azmi and Rokiah Alavi, Journal of World Intellectual Property, Vol 4 No. 6, November 2001.

<sup>5</sup> 'Intellectual property in the FTA: impacts on pharmaceutical spending and access to medicines in Colombia', Mision Salud and Fundacion IFARMA, Miguel Ernesto Cortes Gamba, Bogota, 2006 available from <http://www.ftamalaysia.org/article.php?aid=153>.

<sup>6</sup> 'Intellectual property in the FTA: impacts on pharmaceutical spending and access to medicines in Colombia', Mision Salud and Fundacion IFARMA, Miguel Ernesto Cortes Gamba, Bogota, 2006 available from <http://www.ftamalaysia.org/article.php?aid=153>.

health programs.<sup>7</sup> However, other countries could expect worse outcomes because recent USFTAs can have twice as many provisions that are likely to delay the introduction of cheaper generic versions of medicines as the Jordanian one and the Jordan-USFTA has not yet been in force for the approximately 15 years the WHO's model predicts it will take for the full effects to be felt of these provisions on medicine prices.

The extension of patent terms alone (beyond the 20 years required by TRIPS) as demanded by the USA and European Union (EU) in FTAs has been calculated by the Korean National Health Insurance Corporation to cost 504.5 billion won (US\$529 million) for having to extend medicine patents for 3 years and 722.5 billion won (US\$757 million) if it has to agree to a four year extension in its USFTA negotiations.<sup>8</sup>

Data exclusivity is another monopoly which is often demanded by developed countries such as the USA and EU in their FTAs. It was recently estimated that eight years of data exclusivity alone in Canada would have added \$600 million to prescription medicine costs alone in the last five years.<sup>9</sup>

Linkage is so difficult to do that a US Congressional Report found that even the US Government's Food and Drug Administration does not have the capacity to do it because it 'does not have adequate expertise or resources to review the applicability of patents, and it has been unable to prevent abuses of the system by patentholders that have led to delays in the availability of generic drugs'.<sup>10</sup>

Research at the Australia Institute in Canberra has estimated that if provisions in the Australia-US FTA succeed in delaying by 24 months market entry of generic versions of just the top five Pharmaceutical Benefits Scheme (the 'PBS' is the Australian Government medicine reimbursement scheme) expenditure medicines due to come off patent, this could increase the cost of the PBS by \$1.5 billion over 2006-2009. The budgetary cost could easily swamp the \$53 million a year in economic gains from the agreement estimated by modeling work commissioned by a Senate Committee investigating the FTA.<sup>11</sup>

Malaysia issued a type of compulsory licence to import the cheaper generic version of patented medicines for people with HIV/AIDS. It reduced the average cost of treatment per patient per month by 81% and more than doubled the number of patients who could be treated.<sup>12</sup> The Thai Government recently issued compulsory licences for three types of medicines and estimates that it could save it up to US\$24million each year.<sup>13</sup> The World Bank has estimated that if Thailand uses compulsory licensing to reduce the cost of second-line antiretroviral therapy to treat people living with HIV/AIDS by 90%, the government would reduce its future budgetary obligations by US\$3.2 billion discounted to 2025.<sup>14</sup>

<sup>7</sup> [http://www.oxfam.org/en/files/bp102\\_jordan\\_us\\_fta.pdf/download](http://www.oxfam.org/en/files/bp102_jordan_us_fta.pdf/download)

<sup>8</sup> [http://english.hani.co.kr/arti/english\\_edition/e\\_business/165065.html](http://english.hani.co.kr/arti/english_edition/e_business/165065.html)

<sup>9</sup> [http://www.canadiangenerics.ca/en/news/nov\\_14\\_06.shtml](http://www.canadiangenerics.ca/en/news/nov_14_06.shtml)

<sup>10</sup> and see footnote 44 in the same document,

[http://www.twinside.org.sg/title2/FTAs/Intellectual\\_Property/IP\\_and\\_Access\\_to\\_Medicines/TradeAgreementsandAccessToMedicationsUnderTheBushAdmini.pdf](http://www.twinside.org.sg/title2/FTAs/Intellectual_Property/IP_and_Access_to_Medicines/TradeAgreementsandAccessToMedicationsUnderTheBushAdmini.pdf)

<sup>11</sup> 'Regionalism, Bilateralism, and 'TRIP Plus' Agreements: The Threat to Developing Countries', Ruth Mayne, Occasional Paper, Human Development Report 2005, UNDP.

<sup>12</sup> 'Malaysia's experience in increasing access to antiretroviral drugs: exercising the 'government use' option', Chee Yoke Ling, Intellectual Property Rights Series No. 9, Third World Network, 2006. Earlier version available from

[http://www.twinside.org.sg/title2/FTAs/Intellectual\\_Property/IP\\_and\\_Access\\_to\\_Medicines/Malaysia'sExperienceInIncreasingAccessToAntiretroviralDrugs-CheeYokeLing%5B0ct05%5D.docx](http://www.twinside.org.sg/title2/FTAs/Intellectual_Property/IP_and_Access_to_Medicines/Malaysia'sExperienceInIncreasingAccessToAntiretroviralDrugs-CheeYokeLing%5B0ct05%5D.docx)

<sup>13</sup> [http://www.bangkokpost.net/breaking\\_news/breakingnews.php?id=116803](http://www.bangkokpost.net/breaking_news/breakingnews.php?id=116803)

<sup>14</sup> p169, 'The Economics of Effective AIDS Treatment', Conference Edition, World Bank, Washington, 2006.

The combined effect of the TRIPS+ provisions the USA was asking Colombia to agree to (before the May 2007 deal watered down the TRIPS+ provisions regarding medicines) would cause Colombian medicine manufacturers to lose 64% of their market share by 2030.<sup>15</sup>

North-South FTAs could significantly restrict the ability to effectively issue compulsory licences in future.

Many have expressed their concerns about the way the intellectual property provisions found in USFTAs make medicines more expensive, including the United Nations Special Rapporteurs on the Right to Health,<sup>16</sup> the United Nations Committee on Economic, Social and Cultural Rights,<sup>17</sup> the United Nations Committee on the Rights of the Child,<sup>18</sup> the World Health Assembly,<sup>19</sup> the WHO's Commission on Intellectual Property Rights, Innovation and Public Health,<sup>20</sup> the Global Fund to Fight AIDS, Tuberculosis and Malaria,<sup>21</sup> Ministers of Health from ten Latin American countries,<sup>22</sup> the Ministers of Health<sup>23</sup> of the African Union, the African Union's Ministers of Trade<sup>24</sup>, the UK Government's Commission on Intellectual Property Rights<sup>25</sup> and Nobel Peace Prize winning Doctors Without Borders<sup>26</sup>.

The government of the state of Western Australia was concerned about the impact of the Australia-USFTA on medicine prices in Australia. They noted that 'PBS data indicates that the prices of brand name (patented) medicines fall by an average of more than 30 per cent after patent expiration and the entry of generic medicines. Delays to the availability of generic pharmaceuticals will therefore significantly increase pharmaceutical expenditures in Australia over time particularly in hospitals where generic brands are used extensively... A rise in medicine costs through the PBS and any delays in the availability of generic equivalent medicines will have a direct impact upon the cost of medicines purchased by the public sector. Medicines are the second most expensive item after salaries

<sup>15</sup> 'Intellectual property in the FTA: impacts on pharmaceutical spending and access to medicines in Colombia', Mision Salud and Fundacion IFARMA, Miguel Ernesto Cortes Gamba, Bogota, 2006 available from <http://www.ftamalaysia.org/article.php?aid=153>.

<sup>16</sup> Eg Press Release, 5 July 2004,

<http://www.unhchr.ch/hurricane/hurricane.nsf/view01/35C240E546171AC1C1256EC800308A37?opendocument> and [http://www2.ohchr.org/english/bodies/hrcouncil/docs/11session/A.HRC.11.12\\_en.pdf](http://www2.ohchr.org/english/bodies/hrcouncil/docs/11session/A.HRC.11.12_en.pdf)

<sup>17</sup> See for example [http://www.3dthree.org/pdf\\_3D/CostaRicaCAFTA.pdf](http://www.3dthree.org/pdf_3D/CostaRicaCAFTA.pdf),

[http://www.3dthree.org/pdf\\_3D/3DInformationNote7.pdf](http://www.3dthree.org/pdf_3D/3DInformationNote7.pdf),

[http://www.3dthree.org/pdf\\_3D/EcuadorPress18May04\\_en.pdf](http://www.3dthree.org/pdf_3D/EcuadorPress18May04_en.pdf) and

[http://www.3dthree.org/pdf\\_3D/3DEmailnote4\\_Morocco-June06.pdf](http://www.3dthree.org/pdf_3D/3DEmailnote4_Morocco-June06.pdf)

<sup>18</sup> See for example [http://www.3dthree.org/pdf\\_3D/ElSalvadorCOPressRelease\\_en.pdf](http://www.3dthree.org/pdf_3D/ElSalvadorCOPressRelease_en.pdf),

[http://www.3dthree.org/pdf\\_3D/TBemailnote2eng-june05.pdf](http://www.3dthree.org/pdf_3D/TBemailnote2eng-june05.pdf),

[http://www.3dthree.org/pdf\\_3D/3DEmailnote3\\_Thailand-Jan06.pdf](http://www.3dthree.org/pdf_3D/3DEmailnote3_Thailand-Jan06.pdf),

[http://www.3dthree.org/pdf\\_3D/BotswanaCOPressRelease\\_en.pdf](http://www.3dthree.org/pdf_3D/BotswanaCOPressRelease_en.pdf)

<sup>19</sup> WHA56.27, May 2003, [http://www.who.int/gb/ebwha/pdf\\_files/WHA56/ea56r27.pdf](http://www.who.int/gb/ebwha/pdf_files/WHA56/ea56r27.pdf)

<sup>20</sup> 'Public health, Innovation and Intellectual Property Rights', World Health Organization, April 2006. For example recommendation 4.21.

<sup>21</sup> <http://www.theglobalfund.org/en/mediacenter/pressreleases/2011-05->

[26\\_Global\\_Fund\\_strategy\\_aims\\_to\\_help\\_shape\\_market\\_and\\_ensure\\_sustainability\\_of\\_AIDS\\_treatment/](http://www.theglobalfund.org/en/mediacenter/pressreleases/2011-05-26_Global_Fund_strategy_aims_to_help_shape_market_and_ensure_sustainability_of_AIDS_treatment/)

<sup>22</sup> Declaration of Ministers of South America over Intellectual Property, Access to Medicines and Public Health, Geneva, 23 May 2006. The Ministers of Health were from Argentina, Bolivia, Brazil, Chile, Colombia, Ecuador, Paraguay, Peru, Uruguay and Venezuela, <http://lists.essential.org/pipermail/ip-health/2006-May/009594.html>.

<sup>23</sup> Gaborone Declaration, 2nd Ordinary Session of the Conference of African Ministers of Health, Gaborone, Botswana, 10-14 October 2005, CAMH/Decl.1(II), <http://lists.essential.org/pipermail/ip-health/2005-October/008440.html>.

<sup>24</sup> AU's Ministerial Declaration on EPA Negotiations, AU Conference of Ministers of Trade, 3rd Ordinary Session, 5-9 June 2005, Cairo, Egypt, AU/TI/MIN//DECL.(III),

[www.twinside.org.sg/title2/FTAs/General/AFRICAN\\_UNION.Cairo\\_Decl.doc](http://www.twinside.org.sg/title2/FTAs/General/AFRICAN_UNION.Cairo_Decl.doc).

<sup>25</sup> 'Integrating Intellectual Property Rights and Development Policy: Report of the Commission on Intellectual Property Rights', Commission on Intellectual Property Rights, London, 2002. For example, pages 39, 49, 113.

<sup>26</sup> 'Access to Medicines at Risk Across the Globe', Briefing Note, MSF Campaign for Access to Essential Medicines, May 2004, [www.accessmed-msf.org/documents/ftabriefingenglish.pdf](http://www.accessmed-msf.org/documents/ftabriefingenglish.pdf).

in the health budget and a small increase in costs in addition to the implementation of new medicines in the market will have a significant impact upon the health budget.<sup>27</sup>

In the current Trans-Pacific Partnership (TPP) free trade agreement negotiations involving Australia, Brunei, Chile, Malaysia, New Zealand, Peru, Singapore, the USA and Vietnam, a leaked position paper shows that the New Zealand Government has expressed caution about agreeing to TRIPS-plus provisions given the different levels of economic development amongst the TPP countries.<sup>28</sup>

<sup>27</sup> Western Australian Government Submission to Senate Select Committee on the Free Trade Agreement between Australia and the United States of America

<sup>28</sup> <http://www.citizen.org/documents/NZleakedIPpaper-1.pdf>



# The High Price of “Free” Trade: US Free Trade Agreements and Access to Medicines



Ruth Lopert, George Washington University, Washington DC

**Deborah Gleeson, Latrobe University, Melbourne**

**TPP Stakeholder Forum, San Diego, 2 July 2012**

# Introduction

- Expanding IPRs in bilateral and regional FTAs post-TRIPS
- IPRs in TRIPS, AUSFTA, KORUS, TPPA
- Beyond IPRs –  $R_x$  provisions in AUSFTA, KORUS, TPPA
- Final thoughts

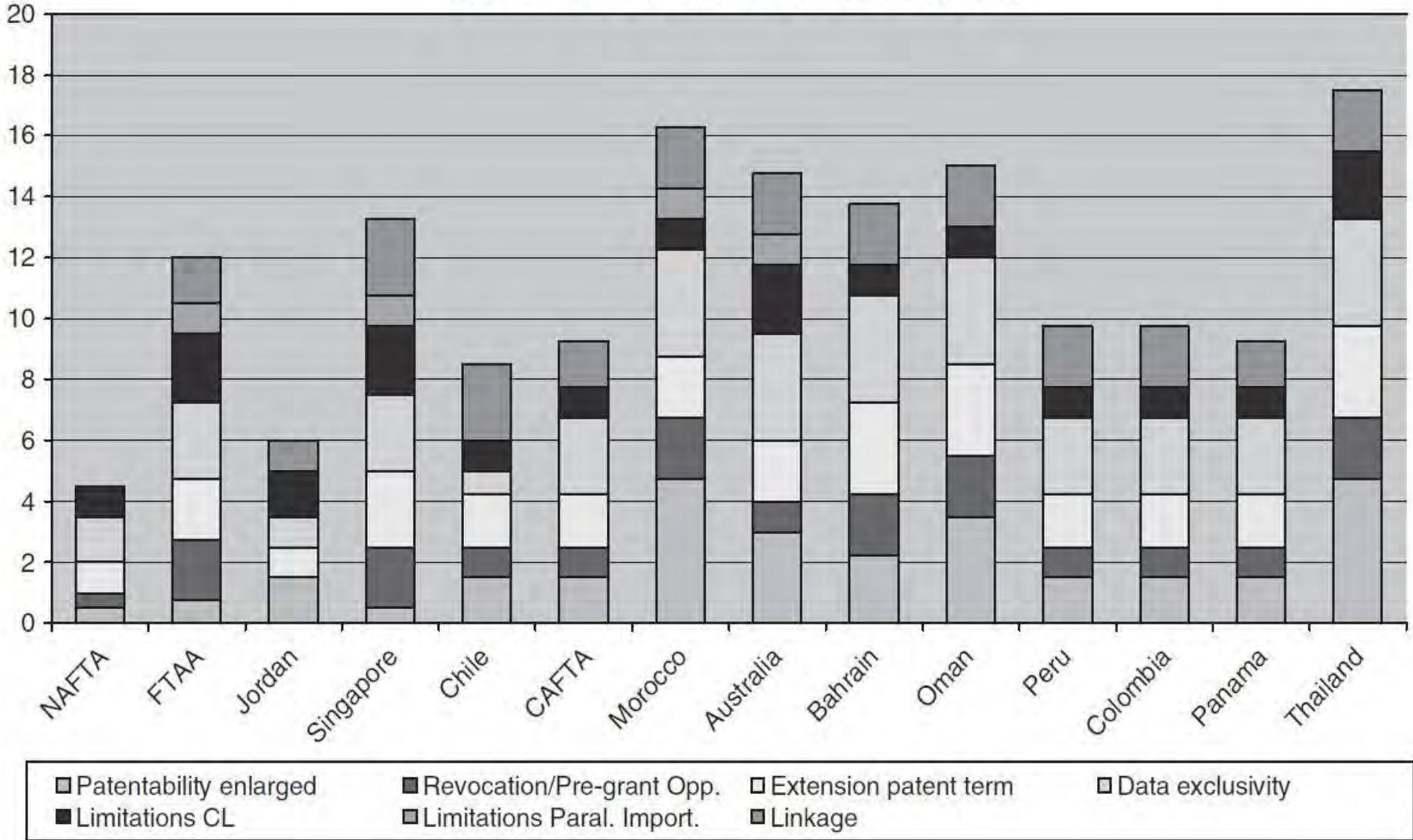


# US Agenda

- TRIPS outcome below US and pharma/PhRMA expectations
- “Forum shifting” by US to pursue increased IPRs for medicines beginning with Jordan US FTA in 2000
- Increasingly TRIPs-Plus obligations
  - extensions to scope of patents
  - limited grounds for patent revocation and elimination of pre-grant opposition
  - patent term restoration
  - prohibition of parallel importation
  - constraints on application of compulsory licensing
  - minimum data protection, extended data protection and data exclusivity provisions
  - linkage between patent status and regulatory approval
- Effects seen empirically, and assessed in modeled analyses
- May 2007 Bipartisan Agreement on Trade Policy - *some* concessions, but only for developing countries

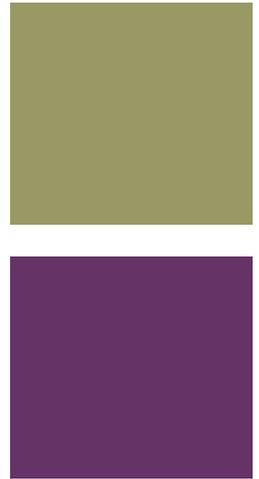


### Evolution of IP provisions in FTAs over time



Krikorian, GP and Syzmkowiak, DM (2007) Intellectual property rights in the making: The evolution of intellectual property rights in US free trade agreements and access to medicine. *Journal of World Intellectual Property*, 10 (5) pp. 388-418.

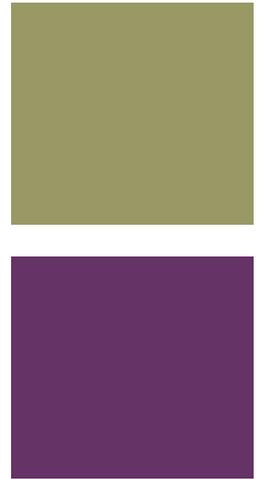
# IP Provisions of AUSFTA, KORUS and TPPA (1)



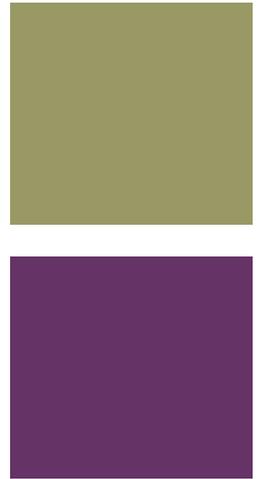
- **Scope of patentability**
  - TRIPS: no reference
  - AUSFTA , KORUS: new uses or methods of using a known product
  - TPPA: new forms, uses and methods; patents for diagnostic, therapeutic and surgical methods
- **Patent term extension**
  - TRIPS: no reference
  - AUSFTA: limited to product patents
  - KORUS: all patents; unreasonable delay defined as 3 years from request for patent examination
  - TPPA: all patents, unreasonable delay defined as 3 years from request for patent examination
- **Pre-grant opposition**
  - TRIPS: no reference
  - AUSFTA: no reference
  - KORUS: effectively eliminated
  - TPPA: explicitly eliminated

## IP Provisions of AUSFTA, KORUS and TPPA (2)

- Data protection for new pharmaceutical products
  - AUSFTA:  $\geq 5$  years undisclosed data,
  - KORUS:  $\geq 5 + 3$ , data *exclusivity (DE)*
  - TPPA: imposes 5+3 DE, 12 years DE for biologics likely
  
- Patent Linkage
  - **AUSFTA:** prevent marketing of generic where product subject to patent, notification to patent holder if market entry during patent term (limited to applications relying on originator data, implemented as self certification)
  - **KORUS:** notification to patent holders of generics requesting marketing approval during patent term, measures to prevent marketing of generic product during patent term
  - **TPPA:** requires *active scan* for existing patents, notification to patent holders, and delay in marketing approval *until any disputes are settled*



# AUSFTA – Beyond IPRs



- USTR’s TPA mandate to seek  
*“the elimination of government measures such as price controls and reference pricing which deny full market access for US products”*
- Australia’s universal pharmaceutical subsidy program, the Pharmaceutical Benefits Scheme, clearly in sight
- Accompanying rhetoric intended to deflect criticism over the high prices of medicines in the US
  - countries that regulate drug prices or utilize evidence based priority setting mechanisms are “free-riding”
  - reducing revenues to the industry, undermining future “innovation”.
- In addition to attempting changes to PBS listing and pricing mechanisms, efforts to gain influence over formulary decision-making

# AUSFTA Rx outcomes

- Widespread public concern focusing on
  - “valuing innovative pharmaceuticals”
  - procedural changes and independent review
  - “dissemination of information’ seen as legalizing DTCA via internet
  - Medicines Working Group as an avenue for US influence
  - patent linkage provision to delay generic market entry
- PBS fundamental building blocks *remained intact*
  - valuing innovation according to “objectively demonstrated therapeutic significance”
  - review process – not an appeal body, unable to remake decision
  - concessions limited to process and transparency in the formulary listing
- US programs carved out
- Initial attempt by the US use FTA to constrain another nation’s domestic drug reimbursement unsuccessful
  - but a precedent in legitimizing provisions of this type within a trade agreement



# KORUS – Beyond IPRs

- Obligations with respect to domestic health programs more intrusive than AUSFTA and now extending to medical devices
  - refers to “patented” rather than “innovative” products
  - reimbursement amounts “*based on competitive market-derived prices*” or determined in a way that “*appropriately recognize(s) the value of the patented pharmaceutical product or medical device*”.
  - requires assessment of innovation based on patent status, and precludes determination based on assessment of value for money or opportunity cost
- Substantial obligations with respect to rulemaking within drug coverage programs
  - significant opportunities for undue industry influence in the listing and pricing processes
  - requires review *body* for listing and *pricing* determinations
- legalization of DTCA via internet
- establishment of a Medicines and Medical Devices Committee



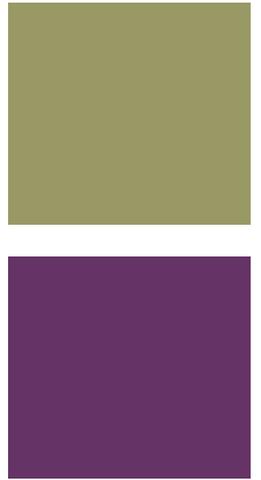
# TPPA – Beyond IPRs

- Provisions directed at Rx coverage programs now directed at developing countries
- “Transparency” Annex similar to KORUS, includes devices, legalizes internet DTCA, requires independent appeal process
- Determination of reimbursement amounts to be based on  
“...*competitive market-derived prices ... that appropriately recognize the value of the patented or generic pharmaceutical products or medical devices*”
  - May preclude both external and therapeutic reference pricing or application of 4<sup>th</sup> hurdle process
- Appeal mechanism facilitates challenges to listing and pricing
- Additional TPP concerns
  - Potential interaction with other chapters eg regulatory coherence, TBT
  - Impact of ISDS provisions
  - Absence of public input and transparency despite extensive consultation with industry through ITAC3 and ITAC15



# Conclusions

- The pursuit of increasing standards of IP protection and provisions that constrain domestic drug coverage programs not only prosecute the interests of a powerful industry
  - also reflects US' enduring adherence to market-based solutions
  - belief that government intervention in response to market failure is largely unnecessary (or at least undesirable)
- *Can a free trade deal ever be of net benefit if the price of improved market access overseas is access to essential medicines at home?*
- At best reflects an absence of policy coherence between trade and health
  - either way makes “free” trade seem a very bad bargain indeed.





Thank you

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# Stakeholder presentation from San Diego, and new empirical study - Notes Memo

**From:** [REDACTED]  
**To:** Brendan.bourke@ipaaustralia.gov.au  
**Sent:** 27-07-2012 1:13:36 PM

all redactions s47F

Hi Brendan,

It was good to meet you in San Diego at the TPP negotiations. I have just been sorting out my notes and realised that you asked for copy of my presentation at the stakeholder forum, but I forgot to send it to you on my return. The slides are attached to this email.

I also thought you might be interested to see a new empirical study published in the Journal of Generic Medicines, which examines the impact of increased intellectual property protections on medicine prices in Jordan following WTO accession and the Jordan-US FTA. It's freely available for a limited time from <http://jgm.sagepub.com/content/9/2/75.full.pdf+html> (please let me know if the link doesn't work and I will send you the full details).

The focus of this article is on data exclusivity, and it adds to the existing evidence base (you have probably already seen the 2007 Oxfam study:

<http://www.oxfam.org/sites/www.oxfam.org/files/all%20costs,%20no%20benefits.pdf>).

I have sent this information to Morna as well.

Regards,  
Deborah

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Political Economy of Health Special Interest Group  
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<Attachment: Gleeson TPP Stakeholder Presentation San Diego July 2012.pdf>

File C2012/12282 FOI 353

was ‘no conflict’ between *Scripps* and *Atlantic*, preferring to lay the blame for the ‘apparent uncertainty [on] the patent community’, Rader believed that there was ‘an apparent conflict’ which needed resolution. The majority of seven judges, however, did not agree, and so leave was refused and these particular proceedings went no further.

The US Supreme Court was eventually brought into the other case in *SmithKline Beecham Corp v Apotex Inc* (2006) 547 US 1218 but, unlike the other proceedings which involved the ‘944 patent, this appeal concerned the validity of the product claim 1 to PHCh in the ‘723 patent.

In this case, the Federal District Court had tried to balance the rights of Apotex (Canadian), SKB (British) and the American public’s need for cheaper drugs by holding the claim to PHCh in the ‘723 patent valid but not infringed. According to the District Court PHC was different from PHCh because the process which Apotex used to make PHC was different from the process claimed in the ‘723 patent. On appeal the CAFC disagreed with the Federal District Court, ruling instead that claim 1 was invalid due to the public use of PHCh (because trace amounts of PHCh were necessarily made during the manufacture of PHC) for more than one year prior to the filing of the patent application. Ironically it was SKB’s own evidence which it tried to use against Apotex in the ‘944 patent case which undermined it in the ‘723 case.

An *en banc* hearing of the CAFC subsequently vacated this first decision and, having directed the CAFC on the law, remanded the appeal back to the CAFC. The CAFC duly delivered a second decision ((2005) 403 F 3d 1331), this time ruling against the validity of claim 1, but for different reasons. In its second attempt to invalidate the patent the CAFC held that claim 1 was invalid because the ‘723 patent was inherently anticipated by the prior art covered by the ‘196 patent’. This, they said, was an example of ‘a prior art reference’ because, even though PHCh was *undisclosed* in the ‘196 patent, it was nonetheless a ‘feature of the claimed invention’. In their opinion, as it was ‘necessarily present, or inherent’ in the production of PHC, it could anticipate. It was irrelevant that in 1977 the inventors of PHC were unaware that PHCh was produced (even in minute amounts) and had therefore failed to disclose it in the ‘196 patent. Citing *Schering Corp v Geneva Pharmaceuticals* (2003) 339 F 3d 1373 with approval, the CAFC reinforced that ‘*inherent anticipation* does not require a person of ordinary skill in the art to recognize the inherent disclosure in the art at the time the prior art is created’.

In what had become a marathon of litigation when it reached the US Supreme Court even the US Solicitor-General (SG) filed a brief as *amicus curiae*, that is as a friend of the Court. This then provided the US Government with an opportunity to make its views publicly known. While

the ultimate legal issue in these proceedings was whether the original patent for PHC granted to Ferrosan AS, which had expired in 1998, anticipated the '723 patent claim to PHCh, the ultimate political issue was the price of medicines for US citizens. In his *amicus curiae* brief, in which the SG agreed with the CAFC, he argued that the US Constitution's grant of power to Congress to promote the progress of science meant that 'patent protection applies only to novel inventions'. He confirmed, "[a] claimed invention may be inherently anticipated by a prior art disclosure if the claimed invention necessarily or inevitably flows from the prior art", see e.g., *Cruciferous Sprout*, 301 F.3d at 1349'.<sup>25</sup> Thus the SG accepted that the production of trace amounts of PHCh was an 'inherent anticipation' because, on the evidence, it was an inevitable by-product of PHC. Describing it as a 'bedrock principle of patent law', he argued: 'if granting patent protection on the disputed claim would allow the patentee to exclude the public from practicing the prior art, then that claim is anticipated, regardless of whether it also covers subject matter not in the prior art'.

For SKB, having lost the '944 patent before the CAFC, this application for leave to appeal to the US Supreme Court was extremely important, given that the market for Paxil was worth billions of dollars. Naturally SKB tried to neutralize the SG's line of reasoning by arguing that such an interpretation of the law posed a general threat to 'the innovation that the patent laws are designed to protect'. The SG countered by pointing out that the more specific and narrower claim to its use as a pharmaceutical to treat anti-depression (claim 5) still provided SKB with patent protection for PHCh as a medicine. 'In this fashion', the SG argued, 'they may retain protection for the actual, practical applications of their new discoveries even if their broader claims to the bare compound are ultimately rejected.' Unfortunately for SKB the US Supreme Court refused leave. That PHC was in the public domain meant that Apotex had every right to manufacture and sell, subject to FDA approval, PHC as a generic medicine. This was good not only for Apotex but also for the American people who needed PHC and would now be able to purchase it at much lower prices.

What is revealing about the history of this litigation is that in 1993 the CAFC had overlooked the SG's reference to the 'bedrock principle' of inherent anticipation in *Bell*, and so upheld as valid a patent over isolated and purified nucleic acid materials which coded for a known protein, whereas in the case of PHCh it applied that very principle to strike down a clearly invalid patent claim which should never have been granted in the first place. Some would argue that the history of the *SKB v Apotex* litigation is a reflection of how well the patent system works, as the invalid patent claim was revoked.

What this case demonstrates instead is just how easy it is for unmeritorious patent claims to be granted, even with extensive pre-grant examination, and how complex, expensive and time-consuming patent litigation is. The irony is that, had it not been for SKB suing Apotex for patent infringement, the validity of these patent claims would not have been scrutinized and probably would have remained on the patents register until their expiry. SKB had enjoyed a lengthy period of patent monopoly protection with PHC and then PHCh, but it sought to use the US patent system to maximize its profits to the detriment of the American people. SKB was not concerned to help those who for many years had been forced to pay a higher than normal price for PHC, and had it not been for the determination of Apotex and its deep pockets it is likely that nothing would have changed. Rather than being an example of how well the US patent system works, this litigation marathon is an example of how inefficient the US patent system is and how the enormous costs of patent litigation (of great benefit only to the patent lawyers involved) is damaging the US economy and is inequitable to the American people.

That, in addition, patents are still being granted for things that are merely isolated versions of naturally existing biological materials is an outcome that must be questioned. Patent law requires more than the mere identification or isolation of a product of nature to qualify as an invention. Given that even the SG accepts that the public domain is the repository of common property that should not be controlled unjustifiably by patents, and that anything inevitably flowing 'from the prior art' is part of the public domain, then it follows that products of nature, even those that are unknown or unappreciated at the time, must be part of the public domain. If patent laws are to be permitted to remove something from the public domain, then there must be some proper basis to justify that removal, even if it be for only a limited period of time and eventually to return to the public domain. That the patent system, despite the law, continues to condone such removal through the administrative actions of patent offices, merely on the basis that isolating a product of nature is an 'invention', means that the patent system is not working as it should and that patent offices are acting *ultra vires*, that is beyond their powers. Even with the pre-grant examination of patents, the patent system remains open to abuse.

The British pharmaceutical company SKB was not in the end deprived entirely of patent protection. Even if the product-by-process claim was invalid, it retained patent protection over the specific process for PHCh production and PHCh as a drug until the '723 patent expired in 2006. In this regard, much like the German patent system which operated between 1877 and 1968, the US patent system seeks to encourage the development of better processes – an incentive that would be removed if a claim over

# TPP - MSF - Notes Memo

File C2012/12282 FOI 357

**From:** [REDACTED]

**To:** brendan.bourke@ipaaustralia.gov.au, [REDACTED]

**Cc:** [REDACTED]

**Sent:** 10-02-2012 10:39:44 AM

all other redactions s47F

Dear [REDACTED] and Mr. Bourke,

It was a pleasure meeting you in Los Angeles during the IP round of the TPP negotiation.

I would like to introduce you to my colleague [REDACTED] that is coordinating our advocacy work from Australia. She is currently travelling for work with limited internet access but I think it is important that you are in contact in preparation of the Australia round.

s33

s33 I am sharing the Oxfam document that I believe provides a good summary of some of the concerns s33

I also would like to share with you an electronic version of the MSF publication I shared with you (Untangling the Web of ARVs price reductions) with ARV pricing and IP data: <http://utw.msfacecess.org/>

We hope this is useful. We would be happy to provide you with more background on this issue and even have a follow up call.

regards,

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

TPP: IP: [REDACTED]

[SEC=IN-CONFIDENCE:FTA] -

Notes Memo

From: [s47F]

To: "Brendan.Bourke@ipaaustralia.gov.au" <Brendan.Bourke@ipaaustralia.gov.au>, "Constantine.Nikolakopoulos@ipaaustralia.gov.au" <Constantine.Nikolakopoulos@ipaaustralia.gov.au>, "Karl.Brennan@innovation.gov.au" <Karl.Brennan@innovation.gov.au>, "Losada-Rodriguez, Ivan (Ivan.Losada-Rodriguez@innovation.gov.au)" <Ivan.Losada-Rodriguez@innovation.gov.au>, "Kate.Moerman@innovation.gov.au" <Kate.Moerman@innovation.gov.au>

Cc: [s47F]

Sent: 04-06-2012 12:11:46 AM

Dear All

[REDACTED]

Post has requested our advice on the queries [REDACTED] concerning which agencies should participate [REDACTED] I would be grateful for your initial views/suggestions in relation to these points by **COB 6 June**, so we can provide early advice to post. Please donâ€™t hesitate to contact me if you need to discuss.

With thanks and regards

[s47F]

[s47F]

Executive Officer  
International Intellectual Property Section  
Office of Trade Negotiations  
Australian Department of Foreign Affairs & Trade  
Tel: [s47F]  
Fax: +61 2 6112 2347

[all other redactions s33]

[REDACTED]

[REDACTED]

s33

Re: TPP: IP: s33

[SEC=IN-CONFIDENCE] - Notes Reply

File C2012/12282 FOI 359

From: [Brendan Bourke](mailto:Brendan.Bourke@ipaustralia.gov.au)

To: "Constantine.Nikolakopoulos@ipaustralia.gov.au" <Constantine.Nikolakopoulos@ipaustralia.gov.au>, "Losada-Rodriguez, Ivan (Ivan.Losada-Rodriguez@innovation.gov.au)" <Ivan.Losada-Rodriguez@innovation.gov.au>, "Karl.Brennan@innovation.gov.au" <Karl.Brennan@innovation.gov.au>, More...

Sent: 06-06-2012 1:50:20 PM

H

Thanks for forwarding this to us and seeking our input.

IP Australia can attend the meeting s33 We will advise of participants at a later date.

all other redactions s47F

s33

**Brendan Bourke**  
Assistant Director  
International Policy & Cooperation  
Business Development & Strategy Group  
IP Australia

---04/06/2012 10:11:49 AM---Dear All Attached is a s33



P + 61 2 6283 2148 | F + 61 2 6283 7999  
E [brendan.bourke@ipaustralia.gov.au](mailto:brendan.bourke@ipaustralia.gov.au)  
A 47 Bowes Street, Woden ACT 2606 | PO Box 200, Woden ACT Australia 2606

Visit us at <http://www.ipaustralia.gov.au>

Please consider the environment before printing this email

From: [Redacted]  
To: "Brendan.Bourke@ipaustralia.gov.au" <Brendan.Bourke@ipaustralia.gov.au>, "Constantine.Nikolakopoulos@ipaustralia.gov.au" <Constantine.Nikolakopoulos@ipaustralia.gov.au>, "Karl.Brennan@innovation.gov.au" <Karl.Brennan@innovation.gov.au>, "Losada-Rodriguez, Ivan (Ivan.Losada-Rodriguez@innovation.gov.au)" <Ivan.Losada-Rodriguez@innovation.gov.au>, "Kate.Moerman@innovation.gov.au" <Kate.Moerman@innovation.gov.au>  
C: [Redacted]  
Date: 04/06/2012 10:11 AM  
Subject: TPP: IP s33 [SEC=IN-CONFIDENCE:FTA]

Dear All

s33

s33

to these points by COB 6 June, so we can provide early advice to post. Please don't hesitate to contact me if you need to discuss.

I would be grateful for your initial views/suggestions in relation

With thanks and regards

Executive Officer  
International Intellectual Property Section  
Office of Trade Negotiations  
Australian Department of Foreign Affairs & Trade

Tel: [Redacted]  
Fax: +61 2 6112 2347

s33

s33

TPP: IP: [REDACTED]  
Memo

[SEC=IN-CONFIDENCE] - Notes

From: "Lunn, Peter" <Peter.Lunn@innovation.gov.au>

all other redactions s33

To: s47F

Cc: "Seymour-Munn, Kate" <Kate.Seymour-Munn@innovation.gov.au>, "Moerman, Kate" <Kate.Moerman@innovation.gov.au>, <Brendan.Bourke@ipaustralia.gov.au>, "Losada-Rodriguez, Ivan" <Ivan.Losada-Rodriguez@innovation.gov.au>, <Matthew.Forno@ipaustralia.gov.au>, More...

Sent: 06-06-2012 3:38:32 PM

s47F

DIISRTE will be attending [REDACTED], names of participants will be advised closer to the date; please note that we have a preference for a meeting on the morning of the 26 July.

A number of Australian interests potentially affected by the provisions might be interested in attending including the Generics Medicines Industry of Australia (GMiA) and the Medical Technology Association of Australia (MTAA) . MTAA and the largest member of the GMiA (Alphapharm, a major generics company manufacturing in Australia, owned by Mylan) both provided submissions to the TPP negotiation process:

[http://www.dfat.gov.au/fta/tpp/subs/tpp\\_sub\\_Medical-Technology-Association-of-Australia.pdf](http://www.dfat.gov.au/fta/tpp/subs/tpp_sub_Medical-Technology-Association-of-Australia.pdf) ;

[http://www.dfat.gov.au/fta/tpp/subs/tpp\\_sub\\_alphapharm\\_110314.pdf](http://www.dfat.gov.au/fta/tpp/subs/tpp_sub_alphapharm_110314.pdf)

We have discussed [REDACTED] with colleagues at IP Australia and agree with their comments as well as have some additional comments.

[REDACTED]

Thanks  
Peter Lunn BA (Hons) LLB  
A/g General Manager

s33 exemption

**RE: [REDACTED] - IPA representation [SEC=IN-CONFIDENCE] - Notes Memo**

**From:** "Seymour-Munn, Kate" <Kate.Seymour-Munn@innovation.gov.au> all other redactions s33  
**To:** <Brendan.Bourke@ipaaustralia.gov.au>  
**Cc:** <Constantine.Nikolakopoulos@ipaaustralia.gov.au>, "Moerman, Kate" <Kate.Moerman@innovation.gov.au>, "Lunn, Peter" <Peter.Lunn@innovation.gov.au>, <Edwina.Lewis@ipaaustralia.gov.au>  
**Sent:** 18-07-2012 4:42:36 PM

Thanks very much for this Brendan. Our representation [REDACTED] is likely to be Peter Lunn, Tricia Berman, Acting Head on Innovation Division and Kate Moerman.

[REDACTED] s47F

s47F so I look forward to finding out how it is all progressing when I return.

Regards  
Kate

---

**From:** Brendan.Bourke@ipaaustralia.gov.au [mailto:Brendan.Bourke@ipaaustralia.gov.au]  
**Sent:** Wednesday, 18 July 2012 4:18 PM  
**To:** Seymour-Munn, Kate  
**Cc:** Constantine.Nikolakopoulos@ipaaustralia.gov.au; Moerman, Kate; Lunn, Peter; Edwina.Lewis@ipaaustralia.gov.au  
**Subject:** Re: [REDACTED] IPA representation [SEC=IN-CONFIDENCE]

Hi Kate

s47F

s47F so I haven't been able to confirm our participants. However at this stage it is likely to be myself and either Matt or Robyn [REDACTED] I won't be able to confirm until next week s47F

Some feedback from the San Diego round just completed:

- [REDACTED]
- [REDACTED]
- the next round is in Virginia, USA. The round is 6-15 September 2012, with the IP group meeting from 8-15 September. [REDACTED]
- there was talk of an intersessional in October, but not going ahead, so the next round after September will be December (venue to be confirmed).

**Brendan Bourke**  
Assistant Director

[REDACTED]

International Policy & Cooperation  
Business Development & Strategy Group  
IP Australia

all other redactions s33



P + 61 2 6283 2148 F + 61 2 6283 7999 M s47F

E [brendan.bourke@ipaaustralia.gov.au](mailto:brendan.bourke@ipaaustralia.gov.au)

A 47 Bowes Street, Woden ACT 2606 PO Box 200, Woden ACT Australia 2606

Visit us at <http://www.ipaustralia.gov.au>

Please consider the environment before printing this email

From: "Seymour-Munn, Kate" <Kate.Seymour-Munn@innovation.gov.au>

To: <Constantine.Nikolakopoulos@ipaaustralia.gov.au>

Cc: <Brendan.Bourke@ipaaustralia.gov.au>, "Moerman, Kate" <Kate.Moerman@innovation.gov.au>, "Lunn, Peter" <Peter.Lunn@innovation.gov.au>

Date: 13/07/2012 02:54 PM

Subject: [REDACTED] IPA representation [SEC=UNCLASSIFIED]

Hi Con

Are you able to advise whether IPA have decided who will attend [REDACTED] When last we all discussed you were going to discuss representation and meeting strategy with Phillip Noonan on his return from overseas.

I realise Brendan may still be away for San Diego but if you could let us know the latest by cob Thu 19 July it would be helpful as we are meeting here on 20th to discuss. As we indicated when we last met, we are aiming to have representation at Division Head level although this may not ultimately be possible due to changing acting arrangements and prior commitments.

Thanks and regards

Kate

**Kate Seymour-Munn**

Acting Manager

Pharmaceuticals & Health Technologies

Innovation Division

---

Department of Industry, Innovation, Science, Research & Tertiary Education

Industry House Level 10

10 Binara St, Canberra City ACT 2601

GPO Box 9839, Canberra ACT 2601

Ph: 61-2-6276 1254 Fax: 61-2 6276 1244

Email: [kate.seymour-munn@innovation.gov.au](mailto:kate.seymour-munn@innovation.gov.au)

Internet: <http://www.innovation.gov.au>

ABN 74 599 608 295

all redactions s33

\*\*\*\*\*

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\*\*\*\*\*

<Attachment: ATT32383877.gif>

TPP: Roundtable [REDACTED] Further Details [SEC=IN-CONFIDENCE] - Notes Memo

From: s47F  
To: [REDACTED]

Cc: "Brendan.Bourke@ipaustrialia.gov.au" <Brendan.Bourke@ipaustrialia.gov.au>,  
"Matthew.Forno@ipaustrialia.gov.au" <Matthew.Forno@ipaustrialia.gov.au>, More...  
"Kate.Seymour-Munn@innovation.gov.au" <Kate.Seymour-Munn@innovation.gov.au>,  
s47F  
s47F "Constantine.Nikolakopoulos@ipaustrialia.gov.au"  
<Constantine.Nikolakopoulos@ipaustrialia.gov.au>, s47F  
More...

Sent: 19-07-2012 12:39:42 AM [REDACTED] all other redactions s33

Dear Colleagues

Thank you for agreeing to participate in the upcoming roundtable [REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]

The group will be led by [REDACTED]  
[REDACTED]

- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]

[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]

**Agenda**

Based on this information, we have developed the following agenda for the roundtable:

1. Welcome and introductions
2. Industry representatives' perspectives [REDACTED]
3. Comments from government representatives and general discussion
4. Closing remarks

We see the purposes of the roundtable as twofold. [REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]

**Government attendees**

DFAT representatives will include: Hamish McCormick (FAS, Office of Trade Negotiations and TPP chief negotiator) who will provide some introductory remarks; Elizabeth Ward (AS, Goods and Investment Branch and TPP deputy chief negotiator)

[REDACTED]  
who will be chairing the discussion; s47F (A/g Director, investment Policy and TPP Section, and TPP transparency lead); s47F (Executive Officer, International Intellectual Property Section and TPP IP lead); s47F (Director, International Intellectual Property Section); and staff from our US Section.

Please let us know the representatives from your agencies (including their positions) who will attend the roundtable, and whether they need a visitor pass, by Monday 23 July. To help keep numbers manageable, we would suggest that a maximum of two people attend from each agency. Please copy your RSVP to s47F

s47F

#### Timing

The roundtable will be held on Thursday 26 July from 10am to 12pm at DFAT. We would appreciate if attendees could arrive at DFAT reception by 9.50am, to be escorted up to the meeting room. Tea and coffee will be served just prior to commencing the roundtable.

If you have any questions, please do not hesitate to contact me or s47F. We look forward to seeing you next week.

Thanks and kind regards

s47F

Executive Officer  
International Intellectual Property Section  
Office of Trade Negotiations  
Australian Department of Foreign Affairs & Trade  
Tel: s47F  
Fax: +61 2 6112 2347

possible portfolio position [SEC=UNCLASSIFIED] - Notes Memo

**From:** "Lunn, Peter" <Peter.Lunn@innovation.gov.au>  
**To:** <Brendan.Bourke@ipaustralia.gov.au>  
**Cc:** "Murray, Jane" <Jane.Murray@innovation.gov.au>  
**Sent:** 24-07-2012 2:18:29 PM

all redactions s33

Brendan  
After our conversation yesterday I jotted down a possible portfolio position, I understood that you called and can you call me if you want to talk about this or something else.

briefing could be along the lines of:

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

Thanks  
Peter Lunn BA (Hons) LLB  
A/g General Manager



. | [REDACTED]

. [REDACTED]

[REDACTED]

. [REDACTED]

[REDACTED]

[REDACTED]



[REDACTED]

*Is there a wider "development" impact from the proposed US text?*

- . The proposals may increase the cost of medicines and/or delay the introduction of generic medicines, which may make it harder for the poorest in developing countries to access necessary treatment. Australia's current aid expenditure on medicines and vaccines would not maintain its current reach.
  - AusAID works through the Global Fund to Fight AIDS, Tuberculosis and Malaria, the GAVI Alliance, and NGOs and other multilateral organisations to ensure that life-saving medicines reach people in developing countries in our region. These organisations often use cheaper, generic pharmaceuticals.
  - A number of NGO stakeholders have met with AusAID to raise their concerns about ensuring continued access to affordable medicines.

120723 TPP - [REDACTED] meeting with PhRMA (brief) (2) with NC comments (2).docx [SEC=IN-CONFIDENCE:BRIEFING] - Notes Memo

From: [REDACTED]  
To: [REDACTED] s47F >  
Cc: "brendan.bourke@ipaustrialia.gov.au" <brendan.bourke@ipaustrialia.gov.au>, [REDACTED] s47F >  
Sent: 24-07-2012 05:06:19 AM

[REDACTED] s47F

[REDACTED] Our suggestion is in red in the attached.

We're happy with the rest of the draft. And happy to discuss further.

[REDACTED] s47F

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<Attachment: 120723 TPP - [REDACTED] meeting with PhRMA (brief) (2) with NC comments (2).docx>

[REDACTED] all other redactions s33



. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]





TPP: IP: Draft brief for [REDACTED] meeting with PhRMA/BIO [SEC=IN-CONFIDENCE] - Notes Memo

**From:** [REDACTED]  
**To:** "Brendan.Bourke@ipaaustralia.gov.au" <Brendan.Bourke@ipaaustralia.gov.au>, [REDACTED]  
**Sent:** 24-07-2012 02:25:50 AM

all redactions s47F

Hi [REDACTED] Brendan, [REDACTED]  
Apologies for the short notice – we’ve received a last minute request for (high-level) brief for a meeting between PhRMA/BIO and [REDACTED]. That meeting is scheduled Thursday afternoon (after our roundtable); the [REDACTED] has requested the brief by COB today. [REDACTED] and I have prepared the attached draft brief and would be grateful for your comments **by 4pm today**.  
Many thanks and regards

[REDACTED]  
[REDACTED]  
Executive Officer  
International Intellectual Property Section  
Office of Trade Negotiations  
Australian Department of Foreign Affairs & Trade  
Tel: [REDACTED]  
Fax: +61 2 6112 2347

<Attachment: 120723 TPP - [REDACTED] meeting with PhRMA (brief).docx>

s33

Re: TPP: IP: Draft brief for [redacted] meeting with PhRMA/BIO [SEC=IN-CONFIDENCE] - Notes Reply

File C2012/12282 FOI 384

From: [Brendan.Bourke@ipaustalia.gov.au](mailto:Brendan.Bourke@ipaustalia.gov.au)  
To: [redacted]  
Cc: [redacted]  
Sent: 24/07/2012 2:37:23 PM

all other redactions s47F

Hi [redacted]

Thanks for sending this to us.

Looks good from our perspective. Have only suggested one change, consistent with our view that [redacted]

s33

<Attachment: 120723 TPP [redacted] with PhRMA (brief)(2).docx>

s33

**Brendan Bourke**  
Assistant Director  
International Policy & Cooperation  
Business Development & Strategy Group  
IP Australia

[redacted] a" --24/07/2012 12:26:00 PM---Hi [redacted] Brendan, [redacted] Apologies for the short notice - we've received a last minute request for



P + 61 2 6283 2148 | F + 61 2 6283 7996 [redacted]  
E [brendan.bourke@ipaustalia.gov.au](mailto:brendan.bourke@ipaustalia.gov.au)  
A 47 Bowes Street, Woden ACT 2606 | PO Box 200, Woden ACT Australia 2606

Visit us at <http://www.ipaustalia.gov.au>

♻️ Please consider the environment before printing this email

From: [redacted]  
To: "Brendan.Bourke@ipaustalia.gov.au" <Brendan.Bourke@ipaustalia.gov.au> [redacted]  
Date: 24/07/2012 12:26 PM  
Subject: TPP: IP: Draft brief for [redacted] PhRMA/BIO [SEC=IN-CONFIDENCE]

s33

Hi [redacted] Brendan, [redacted]

Apologies for the short notice – we've received a last minute request for (high-level) brief for a meeting between PhRMA/BIO and [redacted] the brief by COB today.

s33

That meeting is scheduled Thursday afternoon (after our roundtable); the

s33

[redacted] and I have prepared the attached draft brief and would be grateful for your comments by 4pm today.

Many thanks and regards

[redacted]  
Executive Officer  
International Intellectual Property Section  
Office of Trade Negotiations  
Australian Department of Foreign Affairs & Trade

Tel: [redacted]  
Fax: +61 2 6112 2347

<Attachment: 120723 TPP [redacted] with PhRMA (brief).docx>

s33

s33

s33 exemption

s33 exemption

s33 exemption

s33 exemption

s33 exemption

TPP: IPA brief for meeting [REDACTED] [SEC=IN-CONFIDENCE] - Notes Reply

From: [Brendan.Bourke@ipaaustralia.gov.au](mailto:Brendan.Bourke@ipaaustralia.gov.au)

all redactions s47F

To: [REDACTED]

Cc: [REDACTED]

Matthew Forno/OU=CBR/IPAustralia@IP\_Australia,

peter.lunn@innovation.gov.au

Sent: 25-07-2012 12:01:32 PM

Hi [REDACTED]

As promised, attached is a copy of our brief for the meeting tomorrow. The first couple of pages are our key points, while the rest is more of an 'if needed' basis [REDACTED]).

[REDACTED]

**Brendan Bourke**

Assistant Director

International Policy & Cooperation

Business Development & Strategy Group

IP Australia



P + 61 2 6283 2148 | F + 61 2 6283 7999 | [REDACTED]

E [brendan.bourke@ipaaustralia.gov.au](mailto:brendan.bourke@ipaaustralia.gov.au)

A 47 Bowes Street, Woden ACT 2606 | PO Box 200, Woden ACT Australia 2606

Visit us at <http://www.ipaustralia.gov.au>

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[REDACTED]

s33 exemption

s33 exemption

s33 exemption

s33 exemption

File C2012/12282 FOI 395

**FW: Proposed agenda and participant list [SEC=UNCLASSIFIED] - Notes Memo**

**From:** [Redacted]  
**To:** [Redacted] Brendan Bourke  
(brendan.bourke@ipaustalia.gov.au)" <brendan.bourke@ipaustalia.gov.au>  
**Cc:** [Redacted]  
**Sent:** 01-08-2011 02:57:26 AM

UNCLASSIFIED

all redactions s47F

[Redacted]/Brendan/[Redacted]

We (DFAT) have been asked to host a roundtable on the TPP and Public Health, which is taking place here on Wednesday morning (see details below). With apologies for the very late notice, you are all welcome to come along if you're able. You'll see from the agenda that we will be giving briefings on various aspects of the negotiations [Redacted] the briefings will be based on those we do at stakeholder consultations. The presentations will then be followed by open discussion. Please let me know if you're able to attend so that I can arrange visitor passes for you.

Kind regards,

[Redacted]  
Executive Officer  
FTA Commitments & Implementation Section  
Office of Trade Negotiations  
Department of Foreign Affairs & Trade  
[Redacted]

UNCLASSIFIED

---

**From:** [Redacted]  
**Sent:** Monday, 1 August 2011 11:31 AM  
**To:** [Redacted]  
**Cc:** [Redacted]  
**Subject:** FW: Proposed agenda and participant list [SEC=UNCLASSIFIED]

UNCLASSIFIED

Hello,  
This roundtable is scheduled Wednesday 3 August, 9.30 -11.30am. Westerman Room.  
Judy

**From:** deborah.gleeson@trobe.edu.au [Redacted] **On Behalf Of** Deborah Gleeson  
**Sent:** Thursday, 28 July 2011 1:24 PM

**To:** [Redacted]  
**Subject:** Proposed agenda and participant list [SEC=UNCLASSIFIED]  
Dear [Redacted]

Thanks again for hosting the roundtable discussion on Wednesday.  
Attached is a proposed agenda and the list of participants. On reflection, I thought it would be best to give each of the speakers 10 minutes - we will aim to move quickly through the presentations so that plenty of time will remain for discussion.  
Regards  
Deborah

--  
Deborah Gleeson MPH PhD  
Research Fellow  
School of Public Health  
La Trobe University VIC 3086  
T: 03 9479 3262  
M: 0423 209029

UNCLASSIFIED

<Attachment: TPPA Roundtable - Proposed agenda 110728.doc><Attachment: TPPA Roundtable participant list 110728.doc>

FW: IP: [s33] [SEC=IN-CONFIDENCE] -  
Notes Memo

**From:** [Redacted]  
**To:** "Brendan.Bourke@ipaustrialia.gov.au" <Brendan.Bourke@ipaustrialia.gov.au>, "Constantine.Nikolakopoulos@ipaustrialia.gov.au" <Constantine.Nikolakopoulos@ipaustrialia.gov.au>, "Karl.Brennan@innovation.gov.au" <Karl.Brennan@innovation.gov.au>, "Losada-Rodriguez, Ivan (Ivan.Losada-Rodriguez@innovation.gov.au)" <Ivan.Losada-Rodriguez@innovation.gov.au>, "Kate.Moerman@innovation.gov.au" <Kate.Moerman@innovation.gov.au>  
**Cc:** "Kate.Seymour-Munn@innovation.gov.au" <Kate.Seymour-Munn@innovation.gov.au>, "Paul.Trotman@innovation.gov.au" <Paul.Trotman@innovation.gov.au> [Redacted]  
**Sent:** 15-06-2012 02:25:52 AM

Dear Colleagues

Many thanks for your input on the upcoming [s33]. We have taken your comments on board and [s33]. [s33] We will keep you posted as plans for the visit develop. In the meantime, please don't hesitate to contact me if you would like to discuss.

Kind regards

[Redacted]

Executive Officer  
International Intellectual Property Section  
Office of Trade Negotiations  
Australian Department of Foreign Affairs & Trade

[Redacted] all other redactions s47F

**From:** [Redacted]  
**Sent:** Monday, 4 June 2012 10:12 AM  
**To:** Brendan.Bourke@ipaustrialia.gov.au; Constantine.Nikolakopoulos@ipaustrialia.gov.au; Brennan, Karl; Losada-Rodriguez, Ivan; Moerman, Kate  
**Cc:** [Redacted]  
**Subject:** TPP: [s33] [SEC=IN-CONFIDENCE:FTA]

Dear All

Attached is a cable from Washington advising us of a planned visit [s33] [s33] for TPP-related discussions on 26-27 July 2012. [s33] would like to meet with relevant government agencies, and possibly NGOs, to discuss IP and transparency issues in the TPP. (Note: we have separately e-mailed this to Health and AusAID.)

[Redacted]

would be grateful for your initial views/suggestions in relation to these points by **COB 6 June**, so we can provide early advice to post. Please don't hesitate to contact me if you need to discuss.

With thanks and regards

[Redacted]

Executive Officer  
International Intellectual Property Section  
Office of Trade Negotiations  
Australian Department of Foreign Affairs & Trade



\*\*\*\*\*

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\*\*\*\*\*

<Attachment:

s33



all other redactions s47F

s33 exemption

# IPRIA Project - Evergreening Patents [SEC=UNCLASSIFIED] - Notes Memo

**From:** [Brendan.Bourke@ipaaustralia.gov.au](mailto:Brendan.Bourke@ipaaustralia.gov.au)  
**To:** [REDACTED]  
**Cc:** Adam Wright/OU=CBR/IPAustralia@IP\_Australia, Constantine Nikolakopoulos/OU=CBR/IPAustralia@IP\_Australia  
**Sent:** 21-12-2011 5:08:35 PM

all other redactions s47F

Hi [REDACTED]

I'm working on the Trans Pacific Partnership (TPP). s33

s33

I know evergreening is on the IPRIA work program, but I don't know if work has started yet. If you have any information you can share that might be relevant to the above or point me to any other research you are aware of, I would welcome it.

Thanks and have a great Christmas

Brendan

(Note that I'll be on leave for a few weeks in January, so could you please copy Adam Wright into any email response.)

**Brendan Bourke**

Assistant Director

International Policy & Cooperation

Business Development & Strategy Group

IP Australia



E [brendan.bourke@ipaaustralia.gov.au](mailto:brendan.bourke@ipaaustralia.gov.au)

File C2012/12282 FOI 407

A 47 Bowes Street, Woden ACT 2606 | PO Box 200, Woden ACT Australia 2606

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RE: Update re TPP and DOHA [SEC=IN-CONFIDENCE:FTA] - Notes Memo

**From:** [Redacted]  
**To:** [Redacted]  
**Cc:** [Redacted] "brendan.bourke@ipaustrialia.gov.au"

<brendan.bourke@ipaustrialia.gov.au>,  More...

**Sent:** 22-12-2011 01:26:59 AM

mime.htm

all redactions s47F

<Attachment: mime.htm>

From: [Brendan Bourke@ipaustralia.gov.au](mailto:Brendan.Bourke@ipaustralia.gov.au)  
To: "Seymour-Munn, Kate" <Kate.Seymour-Munn@innovation.gov>  
Cc: Constantine Nikolakopoulos<UU=CBR/IPAustralia@IP\_Australia, Adam Wright<UU=CBR/IPAustralia@IP\_Australia, Edwina Lewis<UU=CBR/IPAustralia@IP\_Australia  
Sent: 23-12-2011 10:28:38 AM

Hi All

Attached is a chart Con put together comparing the TPP proposal with other FTAs. It is similar to some of the charts put together by the NGOs that you may have seen.  
<Attachment: 20111222 Comparative table of key patent provisions from certain US FTAs.doc>

I also note that Oxfam have produced a paper

s33

Have a Merry Christmas

**Brendan Bourke**  
Assistant Director  
International Policy & Cooperation  
Business Development & Strategy Group  
IP Australia

all other redactions s47F

---20/12/2011 11:39:55 AM---I think you said Con was doing some of this type of work? has just forwarded this to me from th



P + 61 2 6283 2148 | F + 61 2 6283 7000  
E [brendan.bourke@ipaustralia.gov.au](mailto:brendan.bourke@ipaustralia.gov.au)  
A 47 Bowes Street, Woden ACT 2606 | PO Box 200, Woden ACT Australia 2606

Visit us at <http://www.ipaustralia.gov.au>

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From: [redacted]  
To: "Brendan Bourke (brendan.bourke@ipaustralia.gov.au)" <brendan.bourke@ipaustralia.gov.au>  
Date: 20/12/2011 11:39 AM  
Subject: FW: Briefing re IP issues [SEC=UNCLASSIFIED]

I think you said Con was doing some of this type of work? has just forwarded this to me from the Public Citizen website, FYI.

M,

FIA Commitments & Implementation Section  
Office of Trade Negotiations  
Department of Foreign Affairs & Trade  
Tel: [redacted]  
Fax: 02 6112 3773

From: [redacted]  
Sent: Tuesday, 20 December 2011 10:41 AM  
To: [redacted]  
Subject: Briefing re IP issues

Dear [redacted]

I realize you may be going on leave, but would like to put in a bid for a telephone briefing on IP issues when you return. Could you please let me know of some possible dates?

Hope you have a happy Christmas and New year . Also below are details of another Public Citizen chart which may be useful, if you have not already received it.

Thanks

Public Citizen has produced a chart comparing the pharmaceutical patent and data protection provisions of the following texts:

- the leaked United States proposals to the Trans-Pacific Free Trade Agreement;
- the World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property Rights; and
- Free Trade Agreements between the United States and Singapore, Australia, Chile, Peru (the "template" agreements).

There is also a short form, two-page version for easy reference.

Both can be found here: <http://www.citizen.org/comparative-chart-trips-tfta-fta>

PDF of long form (full provisions) here: <http://www.citizen.org/documents/Comparative-chart-of-TPETA-TRIPS-FTAs.pdf>

PDF of short form here: [http://www.citizen.org/documents/Comparative-chart-of-TPETA-TRIPS-FTAs\(short-form\).pdf](http://www.citizen.org/documents/Comparative-chart-of-TPETA-TRIPS-FTAs(short-form).pdf)

[redacted] and Campaign Centre  
Level 3, Trades Hall Building  
4-10 Gouldburn St  
Sydney 2000



  
Peter Lunn BA (Hons) LLB  
A/g General Manager

File C2012/12282 FOI 411

all redactions s33

s33 exemption

TPP: [REDACTED] IP - Proposed Agenda for Meeting on Monday 20 Feb  
[SEC=IN-CONFIDENCE] - Notes Memo

From: [Brendan Bourke@ipaaustralia.gov.au](mailto:Brendan.Bourke@ipaaustralia.gov.au)

To: s47F

More...

Sent: 17-02-2012 2:02:38 PM

Hi everyone

After speaking with s47F I am circulating a proposed agenda for Monday's meeting. Unfortunately Melissa Hutchings (DFAT) can't attend but we felt it important, given the time constraints, to keep the ball rolling.

All other redactions s33

Attached is a draft paper that we have been working on. [REDACTED]

The meeting room (NG.F14) is on the ground floor in the Conference Centre (main entrance), so you will not need to sign in. We will let the security guard on the ground floor now so he can point you in the right direction when you arrive.

Look forward to seeing you Monday.

**Brendan Bourke**  
Assistant Director  
International Policy & Cooperation  
Business Development & Strategy Group  
IP Australia



P + 61 2 6283 2148 | F + 61 2 6283 7999 | s47F

E [brendan.bourke@ipaaustralia.gov.au](mailto:brendan.bourke@ipaaustralia.gov.au)

A 47 Bowes Street, Woden ACT 2606 | PO Box 200, Woden ACT Australia 2606

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All other redactions s33

s33

Re: TPP IP text

s33

[SEC=IN-CONFIDENCE] - Notes Reply

File C2012/12282 FOI 439

all other redactions s47F

From: [Brendan Bourke](mailto:Brendan.Bourke@ipaustralia.gov.au) <[Brendan.Bourke@ipaustralia.gov.au](mailto:Brendan.Bourke@ipaustralia.gov.au)>

To: [REDACTED]

Sent: 21-02-2012 10:12:33 AM

H [REDACTED]

s33

**Brendan Bourke**  
Assistant Director  
International Policy & Cooperation  
Business Development & Strategy Group  
IP Australia



P + 61 2 6283 2148 | F + 61 2 6283 7999 | [REDACTED]  
E [brendan.bourke@ipaustralia.gov.au](mailto:brendan.bourke@ipaustralia.gov.au)  
A 47 Bowes Street, Woden ACT 2606 | PO Box 200, Woden ACT Australia 2606

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To: "Brendan Bourke" <[brendan.bourke@ipaustralia.gov.au](mailto:brendan.bourke@ipaustralia.gov.au)> <[brendan.bourke@ipaustralia.gov.au](mailto:brendan.bourke@ipaustralia.gov.au)>, Karl Brennan <[karl.brennan@innovation.gov.au](mailto:karl.brennan@innovation.gov.au)>, "Kirsty Peters" <[kirsty.peters@innovation.gov.au](mailto:kirsty.peters@innovation.gov.au)> <[kirsty.peters@innovation.gov.au](mailto:kirsty.peters@innovation.gov.au)>, Peter Lunn <[peter.lunn@innovation.gov.au](mailto:peter.lunn@innovation.gov.au)> <[peter.lunn@innovation.gov.au](mailto:peter.lunn@innovation.gov.au)>

Date: 13/02/2012 12:09 PM

Subject: TPP IP text [REDACTED] [SEC=IN-CONFIDENCE:FTA]

Morning everyone,

s33

I would be most interested in your views, and thoughts on whether we should aim to put forward something along these lines in Melbourne (which is only 2.5 weeks away!). I'd be most grateful if you could let me know your preliminary thoughts by the end of this week, and we can move forward from there.

Kind regards, [REDACTED]

[REDACTED]  
Acting Director  
FTA Commitments & Implementation Section  
Office of Trade Negotiations  
Department of Foreign Affairs & Trade  
Tel: [REDACTED]  
Fax: 02 6112 3773

[REDACTED] - 13/02/2012 12:09:56 PM---Morning everyone

s33

s33

**Trans Pacific Partnership (TPP): IP** s33

**Meeting**

Monday, 20 February 2012, 3pm-4pm  
 Venue: Room NGF14 (Ground Floor) of IP Australia  
 Discovery House, 47 Bowes Street, Woden ACT 2606

**List of Attendees**

Name	Organisation
Matthew Forno (from 3.30pm)	IP Australia
Brendan Bourke	IP Australia
Adam Wright	IP Australia
Con Nikolakopoulos	IP Australia
[REDACTED]	Department of Industry, Innovation, Science, Research and Tertiary Education
[REDACTED]	Department of Industry, Innovation, Science, Research and Tertiary Education
[REDACTED]	Department of Industry, Innovation, Science, Research and Tertiary Education
[REDACTED]	Department of Industry, Innovation, Science, Research and Tertiary Education
[REDACTED]	Department of Health and Ageing
[REDACTED]	Department of Health and Ageing
[REDACTED]	Department of Health and Ageing
[REDACTED]	Department of Health and Ageing
[REDACTED]	Department of Health and Ageing
[REDACTED]	Department of Health and Ageing
[REDACTED] (apology for not being able to attend)	Department of Foreign Affairs and Trade

all other redactions s47F

**RE: TPP IP patents text. [SEC=IN-CONFIDENCE] - Notes Memo**

**From:** [REDACTED]  
**To:** "Brendan.Bourke@ipaustrialia.gov.au" <Brendan.Bourke@ipaustrialia.gov.au>  
**Sent:** 23-02-2012 05:18:11 AM

Ah, good. [REDACTED]

Many thanks, M.

[REDACTED]

FTA Commitments & Implementation Section  
Office of Trade Negotiations  
Department of Foreign Affairs & Trade

all other redactions s47F

[REDACTED]

[REDACTED]

**From:** Brendan.Bourke@ipaustrialia.gov.au [mailto:Brendan.Bourke@ipaustrialia.gov.au]

**Sent:** Thursday, 23 February 2012 4:16 PM

**To:** [REDACTED]

**Subject:** Re: TPP IP patents text. [SEC=IN-CONFIDENCE]

s33

**Brendan Bourke**  
Assistant Director  
International Policy & Cooperation  
Business Development & Strategy Group  
IP Australia



P + 61 2 6283 2148 F + 61 2 6283 7999 [REDACTED]

E [brendan.bourke@ipaustrialia.gov.au](mailto:brendan.bourke@ipaustrialia.gov.au)

A 47 Bowes Street, Woden ACT 2606 PO Box 200, Woden ACT Australia 2606

Visit us at <http://www.ipaustrialia.gov.au>

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From: [REDACTED]

To: "Brendan Bourke ([brendan.bourke@ipaaustralia.gov.au](mailto:brendan.bourke@ipaaustralia.gov.au))" <[brendan.bourke@ipaaustralia.gov.au](mailto:brendan.bourke@ipaaustralia.gov.au)>

Date: 23/02/2012 04:10 PM

Subject: TPP IP patents text. [SEC=IN-CONFIDENCE:FTA]

---

Brendan, I'm trying to do some work on the brief [REDACTED] s33

s33

[REDACTED] s33

s33

Would you be able to confirm on this one?

Many thanks, M.

[REDACTED]  
FTA Commitments & Implementation Section

Office of Trade Negotiations

Department of Foreign Affairs & Trade

Tel: [REDACTED]

Fax: 02 6112 3773

[REDACTED] s33

<Attachment: image001.gif>

File C2012/12282 FOI 443

s33 exemption

s33

File: 62012/12282 FOI 472

RE: s33

[SEC=UNCLASSIFIED] - Notes Reply

From: [Brendan.Bourke@ipaaustralia.gov.au](mailto:Brendan.Bourke@ipaaustralia.gov.au)

To: [Redacted]

Cc: [Redacted] Matthew Forno/OU=CBR/IPAustralia@IP\_Australia, Adam Wright/OU=CBR/IPAustralia@IP\_Australia, [Redacted] [More...](#)

Sent: 29-02-2012 1:20:07 PM

Hi [Redacted]

Attached is a document that includes our analysis of the s33, that [Redacted] promised I would send to you. [Redacted] has also been working on some facts and figures that aren't included in this document.

s33

I'll bring hard copies down to Melbourne in case you are already on a plane.

<Attachment: TPF s33 - IPA analysis paper.pdf>

See you in Melbourne. I'm hoping the weather is better than it has been in Canberra.

Brendan

all other redactions s47F

**Brendan Bourke**  
Assistant Director  
International Policy & Cooperation  
Business Development & Strategy Group  
IP Australia



P + 61 2 6283 2148 | F + 61 2 6283 7999 | [Redacted]  
E [brendan.bourke@ipaaustralia.gov.au](mailto:brendan.bourke@ipaaustralia.gov.au)  
A 47 Bowes Street, Woden ACT 2606 | PO Box 200, Woden ACT Australia 2606

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s33

Fw: TPP Issues Paper [SEC=IN-CONFIDENCE] - Notes Memo

From: [REDACTED]  
To: "Brendan Bourke" <Brendan.Bourke@ipaaustralia.gov.au>  
Sent: 20-02-2012 3:01:49 PM

all other redactions s47F

Classification: [SEC=IN-CONFIDENCE]

----- Original Message -----

From: [REDACTED]  
Sent: 20/02/2012 02:27 PM ZE10  
To: [REDACTED]  
Cc: [REDACTED]  
Subject: TPP Issues Paper [SEC=IN-CONFIDENCE]

Please find attached our latest version of your TPP issues paper/talking points. As with the previous version, our additions are shown in track changes - we have revised some of the wording on page 7 to add some context

s33

Tracey Duffy, our AS, has cleared the figures (in bold, on page 7) for use in discussions with DFAT and IP Australia.

Regards

[REDACTED]  
Pharmaceutical Policy Branch  
Department of Health & Ageing  
Level 9, Sirius Building, Furzer Street, Woden, ACT 2606  
( [REDACTED] [REDACTED] + MDP900

(See attached file: TPP talking points 20\_02\_12.doc)(See attached file: TPP Talking Points 20\_02\_12 ATTACHMENT A.doc)

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<Attachment: TPP talking points 20\_02\_12.doc><Attachment: TPP Talking Points 20\_02\_12 ATTACHMENT A.doc>

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s33

File C2012/12282 FOI 488

**FW: AusAID views on IP, TPP [SEC=IN-CONFIDENCE:BRIEFING] - Notes Memo**

[SEC=IN-CONFIDENCE:BRIEFING]

**From:** [REDACTED]  
**To:** "brendan.bourke@ipaaustralia.gov.au" <brendan.bourke@ipaaustralia.gov.au>  
**Sent:** 19-07-2012 01:40:52 AM

Brendan  
As discussed please find attached relevant document. Happy to discuss further.

Arnold

[REDACTED]

all other redactions s47F

Senior Sector Specialist | Private Sector and Trade Policy Section | AusAID

[REDACTED]

**From:** [REDACTED]  
**Sent:** Thursday, 7 June 2012 4:14 PM  
**To:** [REDACTED] (DFAT)  
**Cc:** [REDACTED]  
**Subject:** AusAID views on IP, TPP [REDACTED] [SEC=IN-CONFIDENCE:BRIEFING]

Hi [REDACTED]  
Please find attached a two page summary that my branch has worked on in conjunction with our Trade Section on the issues of IP, TPP [REDACTED]

s33

[REDACTED]

Cheers

[REDACTED]

A/g Assistant Director General | Education and Health Branch | AusAID

[REDACTED]

GPO Box 887 Canberra ACT 2601

[www.ausaid.gov.au](http://www.ausaid.gov.au)

s33

s33

File G2012/13282 FOI 489

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<Attachment: Intellectual property regimes s33  
20120605.docx><Attachment: image001.jpg><Attachment: image002.jpg><Attachment:  
image003.jpg><Attachment: image004.jpg><Attachment: image005.jpg>

s33

s33 exemption

s33 exemption

Re: Fw: [REDACTED] Patents and Health [SEC=IN-CONFIDENCE] - Notes Reply

From: Tanya.Duthie@ipaustrialia.gov.au  
To: Adam Wright/OU=CBR/IPAustralia@IP\_Australia  
Cc: "Matt Forno" <matthew.forno@ipaustrialia.gov.au>, "Victor Portellii" <victor.portelli@ipaustrialia.gov.au>, Brendan Bourke/OU=CBR/IPAustralia@IP\_Australia  
Sent: 06-12-2011 5:21:01 PM

all other redactions s33

Hi

Andrew and I have marked up some comments on attached in case they are helpful. [REDACTED]

Key points:

- [REDACTED]
- [REDACTED]
- [REDACTED]
- Not wedded to any of the words or suggestions used in attached, they are intended to be indicative.
- [REDACTED]
- Hope this helps, happy to discuss.

s47F

Cheers

Tanya  
<Attachment: [REDACTED] Patents and Health topic (final) (2) comments.docx>

Adam Wright---06/12/2011 05:32:21 AM---Classification: Unclassified Hi guys,

From: Adam Wright/CBR/IPAustralia  
To: "Victor Portellii" <victor.portelli@ipaustrialia.gov.au>, "Matt Forno" <matthew.forno@ipaustrialia.gov.au>, "Edwina Lewis" <Edwina.Lewis@ipaustrialia.gov.au>, "Tanya Duthie" <Tanya.Duthie@ipaustrialia.gov.au>, "Kieran Power" <Kieran.Power@ipaustrialia.gov.au>  
Cc: s47F  
Date: 06/12/2011 05:32 AM  
Subject: Fw: [REDACTED] on Patents and Health [SEC=UNCLASSIFIED]

Classification: Unclassified

Hi guys,

If you have any comments would be interested in hearing them.

s47F

all other redactions s33

Cheers,  
Adam

---

[Redacted]

[REDACTED]

**Subject:** [REDACTED] on Patents and Health

all redactions s33

s33 exemption

Re: FYI: Trans Pacific Partnership Round 12 update [SEC=IN-CONFIDENCE] - Notes Reply

From: Philip.Noonan@ipaaustralia.gov.au  
To: Brendan Bourke/OU=CBR/IPAustralia@IP\_Australia  
Cc: DL-BDS-International Policy and Cooperation, Fatima Beattie/OU=CBR/IPAustralia@IP\_Australia, Ian Goss/OU=CBR/IPAustralia@IP\_Australia, Robyn Foster/OU=CBR/IPAustralia@IP\_Australia  
Sent: 29-05-2012 4:52:54 PM

all redactions s33

Brendan

[Redacted content]

Philip

Brendan Bourke---29/05/2012 11:53:40 AM---Below is a summary of key points from the most recent round of TPP in Dallas in May, as discussed at

From: Brendan Bourke/CAustralia  
To: DL-BDS-International Policy and Cooperation  
Cc: Philip Noonan/CAustralia, Fatima Beattie/CAustralia, Ian Goss/CAustralia, Robyn Foster/CAustralia  
Date: 29/05/2012 11:53 AM  
Subject: FYI: Trans Pacific Partnership Round 12 update [SEC=IN-CONFIDENCE]

Below is a summary of key points from the most recent round of TPP in Dallas in May, as discussed at section meeting yesterday. These points are expanded from my travel report, which should be circulated soon. Happy to discuss any of this in further detail.

[Redacted content]

[Redacted content]

[Redacted content]

[Redacted content]

[Redacted content]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

Round 13 will be in San Diego USA in early July. [Redacted]

all redactions s33

Fw: Update re TPP and DOHA [SEC=UNCLASSIFIED] - Notes Memo

From: [redacted]  
To: [redacted]  
Cc: [redacted], brendan.bourke@ipaustralia.gov.au  
Sent: 22-12-2011 11:55:44 AM

Dear [redacted]

hi

We had a teleconference with [s33] yesterday [s33]

[s33]

We had a long session last week with the TGA to get their input .

[s33]

[redacted]

regards [all other redactions s47F]

[redacted]  
[redacted]  
Medical Adviser  
Medical Benefits Division  
Australian Government Department of Health and Ageing

[redacted]  
[redacted]

----- Forwarded by Megan Keaney/MBD/Health on 22/12/2011 11:36 AM -----

[redacted] To [redacted]  
[redacted] [redacted]

[s33]

all other redactions s47F

Hi [REDACTED]

We greatly appreciated the opportunity to speak with you and your colleagues yesterday. s33

s33

Two documents we didn't get around to discussing with you yesterday are the Government's Trading Policy Statement, *Trading our way to more jobs and prosperity* and the Productivity Commission's Research Report on Bilateral and Regional Trade Agreements. Both speak of the need to pursue only those trade agreements that are in Australia's economic interests.

The Trading Policy states that the Government agrees with Recommendation 1 of the Productivity Commission Report: [Recommendation 1: The Australian Government should only pursue bilateral and regional trade agreements where they are likely to afford significant net economic benefits. \(page 18\).](#)

According to the Productivity Commission Report:

[In addition to pre-negotiation assessment, the Commission considers that the economic implications of any proposed BRTA should be analysed after the completion of negotiations and prior to the signing of an agreement. At this time, there should be analysis of the likely costs and benefits of the actual provisions of a prospective agreement. \(page 308\)](#)

What the Commission means by this is reflected in the following quote further down on the same page:

[To ensure that such processes are as clear and robust as possible, they should be commissioned and overseen by a body that is independent from the executive. A transparent process should be adopted to ensure that the assumptions made as part of any economic modelling and other analyses are open to public scrutiny. This may also provide scope to formally elicit the views of stakeholders on the proposed agreement. There would be efficiencies \(in time and consistency\) in the same independent body overseeing both the pre- and post-negotiation analyses. Such a process would provide more realistic information about the likely benefits and costs Australia may realise from entering into an agreement and illuminate any potential aspects which would likely have particularly adverse impacts that may have arisen during the course of negotiations, providing a better basis for a final decision by government as to whether the agreement in question should be proceeded with. \(page 308\)](#)

We hope that the recommendations in these government documents will inform the continuing negotiation of the TPPA, especially with respect to the implications of any changes to domestic IP laws.

Kind regards,

[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]

s33

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

all other redactions s47F

From: [REDACTED]

[REDACTED]

Date: 22/12/2011 09:33 AM

Subject: Fw: Another relevant document to discuss at today's telecon [SEC=UNCLASSIFIED]

---

Dear [REDACTED]

Thanks for meeting with us yesterday

The document below might answer the questions I asked yesterday about providing practical examples about how the system currently operates. If you have more to add that would be great

Practical examples about how the new proposals might work would also be vaulable

I look forward to receiving [REDACTED] analysis

thanks

[REDACTED]

[REDACTED]

Medical Adviser

Medical Benefits Division

Australian Government Department of Health and Ageing

Phone: [REDACTED]

[REDACTED]

----- Forwarded by Megan Keaney/MBD/Health on 22/12/2011 09:16 AM -----

21/12/2011 05:15 PM

To [REDACTED]

[REDACTED]

[REDACTED]

Subject Re: Fw: Another relevant document to discuss at today's telecon [SEC=UNCLASSIFIED][Link](#)

all other redactions s47F

[REDACTED]

Ive just found this GMiA submission to a Standing Committee Hearing on Legal and Constitutional Affairs, submitted May 2011.

s33

Regards

[REDACTED]

---

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s33

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s33

TPP: [REDACTED] [SEC=IN-CONFIDENCE:FTA] - Notes  
Memo

**From:** [REDACTED]  
**To:** [REDACTED] "Brendan.Bourke@ipaustrialia.gov.au"  
<Brendan.Bourke@ipaustrialia.gov.au>, [REDACTED]  
"Karl.Brennan@innovation.gov.au" <Karl.Brennan@innovation.gov.au>, [REDACTED]  
**Cc:** [REDACTED]  
**Sent:** 05-09-2012 01:53:19 AM

**For Official Use Only**

all redactions s47F

Dear Colleagues  
I hope this finds you well.

[REDACTED]  
[REDACTED]  
[REDACTED]

Apologies for the tight turnaround, and don't hesitate to contact me if you need to discuss.

Thanks and regards

[REDACTED]  
[REDACTED]

Executive Officer  
International Intellectual Property Section  
Office of Trade Negotiations  
Australian Department of Foreign Affairs & Trade  
Tel: [REDACTED]  
Fax: +61 2 6112 2347

<Attachment: [REDACTED] 26 July 2012.docx>

s33 exemption

s33 exemption

s33 exemption

**Parliamentary Secretary Dreyfus for Information**

**Brief No: B12/2385**

cc: Minister Combet

**Division: Innovation Division**

**MEDICINES AUSTRALIA BOARD DINNER**

**Event: Medicines Australia (MA) Board Dinner**

**Date:** 3 September 2012

**Time:** 18:30 – 21:00

**Address:** Maha Bar & Grill (Private Dining Room), 21 Bond Street, Melbourne

**Time Minister is required for:** No time has been specified.

**Recommendation:**

**Noted/Please Discuss**

1. That you note the information provided. Yes / No

2. That you note that s47G Yes / No

s47G

**Parliamentary Secretary's signature:**

**Date:** / /

**Key Issues / Sensitivities:**

- The key issues for the MA Board will be –

s47G

- According to the invitation, MA Board dinners are informal evenings that can be treated under Chatham House rules, encouraging discussion of important issues between the Australian medicines industry and key policy and decision makers.
  - Previous meetings between Ministers and the MA Board have been conducted in a good spirit with issues raised politely but frankly.
  - MA are providing a final attendance list in the coming days. Previous dinners have had up to 40 attendees.

- s47G
- s47G A Departmental officer is available to attend the dinner with you should you wish.

***What does the pharma sector look like?***

- The global pharmaceutical industry has two significant sectors: the originator and generic medicines producers. These producers often have competing aims, in particular in relation to patents. Originators work hard to extract maximum value from their patented medicines. Generic producers stand ready to enter markets the moment patents expire. Their entry to markets brings price competition.
- MA members represent the originator pharmaceuticals sector although many have significant generic medicines portfolios as patents expire and mergers and acquisitions take advantage of expanding medicines markets in developing countries.
- The pharmaceutical industry in Australia currently invests around \$1 billion per year on R&D and is one of Australia's major high tech industries with exports of around \$4 billion per year.
- The level of investment in Australia by these companies is under constant review by global head offices which regularly benchmark Australian cost and effectiveness against other countries. The high dollar has had a marked negative impact.
- The pharmaceuticals industry in Australia will stress that it can only respond to challenges presented by the emerging markets of Asia if they have confidence that government policies support their businesses.

***How is the relationship with the Government?***

- s47G
- Treasury's Intergenerational Reports have demonstrated that PBS expenditure by the Government was growing at an exponential rate. In essence, the PBS was in danger of becoming financially unsustainable. Government policies have reduced this rate of growth and driven strong price cuts – and in turn the amount of taxpayers' funds needed by Government for PBS costs.
- s47G
- s47G how drugs are listed on the PBS. Past practice was that the Government automatically listed pharmaceuticals on the PBS that were recommended by its expert committees. However in February 2011 Minister Roxon, the then Minister for Health, announced the Government's decision to defer consideration of several drugs until fiscal circumstances allowed (deferrals). The deferrals attracted widespread criticism and many companies claimed adverse financial impacts. A Senate Committee subsequently inquired into this and other aspects of the Government's administration of the PBS.
  - Note that in responding to the Senate Inquiry, Minister Plibersek recently confirmed that the PBS deferrals policy will continue after 1 October 2012, when the current twelve month moratorium ends.

- There are also other pricing policies aimed at PBS sustainability that adversely impact individual companies' revenues - in some cases significantly.

- s33
- Many issues being faced by pharma companies require responses from companies, not government. There is an occasional tendency for such issues to be pleaded to the Government. Large losses in company revenue are mainly due to patent expiry on blockbuster drugs and widespread contraction and consolidation within the industry worldwide.
- **Recent dealings:** s47G  
s47G

***Slipstream Version 29 August 2012***

Peter Chesworth  
General Manager  
Pharmaceuticals, Health Industries & Enabling Technologies  
Innovation Division  
+61 2 6213 6058 / s47F  
29 August 2012

Contact Officer:  
Kate Seymour-Munn  
+61 2 6276 1254

**Consultation:** R&D Tax Incentive Section, Innovation Division, IP Australia

**Attachments:**

Attachment A: Medicines Australia Board members.

Attachment B: List of attendees (to be added once received from MA)

s33

Attachment D: Talking points.

## BACKGROUND:

Overall, the pharmaceutical industry in Australia spends around \$1 billion per year on R&D and employs almost 41,000 people, with around 13,400 people employed in the manufacture of pharmaceuticals. It is one of Australia's major high tech industries with exports of around \$4 billion per year.

Significant global pressures have contributed to its recent contraction in Australia. These include: the 'patent cliff' where many originator drugs are coming off patent – originator companies will lose an estimated \$78 billion in global sales during 2009-2014; and governments worldwide are driving prices down to contain increasing health costs.

Added local pressures from PBS cost savings aimed at PBS sustainability have had adverse financial impacts on some companies and are likely to have ongoing impacts in the future.

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## GENE PATENTS

Over recent years there has been a number of reports relating to the patenting of genetic material: The Australian Law Reform Commission's 2004 report on *Genes and Ingenuity: Gene Patenting and Human Health*; The Senate Community Affairs Committee's *Gene Patents* Report released on 26 November 2010; and the Advisory Council on Intellectual Property's 2011 report on patentable subject matter.

On 23 November 2011, the Government released its response to these three important reports. Among the recommendations accepted were to:

- introduce an object into patent law which includes that patents should not lead to patients being denied reasonable access to healthcare;
- raise patent standards;
- introduce a statutory research exemption;
- introduce a morality exclusion; and
- conduct a review of compulsory licensing.

A ban on gene patents was not recommended or accepted by Government.

A number of the proposed changes are already being implemented by the Government's Intellectual Property *Raising the Bar* Act, which was passed into law on 15 April 2012. It provides for higher patent standards which are aimed to address concerns that broad and speculative patents are not granted. The higher standards will also be better aligned with standards elsewhere, giving Australian business greater certainty that their inventions patented in Australia will also meet the requirements for patent protection elsewhere.

Most provisions in the Act come into effect on 15 April 2013, however, exemptions for researchers and regulatory use apply immediately, which will give comfort to researchers that they can go about their business.

The issue of gene patents is the subject of legal action in the Federal Court of Australia. On 8 June 2010, Cancer Voices Australia instigated legal action against Myriad Genetic Inc and

others in respect of the validity of one of Myriad's patents. This matter was heard on 20-24 February 2012 and judgement is reserved.

### COMPULSORY LICENSING

A key recommendation of the Government's response to the various reports on the gene patents system is a review of compulsory licensing provisions in the *Patents Act 1990*. As the review will concern competition policy the Productivity Commission is conducting this review following your agreement in March 2012 (**B12/859** refers).

### PBS DEFERRALS

- A 12 month moratorium on PBS deferrals ends on 1 October 2012. The Government response to the Senate Finance and Public Administration References Committee's Report on *The Government's administration of the Pharmaceutical Benefits Scheme* has confirmed the continuation of the PBS deferrals policy. The Government retains the option to defer, or not, while the policy is in place. It remains possible that no drugs will be deferred under the policy in the future.
- The deferrals policy is strongly opposed by industry, consumers, clinicians and health groups.
- s47G  
Mr Fladrich has been quoted in the press:" This was the government's opportunity to shut down the deferral issue once and for all...This is an issue not just for us but also for patients and [the Government response to the inquiry] goes against the grain of what the Prime Minister told industry last year".
- There are currently no drugs that have had their listing delayed due to the PBS deferrals policy. The next drugs for new listing or amended listings will be considered by the Pharmaceutical Benefits Pricing Authority (PBPA) at their 22 August 2012 meeting. These drugs will be due for Cabinet consideration after the current moratorium on deferrals expires.

**MEDICINES AUSTRALIA BOARD MEMBERS**

**Mr Mark Masterson – appointed Chairman**

**Dr Dominic Barnes**, Vice President & General Manager, Shire Australia Pty Ltd

**Dr Graeme Blackman**, Chairman, Institute of Drug Technology Australia Ltd

**Mr James Cain**, Managing Director, Bristol-Myers Squibb Australasia

**Mr Mark Fladrich**, Managing Director, AstraZeneca Pty Ltd

**Mr Bruce Goodwin**, Managing Director, Janssen

**Mr Frederic Guerard**, Managing Director, Novartis Pharmaceuticals Australia Pty Ltd

**Mr Rene Klemm**, General Manager, Bayer Australia Limited

**Mr John Latham**, Regional Director (Australia & New Zealand), Pfizer Australia

**Mr Geoff McDonald**, Vice President / General Manager, GlaxoSmithKline

**Mr Chris Miskell**, General Manager Australia & New Zealand, Eli Lilly Australia Pty Ltd

**Ms Kirsten O'Doherty**, General Manager, Abbott Australasia Pty Ltd

**Mr Ian Thompson**, Managing Director, Amgen Australia Pty Ltd

**ATTACHMENT B**

**LIST OF ATTENDEES**

[To be added once available from MA]

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## TALKING POINTS

### THE ECONOMY AND PATENTING

- The Australian economy is undergoing major changes with the mining boom and manufacturing under siege.
- In responding to these challenges the Government is seeking to transition to a high wage, high skill economy.
- A key issue is to encourage an increase in the commercialisation of research. As an industry you have considerable experience in doing that.
- One of these issues is appropriate regulation settings, including those for patents.
- The Government greatly appreciates your strong support for our Raising the Bar reforms.
- As an industry you have a clear appreciation of how patents affect the line between originator and generic medicines.
- When patent term extensions were introduced in the late 1990s it was foreshadowed that the extension would be evaluated against specified criteria, including efficiency and effectiveness.
- This was to be evaluated after 10 years and it is long overdue.
- It is good public policy to carefully examine patenting issues such as patent extension and possible strategic uses of the patent system.

### TRANS-PACIFIC PARTNERSHIP AGREEMENT – if raised

- The Gillard Government Trade Policy clearly states that it will not accept provisions that limit its capacity to continue the Pharmaceutical Benefits Scheme (PBS). Also as the Minister for Trade has stated that Australia will not countenance any outcome which undermines the integrity of the PBS,

limits the availability of generic drugs or which would compromise Australian health policy.

## **GENE PATENTS – if raised**

### ***Government's Position on Gene Patents***

- The Government in its recent response to three important reports on the Australia's patent has made it clear that there will be no ban on gene patents.
- The government is taking steps to address a wide range of concerns raised during the recent inquiries and welcomes Medicines Australia's support on gene patents and the 'Raising the Bar' amendments.

### ***If raised: The Hon Melissa Parkes MP proposed Private Member's Bill***

- It is unclear whether the Bill will be proposed for consideration.
- The Government will consider any such Bill that is introduced. The Bill will also be examined in the light of our international obligations.
- The Government agreed to introduce an object clause in the Patents Act to provide greater clarity regarding the purpose of the patent law. It also stated that the patent system should not lead to patients being denied reasonable access to healthcare.

## **COMPULSORY LICENCING - if raised**

- The Government has asked the productivity Commission to conduct a review of compulsory licensing as indicated in the Government Response to three Gene Patent reports.
- Initial submissions are due on 28 September 2012.

### **R&D TAX INCENTIVE – if raised**

- The Government has tasked the Business Tax Working Group with considering ways to fund a cut to the company tax rate from within the business tax system, so it would be premature to rule anything in or out at this stage.
- I would encourage anyone with concerns about particular options, or ideas to contribute, to engage constructively with the Group.
- Written submissions in response to the discussion paper close on Friday, 21 September 2012.
- The Group will be engaging in a second round of consultation later this year. It intends to release a draft final report in late October 2012 that includes draft recommendations and a summary of feedback on the discussion paper.

### **PBS SUSTAINABILITY – if raised**

- The pharmaceuticals industry enjoys—and will continue to enjoy—the Government's support.
- The Government is mindful of the key role that Medicines Australia has played in promoting the efficiency and sustainability of the PBS through the Memorandum of Understanding (MoU).
- What are Medicine Australia's initial views on a post MoU environment?
- *If needed:* Issues to do with the Pharmaceutical Benefits Scheme (PBS) are best addressed by the Health portfolio.
- The Government recognises that ongoing dialogue with the pharmaceuticals industry is needed to assist in the development of policy which supports pharmaceuticals research and manufacturing in Australia.

- What do you see as some of the opportunities coming up for the pharmaceuticals industry, for example in Asia? How do we realise those opportunities, given budgetary and other constraints?
- The Government will continue to consider all new PBS drug listings in a timely manner.

**RE: Meetings today at DFAT [SEC=IN-CONFIDENCE] - Notes Memo**

**From:** s47F  
**To:** "Tanya.Duthie@ipaaustralia.gov.au" <Tanya.Duthie@ipaaustralia.gov.au>, "Brendan.Bourke@ipaaustralia.gov.au" <Brendan.Bourke@ipaaustralia.gov.au>  
**Sent:** 09-10-2012 02:41:31 AM

all other redactions s33

Hi Tanya, Brendan

Thanks both for your e-mails, and sorry for not giving you more background.

[Redacted]

Thanks again (and good luck this afternoon!)

s47F

**From:** Tanya.Duthie@ipaaustralia.gov.au [mailto:Tanya.Duthie@ipaaustralia.gov.au]  
**Sent:** Tuesday, 9 October 2012 10:41 AM  
**To:** s47F  
**Cc:** Brendan.Bourke@ipaaustralia.gov.au  
**Subject:** Fw: Meetings today at DFAT [SEC=IN-CONFIDENCE]  
Hi s47F

I don't have time to provide input on the [Redacted] non-paper this morning sorry, and Edwina is still o/s. I guess we can say we will consider and get back to them? That said, please let me/Brendan know if there is any urgency.

Cheers

Tanya

**Tanya Duthie**  
A/Director  
International Policy and Cooperation  
IP Australia



P + 61 2 6283 2838 F + 61 2 6283 7999 E [tanya.duthie@ipaaustralia.gov.au](mailto:tanya.duthie@ipaaustralia.gov.au)  
A 47 Bowes Street, Woden ACT 2606 PO Box 200, Woden ACT Australia 2606

Visit us at <http://www.ipaustralia.gov.au>

[Redacted]

all other redactions s33

----- Forwarded by Tanya Duthie/CBR/IPAustralia on 09/10/2012 10:38 AM -----

From: Brendan Bourke/CBR/IPAustralia  
To: s47F  
Cc: Tanya Duthie/CBR/IPAustralia@IP\_Australia  
Date: 09/10/2012 10:00 AM  
Subject: Re: Meetings today at DFAT [SEC=IN-CONFIDENCE]

Hi Morna

I have a conflicting meeting this morning with some of our stakeholders over domestic reforms, so can't make the first session. I should be able to make it this afternoon.

[Redacted]

Is the non-paper [Redacted]

Brendan

**Brendan Bourke**  
Director  
Domestic Policy  
Business Development & Strategy Group  
IP Australia



P + 61 2 6283 2148 F + 61 2 6283 7999 M s47F  
E [brendan.bourke@ipaaustralia.gov.au](mailto:brendan.bourke@ipaaustralia.gov.au)  
A 47 Bowes Street, Woden ACT 2606 PO Box 200, Woden ACT Australia 2606

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all other redactions s33

From: s47F  
To: "Brendan.Bourke@ipaustralia.gov.au" <Brendan.Bourke@ipaustralia.gov.au>  
Date: 09/10/2012 08:41 AM  
Subject: Meetings today at DFAT [SEC=IN-CONFIDENCE:FTA]

---

Hi Brendan

I hope you had a great weekend.

Sorry for the delay in getting details of today's meeting to you. I've pencilled them in around your meeting with Philip so hope they will be okay:

- the first is 11.15am-12.30pm (here) [REDACTED]
- the second is 3.30-4.45pm (here) [REDACTED]

Attached is the non-paper from Leesburg which you should take a look at if you have time, ahead of our first meeting.

Thanks, and look forward to seeing you soon.

s47F

s47F

Executive Officer  
International Intellectual Property Section  
Office of Trade Negotiations  
Australian Department of Foreign Affairs & Trade

Tel: s47F

Fax: +61 2 6112 2347

<Attachment: image001.gif>

# Meetings today at DFAT [SEC=IN-CONFIDENCE:FTA] - Notes Memo

**From:** s47F  
**To:** "Brendan.Bourke@ipaaustralia.gov.au" <Brendan.Bourke@ipaaustralia.gov.au>  
**Sent:** 08-10-2012 9:40:54 PM

all other redactions s33

Hi Brendan

I hope you had a great weekend.

Sorry for the delay in getting details of today's meeting to you. I've pencilled them in around your meeting with Philip so hope they will be okay:

- the first is 11.15am-12.30pm (here) [REDACTED]
- the second is 3.30-4.45pm (here) [REDACTED]

Attached is the [REDACTED] from Leesburg which you should take a look at if you have time, ahead of our first meeting.

Thanks, and look forward to seeing you soon.

s47F

Executive Officer  
International Intellectual Property Section  
Office of Trade Negotiations  
Australian Department of Foreign Affairs & Trade  
Tel: s47F  
Fax: +61 2 6112 2347

<Attachment : [REDACTED]>

s33 exemption

s33 exemption

s33 exemption

s33 exemption

TPP: IP: Brief for Office for PhRMA/BIO visit [SEC=UNCLASSIFIED,  
CAVEAT=FOR-OFFICIAL-USE-ONLY] - Notes Memo

**From:** s47F  
**To:** "Brendan.Bourke@ipaaustralia.gov.au" <Brendan.Bourke@ipaaustralia.gov.au>  
**Sent:** 04-10-2012 05:00:19 AM

---

Hi Brendan

As promised, attached is the short brief we prepared on IP for our Office for the PhRMA/BIO visit. Sorry for the delay in sending this through!

Cheers

s47F

Executive Officer  
International Intellectual Property Section  
Office of Trade Negotiations  
Australian Department of Foreign Affairs & Trade

Tel: s47F

Fax: +61 2 6112 2347

<Attachment: 120723 TPP - s33 meeting with PhRMA (brief) - IP issues.docx>

**TPP Briefing for [REDACTED] Meeting with PhRMA and BIO – July 2012**

*What is the Australian Government's position on health issues in the TPP?*

- . The Australian Government would favourably consider proposals in the TPP that promote access to quality, affordable medicines in the TPP region.
- . The Australian Government's Trade Policy Statement, released in April 2011, made clear that Australia will not support provisions in trade agreements that constrain our ability to regulate legitimately on public policy matters, such as health.

*Would the Australian Government agree to provisions that impact the PBS?*

- . The Pharmaceutical Benefits Scheme (PBS) is an integral part of Australia's health system
  - and the ability to ensure access to quality, affordable medicines for Australian consumers is a priority.
- . The Australian Government would not accept an outcome in the TPP that would adversely affect the integrity of the PBS, limit the availability of generic drugs, or compromise Australia's health system more generally.

*Proposed US text on pharmaceutical patents*

- . Australia provides strong and balanced IP protection for pharmaceuticals.
- . We support the stated US objectives (in the Trade Enhancing Access to Medicines White Paper), of reducing barriers to trade, promoting transparency and procedural fairness and expediting access to both innovative and generic medicines.
- . However, the current US proposal on pharmaceutical patents raises significant concerns for Australia
  - we are not convinced that [REDACTED] [REDACTED] would result in benefits to Australia and the TPP region
    - : we have seen no evidence to support this proposition
    - : to the contrary, our research suggests that such provisions would likely result in costs to the Australian government and consumers, as well as the region
      - : and delays in generic drugs reaching the market.

*Possible "development" impact of the US proposals*

- . The Australian government, and our stakeholders, are also concerned that the US proposals may increase the cost of medicines, and delay the introduction of generic medicines, for developing countries in the region
  - this could make it harder for the poorest in developing countries to access necessary treatment
  - and limit the current reach of Australia's aid expenditure on medicines and vaccines.



<Attachment: [redacted] 1 222080-1.doc>

all redactions s33

s33 exemption

s33 exemption

## Trans Pacific Partnership [REDACTED]

The Trans Pacific Partnership (TPP) is a proposed plurilateral free trade agreement currently involving 9 of the 21 APEC members. The Parties are Australia, Brunei, Chile, Malaysia, New Zealand, Peru, Singapore, the United States, and Vietnam. Australia has bilateral or regional FTAs with all current parties except Peru.

It is possible that further countries will join the TPP in future. Japan and Canada have expressed strong interest and a number of other countries are paying close attention, particularly in light of the attention given to the TPP at the recent APEC leaders meeting in Yokohama. The 2010 APEC Leader's Declaration identified the TPP, along with other key regional agreements, as possible pathways towards a Free Trade Area of the Asia-Pacific.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

s33 exemption

s47F [Redacted]

s47F [Redacted]

s47F [Redacted]

s47F [Redacted]

s47F [Redacted]

Best wishes to **all of you** over at Health for Christmas and New Year, and thanks so much for all your assistance and support during 2011. I am certainly aware of the workload that TPP is placing on all of us, and am most appreciative of the time and effort you've been putting in.

Kind regards, s47F [Redacted]

all other redactions s33 [Redacted]

s47F [Redacted]

FTA Commitments & Implementation Section  
Office of Trade Negotiations  
Department of Foreign Affairs & Trade  
Tel: s47F [Redacted]  
Fax: 02 6112 3773

## Attachment: Government responses to recommendations of the Productivity Commission report on bilateral and regional trade agreements

### Recommendations

### Government response

**Recommendation 1:** The Australian Government should only pursue bilateral and regional trade agreements where they are likely to:

- afford significant net economic benefits; and
- be more cost-effective than other options for reducing trade and investment barriers, including alternative forms of bilateral and regional action.

Agreed — consistent with the approach articulated in the Statement.

**Chapter 12 Recommendation 2:** The Australian Government should ensure that any bilateral and regional trade agreement it negotiates:

- as far as practicable, avoids discriminatory terms and conditions in favour of arrangements based on non-

Agreed - consistent with the approach

discriminatory (most-favoured-nation) provisions,

- does not preclude or prejudice similar arrangements with other trading partners;
- and does not establish treaty obligations that could inhibit or delay unilateral, plurilateral or multilateral reform.

articulated in the Statement.

**Recommendation 3:** The Australian Government should adopt the composite model for rules to determine origin in merchandise trade, as in AANZFTA, as the basis for rules of origin in any future preferential trade agreement. In adopting this model:

Chapter  
13

- a choice of Regional Value Content and Change in Tariff Classification rules for determining origin should be afforded for each item of merchandise;
- the least restrictive variant of each test should be adopted, consistent with preventing trade deflection; and
- Australia should seek a waiver to rules of origin requirements where the difference between the most-favoured-nation tariff rates in the partner countries is 5 percentage points or less.

Agreed.

Chapter  
14

**Recommendation 4:** The Australian Government should not include matters in bilateral and regional trade agreements that would serve to increase barriers to trade, raise costs or affect established social policies without a comprehensive review of the implications and available options for change.

Agreed - consistent with approach articulated in the Statement

**Recommendation 5:** The Australian Government should improve the scrutiny of the potential impacts of prospective trade agreements, and opportunities to reduce barriers to trade and investment more generally.

Agreed in part.

a) It should prepare a trade policy strategy which identifies impediments to trade and investment and available opportunities for liberalisation, and includes a priority list of trading partners. This trade policy strategy should be reviewed by Cabinet on an annual basis, and be prepared before the pursuit of any further BRTAs. A public version of the Cabinet determined strategy should be released.

Recommendation 5(a): agreed.

b) Before entering negotiations with any particular prospective partner, it should undertake a transparent analysis of the potential impacts of the options for advancing trade policy objectives with the partner. All quantitative analysis and modelling should be overseen by an independent body.

Recommendation 5(b): agreed in part — an assessment of the benefits of a proposed free trade agreement should be transparent and credible. However, over-reliance on highly abstract quantitative analysis can be very misleading.

c) It should commission and publish an independent and transparent assessment of the final text of the agreement, at the conclusion of negotiations, but before an agreement is signed.

Rec 5(c): not agreed. Quantitative analysis can be highly misleading, with conclusions heavily dependent on simplifying assumptions used in modelling. Agreements will be presented for consideration by the Joint Standing Committee on Treaties before ratification.

Chapter  
15

**Recommendation 6:** If it is deemed that capacity building should be part of a trade agreement development process, the Australian Government should fund and deliver capacity building programs in a manner that minimises potential (or perceived) conflicts of interest. Any such programs should not impose an obligation to negotiate a trade agreement.

Agreed.

Chapter  
13

**Recommendation 7:** To enhance transparency and public accountability and enable better decision making regarding the negotiation of trade agreements, the Department of Foreign Affairs and Trade should publish estimates of the expenditure

Agreed.

Chapter

7

C2012/12282 FOI 554

incurred in negotiating bilateral and regional trade agreements and multilateral trade agreements. These should include estimates for the costs of negotiating recent agreements.

**Recommendation 8:** The Australian Government should examine the potential to further reduce existing Australian barriers to trade and investment through unilateral action as a priority over pursuing liberalisation in the context of bilateral and regional trade agreements. The Government should not delay beneficial domestic trade liberalisation and reform in order to retain 'negotiating coin'.

Agreed - consistent with the approach articulated in the Statement.

Chapter 12

**Recommendation 9:** The Australian Government should support worthwhile efforts to achieve multilateral liberalisation. Should meaningful progress within the WTO prove elusive, the Government should weigh up with like-minded countries the feasibility of appropriate broadly based agreements to advance reform.

Agreed - consistent with the approach articulated in the Statement.

**Recommendation 10:** The Australian Government should lend support to initiatives directed at the establishment of domestic institutions in key trading countries to provide transparent information and advice on the community-wide impacts of trade, investment and associated policies.

Agreed — consistent with the approach articulated in the Statement.

From: s47F  
Sent: Thursday, 22 December 2011 11:56 AM  
To: s47F  
Cc: s47F  
brendan.bourke@ipaaustralia.gov.au  
Subject: Fw: Update re TPP and DOHA [SEC=UNCLASSIFIED]

Dear s47F

all other redactions s33

hi

[Redacted]

[Redacted]

[Redacted]

[Redacted]

In relation to [Redacted], in my reading on the subject, I did come across the Productivity Commission report she refers to. Do you know whether the government has accepted or not the Productivity Commission's recommendations that may be relevant to TPP?

s47F

Hope you enjoy a good break over the next few weeks

regards

all other redactions s33

s47F

s47F

Medical Adviser  
Medical Benefits Division  
Australian Government Department of Health and Ageing

Phone: s47F

s47F

----- Forwarded by s47F on 22/12/2011 11:36 AM -----

s47F

To s47F

s47F

22/12/2011 11:12 AM

Subject Re: Another relevant document to discuss at today's telecon [SEC=UNCLASSIFIED]

Hi s47F

We greatly appreciated the opportunity to speak with you and your colleagues yesterday. Coincidentally, when we finished the call we agreed that we would work through the attached document to quantify - where we can - the costs to the government of the delays in market entry of the generic. We will work on this and have something for you in February.

Two documents we didn't get around to discussing with you yesterday are the Government's Trading Policy Statement, *Trading our way to more jobs and prosperity* and the Productivity Commission's Research Report on Bilateral and Regional Trade Agreements. Both speak of the need to pursue only those trade agreements that are in Australia's economic interests.

The Trading Policy states that the Government agrees with Recommendation 1 of the Productivity Commission Report: [Recommendation 1: The Australian Government should only pursue bilateral and regional trade agreements where they are likely to afford significant net economic benefits. \(page 18\).](#)

According to the Productivity Commission Report:

[In addition to pre-negotiation assessment, the Commission considers that the economic implications of any proposed BRTA should be analysed after the completion of negotiations and prior to the signing of an agreement. At this time, there should be analysis of the likely costs and benefits of the actual provisions of a prospective agreement. \(page 308\)](#)

What the Commission means by this is reflected in the following quote further down on the same page:

[To ensure that such processes are as clear and robust as possible, they should be commissioned and overseen by a body that is independent from the executive. A transparent process should be adopted to ensure that the assumptions made as part of any economic modelling and other analyses are open to public scrutiny. This may also provide scope to formally elicit the views of stakeholders on the proposed agreement. There would be efficiencies \(in time and consistency\) in the same independent body overseeing both the pre- and post-negotiation analyses. Such a process would provide more realistic information about the likely benefits and costs Australia may realise from entering into an agreement and illuminate any potential aspects which would likely have particularly adverse impacts that may have arisen during the course of negotiations, providing a better basis for a final decision by government as to whether the agreement in question should be proceeded with. \(page 308\)](#)

We hope that the recommendations in these government documents will inform the continuing negotiation of the TPPA, especially with respect to the implications of any changes to domestic IP laws.

Kind regards,

s47F

s47F

C2012/12282 FOI 556

From: s47F

Date: 22/12/2011 09:33 AM

Subject: Fw: Another relevant document to discuss at today's telecon [SEC=UNCLASSIFIED]

all other redactions s33

Dear s47F

Thanks for meeting with us yesterday

The document below might answer the questions I asked yesterday about providing practical examples about how the system currently operates. If you have more to add that would be great

I look forward to receiving s47F analysis

thanks

s47F

s47F

Medical Adviser  
Medical Benefits Division  
Australian Government Department of Health and Ageing

s47F

----- Forwarded by Megan Keaney/MBD/Health on 22/12/2011 09:16 AM -----

s47F

21/12/2011 05:15 PM

To: s47F

Subject: Re: Fw: Another relevant document to discuss at today's telecon [SEC=UNCLASSIFIED] [Link](#)

s47F

[REDACTED]

Regards

s47F

all other redactions s33

---

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s33 exemption

TPP: IP: s33  
Notes Memo

1584  
[SEC=IN-CONFIDENCE:FTA] -

**From:** [REDACTED]  
**To:** "Brendan.Bourke@ipaustrialia.gov.au" <Brendan.Bourke@ipaustrialia.gov.au>,  
"Constantine.Nikolakopoulos@ipaustrialia.gov.au" <Constantine.Nikolakopoulos@ipaustrialia.gov.au>,  
"Matthew.Forno@ipaustrialia.gov.au" <Matthew.Forno@ipaustrialia.gov.au>,  
"Karl.Brennan@innovation.gov.au" <Karl.Brennan@innovation.gov.au>, "Losada-Rodriguez, Ivan  
(Ivan.Losada-Rodriguez@innovation.gov.au)" <Ivan.Losada-Rodriguez@innovation.gov.au>, More...  
**Cc:** [REDACTED]  
**Sent:** 28-06-2012 9:49:50 PM

Dear All

Please find attached further cable from Washington regarding the s33  
We have now agreed a time for the meeting "the morning of 26 July. Please add this to your calendar and [REDACTED] and I will  
be in touch when we are back from San Diego with further details about the visit (Health and AusAID have confirmed they will  
also attend).  
If you have any questions in our absence please contact [REDACTED] (copied in here).

Kind regards

[REDACTED]

all other redactions s47F

[REDACTED]  
Executive Officer  
International Intellectual Property Section  
Office of Trade Negotiations  
Australian Department of Foreign Affairs & Trade

Tel: [REDACTED]  
Fax: +61 2 6112 2347

s33

s33

[SEC-IN-CONFIDENCE] (Notes Reply)

[SEC-IN-CONFIDENCE] - Notes Reply

From: [Brendan.Bourke@ipaustrialia.gov.au](mailto:Brendan.Bourke@ipaustrialia.gov.au)  
To: [REDACTED]  
Cc: "Edwina.Lewis@ipaustrialia.gov.au" <Edwina.Lewis@ipaustrialia.gov.au>, [REDACTED]  
Sent: 25-09-2012 10:38:15 AM

Hi [REDACTED]

I haven't had a detailed look at this at any stage, so my comments should be read in that context.

s33

**Brendan Bourke**  
Director  
Domestic Policy  
Business Development & Strategy Group  
IP Australia



P + 61 2 6283 2148 | F + 61 2 6283 7999 | [REDACTED]  
E [brendan.bourke@ipaustrialia.gov.au](mailto:brendan.bourke@ipaustrialia.gov.au)  
A 47 Bowes Street, Woden ACT 2606 | PO Box 200, Woden ACT Australia 2606

Visit us at <http://www.ipaustrialia.gov.au>

Please consider the environment before printing this email

From: [REDACTED]  
To: "Brendan.Bourke@ipaustrialia.gov.au" <Brendan.Bourke@ipaustrialia.gov.au>  
Cc: "Edwina.Lewis@ipaustrialia.gov.au" <Edwina.Lewis@ipaustrialia.gov.au>, [REDACTED]  
Date: 24/09/2012 04:58 PM  
Subject: TPP [REDACTED] [SEC-IN-CONFIDENCE:FTA]

Hi Brendan

In Edwina's absence I am writing to seek your views on two IP-related proposals

s33

s33

all other redactions s47F

[REDACTED] --24/09/2012 04:58:57 PM--Hi Brendan In Edwina's absence I am writing to seek your views on two IP-related proposals put forward

It would be great if I could get your thoughts by **3pm tomorrow** Tuesday 25 September, if possible, as this will allow Chris to meet his deadline of COB tomorrow. Sorry for the tight turnaround.

With thanks and regards

[REDACTED]

[REDACTED]  
Executive Officer  
International Intellectual Property Section  
Office of Trade Negotiations  
Australian Department of Foreign Affairs & Trade

Tel: [REDACTED]  
Fax: +61 2 6112 2347

s33

[SEC-IN-CONFIDENCE].ahm[30/05/2013 10:37:31 AM]

Re: TPP

s33

[SEC-IN-CONFIDENCE] (Notes Reply)

[attachment

s33

deleted by Brendan Bourke/CBR/IPAustralia]

s33

News from the USPTO

USPTO News

to:

brendan.bourke

21/06/2012 03:48 AM

Classification

UNCLASSIFIED

Privacy

Categories

Hide Details

From: USPTO News <noreply@usptoenews.gov>

To: brendan.bourke@ipaustrialia.gov.au

## USPTO Director's Forum Blog

### [Ensuring Quality Inter Partes and Post Grant Reviews](#)

In pursuing our mission to ensure the highest possible level of patent quality, the USPTO has for decades employed the BRI standard—broadest reasonable claim interpretation—to construe claims before the Office. Using this standard, we give patent claims in front of the USPTO their broadest reasonable interpretation. This approach has for decades been uncontroversial, because it represents good policy and strikes a fair balance. It ensures that the public can clearly understand the outer limits applicants and patentees will attribute to their claims. And since applicants and patentees have the opportunity to amend their claims when working with the USPTO, they are able to resolve ambiguities and overbreadth through this interpretive approach, producing clear and defensible patents at the lowest cost point in the system.

Recently it has been suggested that the Office use the district court's higher standard, construing claims more narrowly so as to preserve their validity in implementing the new America Invents Act (AIA) *inter partes* and post grant review proceedings. Unfortunately, this change would not be workable or appropriate. Employing a district court approach to claim construction in the new proceedings would impair the efficient operation of the Office and result in facially inconsistent results, as well as constitute bad policy for our country's IP system.

As alluded to above, patent claims serve an important public notice function. An essential purpose of the broadest reasonable claim interpretation standard in the amendment process is to encourage an

inventor to fashion clear, unambiguous claims. Patent owners in *inter partes* and post grant reviews will be afforded opportunities to amend their claims commensurate with their contribution to the art. Only through the use of the broadest reasonable claim interpretation standard can the Office ensure that uncertainties of claim scope are removed by the inventor. In contrast, patents before a district court are presumed valid with a heightened “clear and convincing” standard of proof to demonstrate invalidity. Consistent with this heightened presumption of validity—and as there is no opportunity to amend and resolve ambiguities—district courts construe claims to uphold validity. The Office however, is not so limited in its approach to claim interpretation, given its authority to amend patent claims.

Some have expressed a concern that applying the broadest reasonable interpretation standard to *inter partes* and post grant reviews could lead to double standards between ongoing patent litigation and the Office’s reviews. The AIA however, addresses this concern. Specifically, the AIA imposes limitations on a petitioner’s ability to file a review when there is ongoing district court litigation, while providing time limits for the Office to complete its reviews. By placing limits on the filing and completion of the reviews, and encouraging coordination between the Office and district courts, the AIA provides improved mechanisms to avoid conflicts.

On the other hand, inconsistent results would become a major issue if the Office adopted a standard of claim construction other than the broadest reasonable interpretation for post-grant reviews. Specifically, the AIA contemplates that there will be multiple proceedings in the Office, and thus requires the Office to establish rules concerning the relationships between the various proceedings. For example, there may be an *inter partes* review of a patent that is also subject to an *ex parte* reexamination, where the patent is part of a family of co-pending applications all employing the same claim terminology. Major difficulties would arise where the Office is handling multiple proceedings with different claim construction standards applicable. In this world, the same amendment made in an *inter partes* review and a pending application could result in an allowance in one case and a rejection in the other. Or, the introduction of narrower language in a pending application and broader language in an *inter partes* review could result in an allowance of the broader language and a rejection of the narrower language. Clearly, these examples and many others would produce bizarre results, unhelpful to patentees, applicants, the public, and the system.

To avoid the potential of having distinct alternative claim constructions for a claim term arising in the various proceedings before the Office and the inconsistent results flowing therefrom, the Office has chosen to continue to employ a single standard, the broadest reasonable interpretation standard, for proceedings before the Office. Continued use of the broadest reasonable claim interpretation will ensure the Office serves the patent community and makes full use of its resources in processing patent claims efficiently, effectively and consistently.

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**IN-CONFIDENCE****Cyber Policy Group****Whole-of-government – XX 2012**

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- Agenda Item:** New generic Top Level Domains (new gTLDs)
- Sponsor:** Department of Broadband, Communications and the Digital Economy
- Purpose:** For action
- Recommendation/s:** That the CPG:
- i. **Review the proposed Australian Government positions on new gTLD applications, and provide any comments by 31 August 2012**
- 

**Issue:** Applications for new generic Top Level Domains (gTLDs) were made public on 13 June 2012. Governments have until mid-October 2012 to issue early warning notices about applications that violate national laws or raise concerns or sensitivities.

**Background:** The Internet Corporation for Assigned Names and Numbers (ICANN) received 1,930 applications for new gTLDs. ICANN has published details of each application on its website for public comment. Governments have until mid-October 2012 to flag any applications that raise concerns.

Applications could raise concerns for several reasons, including:

- names with consumer trust implications, such as '.bank';
- names typically associated with government activity, such as '.navy'; and
- names that may be contentious in some countries, such as '.islam'.

Attachment A provides a high level overview of the process and next steps. Attachment D provides a brief analysis of each application, including a preliminary view on whether or not the Australian Government should issue any early warnings.

Contact officer and agency	Peter Nettlefold
Contact details	Ph: 6271 1021 Email: Peter.Nettlefold@dbcde.gov.au
Date	11 July 2012
Approved by	Andrew Maurer

**IN-CONFIDENCE**

**IN-CONFIDENCE****Attachment A****Australian Government positions on new gTLDs applications**Background

As foreshadowed in earlier briefing to the CPG (on 6 December 2011 and 15 May 2012), the Internet Corporation for Assigned Names and Numbers (ICANN) has launched a program to allow the introduction of new generic Top Level Domains (gTLDs). On 13 June 2012, ICANN published details of all 1,930 received applications. Approximately 40 applications were made by Australian interests (see Attachment B).

ICANN's Governmental Advisory Committee (GAC) will also act as the coordinating body for governmental input on any contentious new gTLD applications. Australia is represented in the GAC by the Department of Broadband, Communications and the Digital Economy (DBCDE). The development of Australian Government positions is being coordinated through the Cyber Policy Group.

Government interventions

In the event that an application raises concerns, there are two main ways that the Australian Government could intervene.

1. Issue an 'early warning' notice through the GAC. This is an informal process intended to trigger either voluntary withdrawal by the applicant, or to initiate discussions on ways to address any concerns with the application. An early warning does not require GAC approval or endorsement, and can be raised by one or more countries.
2. Advocate that the GAC provide consensus 'advice' to the ICANN Board on a particular application (the GAC can provide advice to the Board on any application for any reason, and the Board would need to consider that advice and provide justification if it is not followed).

Proposed steps and anticipated timeframes for finalising Australian Government positions on any contentious applications are at Attachment C.

Australian Government positions

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comprehensive public information on each application is available at: <http://gtdresult.icann.org/application-result/applicationstatus>

Action

Questions and portfolio positions on the DBCDE 'traffic light' report can be directed to Peter Nettlefold at [peter.nettlefold@dbcde.gov.au](mailto:peter.nettlefold@dbcde.gov.au) or on 02 6271 1021. Portfolio positions are requested by 31 August 2012.

### **Australian gTLD applications**

Applications for gTLDs from Australian interests include:

- geographic names (.melbourne and .sydney)
- media and communications company names (.auspost, .iinet, .sbs, .seven and .yellowpages)
- banking and finance company names (.amp, .anz, .cba, .commbank, .nab, .netbank, and .ubank )
- other company and organisation names (.afl, .cpa, .globalx, .iselect, .kred, .seek, .tab, .webjet, and .woodside)
- universities (.bond, .latrobe, .monash, and .rmit)
- generic names (.best, .book, .cancerresearch, .ceo, .compare, .courses, .film, .movie, .physio, .salon, .select, .study, and .tennis).

**IN-CONFIDENCE****Attachment C****Timeline for GAC Early Warning and Advice Process**

<b>Date</b>	<b>Action</b>
13 June 2012	<ul style="list-style-type: none"> <li>• Applications for new gTLDs were made public</li> </ul>
24-29 June 2012	<ul style="list-style-type: none"> <li>• DBCDE representatives attended ICANN meeting, and discussed potentially contentious applications with other governmental representatives</li> </ul>
11 July 2012	<ul style="list-style-type: none"> <li>• DBCDE provided preliminary assessment of new gTLD applications to Cyber Policy Coordinator, for circulation to the CPG</li> </ul>
August 2012	<ul style="list-style-type: none"> <li>• If needed, CPG meets to discuss contentious strings and portfolio positions</li> <li>• Portfolio positions on the DBCDE 'traffic light' report and any proposed early warnings provided to DBCDE and the Cyber Policy Coordinator</li> </ul>
September 2012	<ul style="list-style-type: none"> <li>• Australian Government positions on any Early Warnings finalised, and discussions on whether to issue GAC Advice initiated</li> </ul>
September /early October 2012	<ul style="list-style-type: none"> <li>• Australian Government Early Warnings passed to GAC</li> </ul>
14-19 October	<ul style="list-style-type: none"> <li>• ICANN meeting in Toronto</li> <li>• Preliminary GAC discussion on whether to issue GAC Advice on any applications</li> </ul>
Q4 2012	<ul style="list-style-type: none"> <li>• CPG meets to discuss any applications that may be subject to GAC Advice (including objections being raised by other countries)</li> <li>• Australian Government negotiating positions on GAC Advice finalised</li> </ul>
Q1 2013	<ul style="list-style-type: none"> <li>• Intergovernmental discussions on any proposed GAC Advice</li> <li>• Australian Government positions on GAC Advice finalised</li> </ul>
April 2013	<ul style="list-style-type: none"> <li>• ICANN meeting in Beijing</li> <li>• Any consensus GAC Advice negotiated in face-to-face GAC meetings</li> <li>• Any consensus GAC Advice provided to the ICANN Board</li> </ul>

**IN-CONFIDENCE**



Unfortunately, DBCDE has advised the free text column (column G) in the earlier Attachment D was scrambled. The other columns were unaffected. The corrected version is attached.

Regards,  
CPG Secretariat

all redactions s47F

-----  
Further to the email below, just to confirm that DBCDE is happy for any comments to go directly to them by 31 August. We have now copied in the relevant DBCDE staff to the email.

-----  
Good afternoon,

As you may recall, at the 15 May 2012 CPG meeting, DBCDE advised that ICANN would be releasing proposed new gTLDs for comment. ICANN received 1930 applications for new gTLDs and has now provided these for comment by government by mid October. DBCDE has asked the CPG Secretariat to circulate the proposed Australian Government positions on new gTLD applications for comment by **31 August**.

DCBDE will be happy to meet with portfolio representatives to discuss the gTLD process and the preliminary assessments done by DBCDE. Peter Nettlefold is the contact person in DBCDE (available on 02 6271 1021 or [peter.nettlefold@dbcde.gov.au](mailto:peter.nettlefold@dbcde.gov.au)). [REDACTED] Tristan Kathage can be contacted regarding gTLD matters (available on 02 6271 1951 or [tristan.kathage@dbcde.gov.au](mailto:tristan.kathage@dbcde.gov.au)).

Regards,

[REDACTED]  
Adviser|Cyber Policy and Homeland Security Division

Department of the Prime Minister and Cabinet

---

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---

<Attachment: Attachment D DBCDE preliminary gTLD assessments.xlsx><Attachment: 2012-07-04 CPG paper on contentious gTLDs.docx>

s33 exemption

**RE: TPP [REDACTED] [SEC=IN-CONFIDENCE] - Notes Memo**

**From:** s47F  
**To:** "Brendan.Bourke@ipaustrialia.gov.au" <Brendan.Bourke@ipaustrialia.gov.au>  
**Cc:** "Edwina.Lewis@ipaustrialia.gov.au" <Edwina.Lewis@ipaustrialia.gov.au>, s47F  
**Sent:** 29-08-2012 05:51:03 AM

all other redactions s33

**For Official Use Only**

Hi Brendan

Yes, sorry I should have sent this through sooner. Attached is a [REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]

We received a copy of this s47F a few months back and provided the talking points below. If you have anything to add please let me know. The issue has not been discussed since we provided the points and is not on the agenda for [REDACTED]

s33 exemption

s33 exemption

s33 exemption

**RE: TPP: [REDACTED] [SEC=IN-CONFIDENCE] - Notes Memo**

**From:** s47F  
**To:** "Brendan.Bourke@ipaaustralia.gov.au" <Brendan.Bourke@ipaaustralia.gov.au>  
**Cc:** "Edwina.Lewis@ipaaustralia.gov.au" <Edwina.Lewis@ipaaustralia.gov.au>, s47F  
**Sent:** 25-09-2012 06:27:23 AM all other redactions s33

Hi Brendan

Many thanks for this. On [REDACTED]  
[REDACTED]

Does this help? Happy to discuss.

Thanks

s47F  
**From:** Brendan.Bourke@ipaaustralia.gov.au [mailto:Brendan.Bourke@ipaaustralia.gov.au]  
**Sent:** Tuesday, 25 September 2012 10:38 AM  
**To:** s47F  
**Cc:** Edwina.Lewis@ipaaustralia.gov.au; s47F  
**Subject:** Re: TPP: [REDACTED] [SEC=IN-CONFIDENCE]

Hi s47F

I haven't had a detailed look at this at any stage, so my comments should be read in that context.

[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]

[REDACTED]  
[REDACTED]  
[REDACTED]

[REDACTED]  
[REDACTED]

**Brendan Bourke**  
Director

Domestic Policy  
Business Development & Strategy Group  
IP Australia

all other redactions s33



P + 61 2 6283 2148 F + 61 2 6283 7999 s47F

E [brendan.bourke@ipaaustralia.gov.au](mailto:brendan.bourke@ipaaustralia.gov.au)

A 47 Bowes Street, Woden ACT 2606 PO Box 200, Woden ACT Australia 2606

Visit us at <http://www.ipaustralia.gov.au>

Please consider the environment before printing this email

From: s47F

To: "[Brendan.Bourke@ipaaustralia.gov.au](mailto:Brendan.Bourke@ipaaustralia.gov.au)" <[Brendan.Bourke@ipaaustralia.gov.au](mailto:Brendan.Bourke@ipaaustralia.gov.au)>

Cc: "[Edwina.Lewis@ipaaustralia.gov.au](mailto:Edwina.Lewis@ipaaustralia.gov.au)" <[Edwina.Lewis@ipaaustralia.gov.au](mailto:Edwina.Lewis@ipaaustralia.gov.au)>, s47F

Date: 24/09/2012 04:58 PM

Subject: TPP: [REDACTED] [SEC=IN-CONFIDENCE:FTA]

Hi Brendan

In Edwina's absence I am writing to seek your views [REDACTED]  
[REDACTED]

- [REDACTED]
- [REDACTED]

[REDACTED]  
[REDACTED]

[REDACTED]  
[REDACTED]

[REDACTED]  
[REDACTED]

[REDACTED]  
[REDACTED]  
[REDACTED]

all other redactions s33

[REDACTED]

It would be great if I could get your thoughts **by 3pm tomorrow** Tuesday 25 September, if possible, as this will allow Chris to meet his deadline of COB tomorrow. Sorry for the tight turnaround.

With thanks and regards

s47F

s47F

Executive Officer  
International Intellectual Property Section  
Office of Trade Negotiations

Australian Department of Foreign Affairs & Trade

Tel: **s47F**  
Fax: +61 2 6112 2347

**all other redactions s33**

[attachment "Re TPP [REDACTED]" deleted by Brendan Bourke/CBR/IPAustralia]

<Attachment: image001.gif>

s33 exemption

s33 exemption

**IPA comments on [REDACTED] [SEC=IN-CONFIDENCE] - Notes Memo**

**From:** [Edwina.Lewis@ipaaustralia.gov.au](mailto:Edwina.Lewis@ipaaustralia.gov.au)

**To:** s47F

all other redactions s33

**Sent:** 04-09-2012 3:07:24 PM

Hi s47F

Here are our comments on [REDACTED]. I think we have discussed everything in there already. I have made a start on redrafting the wording for [REDACTED] as per [REDACTED].

<Attachment: [REDACTED] - IPA comments.doc>

I am still awaiting comments from [REDACTED], but will get comments to you as soon as possible.

Cheers

**Edwina LEWIS (Ms)**  
Assistant Director  
International Policy and Cooperation  
IP Australia



Ph +61 2 62832610 | s47F | [edwina.lewis@ipaaustralia.gov.au](mailto:edwina.lewis@ipaaustralia.gov.au)  
47 Bowes Street Woden ACT Australia 2606 | PO Box 200 Woden ACT Australia 2606  
Visit us at <http://www.ipaustralia.gov.au>

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s33 exemption

# RE: TPP regulatory coherence [SEC=IN-CONFIDENCE] - Notes Reply

**From:** [Edwina.Lewis@ipaaustralia.gov.au](mailto:Edwina.Lewis@ipaaustralia.gov.au)  
**To:** [s47F]  
**Cc:** "Brendan.Bourke@ipaaustralia.gov.au" <Brendan.Bourke@ipaaustralia.gov.au> [s47F]  
**Sent:** 30-08-2012 11:09:50 AM

Thanks for sending this through [s47F]

[all other redactions s33]

Nothing to add and agree with the talking points below.

**Edwina LEWIS (Ms)**

Assistant Director  
International Policy and Cooperation  
IP Australia



Ph +61 2 62832610 | [s47F] | [edwina.lewis@ipaaustralia.gov.au](mailto:edwina.lewis@ipaaustralia.gov.au)  
47 Bowes Street Woden ACT Australia 2606 | PO Box 200 Woden ACT Australia 2606  
Visit us at <http://www.ipaaustralia.gov.au>

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[s47F] ---29/08/2012 03:51:13 PM---For Official Use Only Hi Brendan

**From:** [s47F]  
**To:** "Brendan.Bourke@ipaaustralia.gov.au" <Brendan.Bourke@ipaaustralia.gov.au>  
**Cc:** "Edwina.Lewis@ipaaustralia.gov.au" <Edwina.Lewis@ipaaustralia.gov.au>, [s47F]  
**Date:** 29/08/2012 03:51 PM  
**Subject:** RE: TPP regulatory coherence [SEC=IN-CONFIDENCE]

**For Official Use Only**

Hi Brendan

Yes, sorry I should have sent this through sooner. Attached is a [redacted]  
[redacted]  
[redacted]  
[redacted]

We received a copy of this [s47F] a few months back and provided the talking points below. If you have anything to add please let me know. The issue has not been discussed since we provided the points and is not on

the agenda [REDACTED].

all other redactions s33

[REDACTED]

[REDACTED]

[REDACTED]

With thanks and regards

s47F

s47F

Executive Officer  
International Intellectual Property Section  
Office of Trade Negotiations  
Australian Department of Foreign Affairs & Trade

s47F

**From:** Brendan.Bourke@ipaaustralia.gov.au [mailto:Brendan.Bourke@ipaaustralia.gov.au]

**Sent:** Friday, 17 August 2012 11:04 AM

**To:** s47F

**Subject:** TPP regulatory coherence [SEC=IN-CONFIDENCE]

Hi [s47F]

[all other redactions s33]

At the [redacted]  
[redacted]

Do you have nay information or a copy of the proposal that you could forward to me on this?

Thanks

Brendan

**Brendan Bourke**

Assistant Director

International Policy & Cooperation

Business Development & Strategy Group

IP Australia



P + 61 2 6283 2148 | F + 61 2 6283 7999 | [s47F]

E [brendan.bourke@ipaaustralia.gov.au](mailto:brendan.bourke@ipaaustralia.gov.au)

A 47 Bowes Street, Woden ACT 2606 | PO Box 200, Woden ACT Australia 2606

Visit us at <http://www.ipaustralia.gov.au>

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[attachment [redacted] " deleted by Edwina Lewis/CBR/IPAustralia]

Re: TPP: [REDACTED] [SEC=IN-CONFIDENCE] -  
Notes Reply

From: [Edwina.Lewis@ipaaustralia.gov.au](mailto:Edwina.Lewis@ipaaustralia.gov.au)

To: [REDACTED]

all other redactions s33

Cc: [Brendan.Bourke@ipaaustralia.gov.au](mailto:Brendan.Bourke@ipaaustralia.gov.au)

Sent: 03-09-2012 12:16:39 PM

- Hi [REDACTED]
- 
- See IP Australia's comments below in Green.

**Edwina LEWIS (Ms)**

Assistant Director  
International Policy and Cooperation  
IP Australia



Ph +61 2 62832610 | [REDACTED] [edwina.lewis@ipaaustralia.gov.au](mailto:edwina.lewis@ipaaustralia.gov.au)  
47 Bowes Street Woden ACT Australia 2606 | PO Box 200 Woden ACT Australia 2606  
Visit us at <http://www.ipaaustralia.gov.au>

Please consider the environment before printing this email

[REDACTED] ---29/08/2012 01:00:11 PM---For Official Use Only Hi Brendan, Edwina

From: [REDACTED]

To: "Brendan.Bourke@ipaaustralia.gov.au" <Brendan.Bourke@ipaaustralia.gov.au>, "Edwina.Lewis@ipaaustralia.gov.au" <Edwina.Lewis@ipaaustralia.gov.au>

Cc: [REDACTED]

Date: 29/08/2012 01:00 PM

Subject: TPP: IP: [REDACTED] [SEC=IN-CONFIDENCE:FTA]

**For Official Use Only**

Hi Brendan, Edwina

I've received a request from [REDACTED] and would be grateful for your thoughts. The request and background information are at the bottom of this e-mail, and my initial responses and [REDACTED] are below. [REDACTED]

s47F

, we'd be grateful for any views you are able to provide by **midday Monday 3 September.**

With thanks and regards

all other redactions s33

s47F

Questions on [REDACTED]

all redactions s33

[REDACTED]

all redactions s33

[REDACTED]

[REDACTED]

[REDACTED]

- [REDACTED]
- [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

- [REDACTED]

[REDACTED]

- [REDACTED]

[REDACTED]

- [REDACTED]



Re: TPP: [REDACTED] [SEC=IN-CONFIDENCE] (Notes Reply) **File G2012/12298 FOI 138**

**all redactions s33**

[attachment [REDACTED] deleted by Edwina Lewis/CBR/IPAustralia]

Re: TPP: IP: Leesburg: s33 Brief [SEC=IN-CONFIDENCE] - Notes Reply

From: [Edwina.Lewis@ipaaustralia.gov.au](mailto:Edwina.Lewis@ipaaustralia.gov.au)

To: [Redacted]

all other redactions s47F

Sent: 05-09-2012 2:18:01 PM

Hi [Redacted]

Sorry it has taken this long to get back to you. Here are our comments as they stand at the moment. Happy to talk through on Friday.

[Redacted]

<Attachment: TPP DRAFT Brief, s33, Leesburg - IPA comments FINAL.DOCX>

See you tomorrow no doubt!

**Edwina LEWIS (Ms)**  
Assistant Director  
International Policy and Cooperation  
IP Australia



Ph +61 2 62832610 | [Redacted] | [edwina.lewis@ipaaustralia.gov.au](mailto:edwina.lewis@ipaaustralia.gov.au)  
47 Bowes Street Woden ACT Australia 2606 | PO Box 200 Woden ACT Australia 2606  
Visit us at <http://www.ipaustralia.gov.au>  
Please consider the environment before printing this email

[Redacted] ---23/08/2012 04:12:00 PM---For Official Use Only Dear Brendan, Edwina, Bronwyn

From: [Redacted]  
To: "Brendan.Bourke@ipaaustralia.gov.au" <Brendan.Bourke@ipaaustralia.gov.au>, "Edwina.Lewis@ipaaustralia.gov.au" <Edwina.Lewis@ipaaustralia.gov.au>, [Redacted]  
Cc: [Redacted]  
Date: 23/08/2012 04:12 PM  
Subject: TPP: IP: Leesburg: [Redacted] Brief [SEC=IN-CONFIDENCE:FTA]

**For Official Use Only**

Dear Brendan, Edwina, [Redacted]

s33

As promised, please see attached [REDACTED], with requests for input, for the next TPP round in Leesburg (8-15 September).

**all other redactions s33**

I welcome your comments on all aspects [REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]

I propose a meeting next week to discuss the draft – would Thursday or Friday from 10am-12pm suit? Please let me know your preference. I would be grateful for any written comments ahead of the meeting if possible, and final comments on the brief by **midday Tuesday 4 September**.

With thanks in advance, and I look forward to hearing from you.

Kind regards

**s47F**

**s47F**

Executive Officer  
International Intellectual Property Section  
Office of Trade Negotiations  
Australian Department of Foreign Affairs & Trade

Tel: **s47F**  
Fax: +61 2 6112 2347

[attachment [REDACTED] deleted by Edwina Lewis/CBR/IPAustralia]

Re: TPP: [REDACTED] [SEC=IN-CONFIDENCE]  
- Notes Reply

From: [Edwina.Lewis@ipaaustralia.gov.au](mailto:Edwina.Lewis@ipaaustralia.gov.au)

To: [REDACTED]

all other redactions s33

Sent: 04-09-2012 1:57:01 PM

Hi [REDACTED]

Please see comments on [REDACTED] done by Brendan.

[REDACTED]

**Trade Marks**

[REDACTED]

• [REDACTED]

• [REDACTED]

• [REDACTED]

**Patents**

• [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

all other redactions s33

[REDACTED]

[REDACTED]

• <Attachment: [REDACTED] >

• [REDACTED]

• [REDACTED]

**Edwina LEWIS (Ms)**

Assistant Director  
International Policy and Cooperation  
IP Australia



Ph +61 2 62832610 | [REDACTED] | [edwina.lewis@ipaustalia.gov.au](mailto:edwina.lewis@ipaustalia.gov.au)  
47 Bowes Street Woden ACT Australia 2606 | PO Box 200 Woden ACT Australia 2606  
Visit us at <http://www.ipaustalia.gov.au>

Please consider the environment before printing this email

[REDACTED] ---29/08/2012 05:18:07 PM---For Official Use Only Hi Brendan, Edwina

From: [REDACTED]  
To: "Brendan.Bourke@ipaustalia.gov.au" <Brendan.Bourke@ipaustalia.gov.au>, "Edwina.Lewis@ipaustalia.gov.au" <Edwina.Lewis@ipaustalia.gov.au>  
Cc: [REDACTED]  
Date: 29/08/2012 05:18 PM  
Subject: TPP: [REDACTED] [SEC=IN-CONFIDENCE:FTA]

**For Official Use Only**

**all other redactions s33**

Hi Brendan, Edwina

Another request [REDACTED] – I’m confident this is the last! As you know, [REDACTED] will be discussed during the [REDACTED] and, for completeness, I wanted to run these provisions by you to see if you have any new views. We can discuss at our meeting on Friday morning if that suits.

Many thanks

**s47F**

**s47F**

Executive Officer  
International Intellectual Property Section  
Office of Trade Negotiations  
Australian Department of Foreign Affairs & Trade

Tel: **s47F**

Fax: +61 2 6112 2347

[REDACTED]

[REDACTED]

[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

s33 exemption

**TPP: IP: Leesburg: [REDACTED] [SEC=IN-CONFIDENCE:FTA] - Notes Memo**

all other redactions s33

**From:** s47F  
**To:** "Brendan.Bourke@ipaustrialia.gov.au" <Brendan.Bourke@ipaustrialia.gov.au>, "Constantine.Nikolakopoulos@ipaustrialia.gov.au" <Constantine.Nikolakopoulos@ipaustrialia.gov.au>, s47F  
**Cc:**  
**Sent:** 20-08-2012 09:30:50 AM

**For Official Use Only**

Dear All  
I hope this finds you well.  
I am writing to confirm details for the upcoming 14<sup>th</sup> TPP round in Leesburg, USA, and to seek your input on the attached draft brief on [REDACTED]. The IP Group has agreed to spend [REDACTED]. The IP negotiations will take place from 8-15 September (with one free day). The formal stakeholder session will be on Sunday 9 September.  
The attached draft brief sets out the text on [REDACTED] as at the end of the San Diego round (this is the marked-up version so you can see changes from the round). I've inserted briefing notes under the provisions that will be discussed in Leesburg with requests for input in the column marked "Actions from 13<sup>th</sup> Round". I would be grateful for input on relevant issues for your agency **by midday Friday 31 August**. We will hold a meeting to discuss the draft brief on Monday 3 September at 3.30pm. Please let me know if you are able to make it, and will need a visitor's pass.  
Many thanks for your continuing help on various aspects of the negotiations, it is greatly appreciated. If you have any questions or would like to discuss, please don't hesitate to contact me.

Kind regards  
s47F

Executive Officer  
International Intellectual Property Section  
Office of Trade Negotiations  
Australian Department of Foreign Affairs & Trade  
Tel: s47F  
Fax: +61 2 6112 2347

<Attachment: TPP DRAFT Brief, [REDACTED], Leesburg.doc>

s33 exemption

**TPP: IP: Leesburg: [REDACTED] Brief [SEC=IN-CONFIDENCE:FTA] - Notes Memo**

**From:** s47F [REDACTED] all other redactions s33  
**To:** [REDACTED] Bourke@ipaustrialia.gov.au>, "Edwina.Lewis@ipaustrialia.gov.au" <Edwina.Lewis@ipaustrialia.gov.au>, s47F [REDACTED]  
**Cc:** s47F [REDACTED]  
**Sent:** 23-08-2012 06:11:16 AM

**For Official Use Only**

Dear Brendan, Edwina, s47F [REDACTED]  
As promised, please see attached draft brief on [REDACTED], with requests for input, for the next TPP round in Leesburg (8-15 September).

I welcome your comments on all aspects of the brief, [REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]

I propose a meeting next week to discuss the draft â€“ would Thursday or Friday from 10am-12pm suit? Please let me know your preference. I would be grateful for any written comments ahead of the meeting if possible, and final comments on the brief by **midday Tuesday 4 September**.

With thanks in advance, and I look forward to hearing from you.  
Kind regards

s47F [REDACTED]

Executive Officer  
International Intellectual Property Section  
Office of Trade Negotiations  
Australian Department of Foreign Affairs & Trade  
Tel: s47F [REDACTED]  
Fax: +61 2 6112 2347

<Attachment: TPP DRAFT Brief, [REDACTED], Leesburg.DOCX>



all other redactions s33

Cc:

From: s47F

To: s47F

Cc:

---

Hi s47F we're going through the [REDACTED] text at the moment in LA and at the bit that we spoke about last week. [REDACTED]

[REDACTED] Grateful you could let me know what you think as soon as you can.

The issue of [REDACTED]

Many thanks, s47F

Sent with Good (www.good.com)

**TPP: IP: Leesburg: [REDACTED] [SEC=IN-CONFIDENCE:FTA]**  
**- Notes Memo**

all other redactions s33

**From:** s47F  
**To:** "Brendan.Bourke@ipaaustralia.gov.au" <Brendan.Bourke@ipaaustralia.gov.au>, "Edwina.Lewis@ipaaustralia.gov.au" <Edwina.Lewis@ipaaustralia.gov.au>  
**Cc:** s47F  
**Sent:** 29-08-2012 07:17:56 AM

**For Official Use Only**

Hi Brendan, Edwina

Another request for Leesburg " "™m confident this is the last! As you know, [REDACTED] will be discussed during [REDACTED]

[REDACTED] and, for completeness, I wanted to run these provisions by you to see if you have any new views. We can discuss at our meeting on Friday morning if that suits.

Many thanks

s47F

Executive Officer  
International Intellectual Property Section  
Office of Trade Negotiations  
Australian Department of Foreign Affairs & Trade

Tel: s47F  
Fax: +61 2 6112 2347

[REDACTED]

[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

all redactions s33

[REDACTED]

s33 exemption

**TPP: IP: Briefs for Leesburg [SEC=IN-CONFIDENCE:FTA] - Notes Memo**

**From:** [Redacted] all other redactions s47F  
**To:** "Edwina.Lewis@ipaustrialia.gov.au" <Edwina.Lewis@ipaustrialia.gov.au>  
**Cc:** "Brendan.Bourke@ipaustrialia.gov.au" <Brendan.Bourke@ipaustrialia.gov.au>, [Redacted]  
**Sent:** 05-09-2012 9:47:41 PM

**For Official Use Only**

Hi Edwina

Attached are our updated briefs on [Redacted s33], and [Redacted s33], for Leesburg. Many thanks for all your (and Brendan's) help in the lead up - it's been a big effort and it should be a very interesting round!

See you soon

[Redacted]  
[Redacted]

Executive Officer  
International Intellectual Property Section  
Office of Trade Negotiations  
Australian Department of Foreign Affairs & Trade  
Tel: + [Redacted]  
Fax: +61 2 6112 2347

<Attachment: TPP DRAFT Brief, [Redacted s33] Leesburg.doc><Attachment: TPP DRAFT Brief, [Redacted s33] Leesburg.DOCX>

s33 exemption

TPP s33 briefing - Leesburg Round [SEC=IN-CONFIDENCE:FTA] - Notes Memo

From: [redacted] all other redactions s47F  
To: [redacted]  
Cc: [redacted] More...  
Sent: 24-08-2012 07:37:48 AM

Dear all  
Attached is draft briefing for the s33 negotiations at the Leesburg Round of Trans-Pacific Partnership negotiations (6-15 September). I am still waiting for input on a range of issues, but wanted to circulate this more broadly to allow everyone time to have a look and get back to me with any comments/queries.  
In summary, the key updates to Australia's positions are s33  
s33. It may be easier for you just to look for the green text throughout the brief.  
We will also have a negotiating session on s33  
s33. We will pass it on to you as soon as we receive it.  
Please let me know if you have comments or questions by **midday on Friday 31 August**. As always, please also let me know if you would like to be removed from this consultation list, or if you have colleagues you would like me to add to the list.

Best regards,  
[redacted]  
[redacted]  
Services Trade and Negotiations Section  
Australian Department of Foreign Affairs and Trade  
Tel: +[redacted]  
Fax: +61 2 6273 1527

<Attachment: TPP 14th Round - s33 Brief (Leesburg).docx>

RE: s33

s33 [SEC=UNCLASSIFIED] - Notes Memo

**From:** s47F  
**To:** "David.Bamford@ipaustralia.gov.au" <David.Bamford@ipaustralia.gov.au>  
**Cc:** "Andrew.Wilkinson@ipaustralia.gov.au" <Andrew.Wilkinson@ipaustralia.gov.au>, "Brendan.Bourke@ipaustralia.gov.au" <Brendan.Bourke@ipaustralia.gov.au>, "Frances.Roden@ipaustralia.gov.au" <Frances.Roden@ipaustralia.gov.au>, "Natalia.Reynolds@ipaustralia.gov.au" <Natalia.Reynolds@ipaustralia.gov.au>, s47F  
s47F  
**Sent:** 28-08-2012 11:22:04 PM

Hi David  
Below are a couple of quick responses. Please note these are policy responses, not legal ones.

s33 exemption



s47F

all other redactions s33

Services Trade and Negotiations Section

Australian Department of Foreign Affairs and Trade

Tel: s47F

Fax: +61 2 6273 1527

<Attachment: TPP [REDACTED] [REDACTED] post-Leesburg Round.docx><Attachment: [REDACTED]

>

s33 exemption

**Text Clearance for Leesburg TPP round [REDACTED] [SEC=IN-CONFIDENCE:FTA] - Notes Memo**

**From:** [REDACTED]  
**To:** [REDACTED]  
**Cc:** "brendan.bourke@ipaaustralia.gov.au" <brendan.bourke@ipaaustralia.gov.au>, [REDACTED]  
**Sent:** 27-08-2012 06:28:53 AM

[More...](#)

**exemptions under ss 33 and 47F**

Dear All,  
The attached provides [REDACTED] text pertinent to this coming round [REDACTED]. Please clear internally and respond by **COB Tuesday 4 September**. Also, please note this will be my final TPP negotiation and [REDACTED] will be taking over from me. We will hold a debrief and hand-over meeting at the beginning of October.

I look forward to hearing from you all next week or sooner and I look to have the brief circulated on 5 or 6 September.

Many thanks for your help.

[REDACTED]  
[REDACTED]  
Legal Specialist  
Trade and Environment Section  
Office of Trade Negotiations DFAT  
PH: [REDACTED] FAX: 6273 1527

<Attachment: Text Clearance for Leesburg TPP round [REDACTED].docx>

s33 exemption

TPP: IP: [REDACTED] : Cross-References [SEC=IN-CONFIDENCE:FTA]  
- Notes Memo

From: [REDACTED]  
To: "Brendan.Bourke@ipaustrialia.gov.au" <Brendan.Bourke@ipaustrialia.gov.au>,  
"Edwina.Lewis@ipaustrialia.gov.au" <Edwina.Lewis@ipaustrialia.gov.au>  
Cc: [REDACTED] >  
Sent: 29-08-2012 02:59:56 AM

exemptions under ss 33 and 47F

**For Official Use Only**

Hi Brendan, Edwina

I've received a request from [REDACTED], [REDACTED], on [REDACTED] and would be grateful for your thoughts. The request and background information are at the bottom of this e-mail, and my initial responses and the current [REDACTED] text are below. [REDACTED]

As [REDACTED] is heading to TPP on Tuesday, we'd be grateful for any views you are able to provide by **midday Monday 3 September**.

With thanks and regards

[REDACTED]

Questions on [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Questions on [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

- [REDACTED]

[REDACTED]

**BACKGROUND INFORMATION**

[REDACTED]

- [REDACTED]

- [REDACTED]

[REDACTED]

[REDACTED]

[Redacted text block]

- [Redacted list item 1]
- [Redacted list item 2]
- [Redacted list item 3]
- [Redacted list item 4]
- [Redacted list item 5]
- [Redacted list item 6]
- [Redacted list item 7]

- [Redacted text block 1]
- [Redacted text block 2]

[Redacted text block]

[REDACTED]

- [REDACTED]
- [REDACTED]

<Attachment: [REDACTED]>

exemptions under ss 33 and 47F

## TPP Round 14 (Leesburg) - logistical information [SEC=UNCLASSIFIED] - Notes Memo

**From:** [REDACTED] all redactions s47F  
**To:** [REDACTED]  
**Cc:** [REDACTED]  
**Sent:** 19-07-2012 04:19:05 AM

Dear Colleagues

The 14<sup>th</sup> round of Trans-Pacific Partnership agreement (TPP) negotiations will take place in Leesburg, Virginia on 6<sup>th</sup> 15 September.

We are yet to receive a negotiating schedule for the round, however consideration of hotel arrangements is underway because there will be a very limited number of rooms available to each delegations at the negotiating venue and also a limited number of other hotels in the area. For this reason I would be grateful if you could advise me if you plan to attend the round **by COB tomorrow (Friday 20/7)**. I realise this will be pending formal departmental approval and other travel planning, however I would like to have a sense of who may attend so I can pass on more detailed information and have better sense of total delegation numbers.

Kind regards

---

[REDACTED]  
Investment Policy & Trans-Pacific Partnership Section  
Goods & Investment Branch | Office of Trade Negotiations  
Department of Foreign Affairs and Trade  
[REDACTED]

s33 exemption

s33 exemption

**RE: TPP14 (Leesburg): Hotels and draft schedule [SEC=IN-CONFIDENCE] - Notes Memo**

**From:** [Redacted]  
**To:** [Redacted]  
**Cc:** [Redacted]  
**Sent:** 20-07-2012 06:53:51 AM

Hi All  
 Eagle-eyed [Redacted] has picked up that the Homewood Suites link is wrong – it takes you to book at a Homewood Suites which is different to the one USTR is describing, so hold fire on booking there. I have alerted the US so we can sort out which Homewood Suites they actually mean!

all redactions s47F

**Sent:** Friday, 20 July 2012 4:05 PM

**To:** [Redacted]  
 [Redacted]  
 [Redacted]  
 [Redacted]  
 [Redacted]  
 [Redacted]  
 [Redacted]

**Subject:** TPP14 (Leesburg): Hotels and draft schedule [SEC=IN-CONFIDENCE]

Dear Colleagues

As promised, an update on arrangements for Leesburg. First, attached is the first draft schedule – this has been circulated for comment today so it is subject to change.

Second, as I foreshadowed yesterday, the hotel arrangements are very challenging. There is not enough room at the venue – the [Lansdowne Resort](#) - to accommodate all delegates. As a result each country has been allocated 21 rooms for each night of the round, with other rooms available at the **Courtyard Marriott Dulles Town Centre** and the **Homewood Suites in Leesburg**. USTR will run buses – all day and evening – to/from these hotels. I have copied more info from USTR below on these options.

After Leads are accommodated in these 21 rooms at the Lansdowne, there will be several (3 or 4 tbc) that we will be able to offer to some of you. While I do accept bribes of chocolate, it will be easiest to allocate the spare rooms to whoever is going to be in Leesburg for the full round. [The added complication will be different department travel approval/booking rules, as the rooms at the Lansdowne have to be held with a credit card and a 50% (refundable to a point) deposit. But we’ll cross that bridge when we come to it.]

For the **Homewood Suites** and **the Marriot**, it is first in gets the rooms (no allocating), and the Homewood Suites booking link is available below. The Marriot link should be sent out early next week. I know travel booking rules will get in the way but I strongly advise you to books rooms at either of these hotels, or start making plans for other hotels in the area and hiring a car which may be the best option for departments sending more than 1 person (or combine the two needs and get a Winnebago, as I understand Team DIISRTE are considering –). Leesburg, Dulles Town Centre, and even Dulles Airport hotels are options if you have a car. I would not suggest relying on taxis as I’m not sure that they will be plentiful, at short notice, for relatively short hops around the suburbs.

To make things worse on the accommodation front, Leesburg is far enough away from home that even the US delegation will be taking hotel rooms at the Homewood Suites and Marriott, rather than face the hour+ commute from their homes in DC and surrounds. So I imagine these

options will book out fast.

I know these arrangements are not optimal, but I wanted to let you know early so you could start talking to your travel people and researching the area so you don't actually have to camp.

I will send through any further information I get from the US as soon as I get it.

Cheers

all redactions s47F

---

Investment Policy & Trans-Pacific Partnership Section  
Goods & Investment Branch | Office of Trade Negotiations  
Department of Foreign Affairs and Trade

<< File: LD\_Draft Schedule7192012\_revised.xlsx >>

**Lansdowne**

Room Rate: **\$185**, includes wireless internet

Main meeting space

Has 4 restaurants on site

**Courtyard Dulles Town Center (Marriott)**

Room Rate: **\$108**, includes wireless internet

Located within 5 miles of Lansdowne

It is located adjacent to the [Dulles Town Center](#), which has restaurants and a shopping mall.

BOOKING LINK: TBA

**Homewood Suites (Hilton)**

Room Rate: **\$108**, includes wireless internet & breakfast

Located within 5 miles of Lansdowne

Has kitchens in rooms/suites

1 mile from the downtown historic district

Across a highway bypass from the Leesburg Premium Outlet Mall

BOOKING LINK: [http://homewoodsuites.hilton.com/en/hw/groups/personalized/W/WASLDHW-TPP-20120905/index.jhtml?WT.mc\\_id=POG](http://homewoodsuites.hilton.com/en/hw/groups/personalized/W/WASLDHW-TPP-20120905/index.jhtml?WT.mc_id=POG)

# TPP14 (Leesburg): Hotels and draft schedule [SEC=IN-CONFIDENCE] - Notes Memo

**From:** [REDACTED]

**To:** [REDACTED]

**Cc:** [REDACTED]

**Sent:** 20-07-2012 06:04:41 AM

all redactions s47F

Dear Colleagues

As promised, an update on arrangements for Leesburg. First, attached is the first draft schedule – this has been circulated for comment today so it is subject to change.

Second, as I foreshadowed yesterday, the hotel arrangements are very challenging. There is not enough room at the venue – the [Lansdowne Resort](#) - to accommodate all delegates. As a result each country has been allocated 21 rooms for each night of the round, with other rooms available at the **Courtyard Marriott Dulles Town Centre** and the **Homewood Suites in Leesburg**. USTR will run buses – all day and evening – to/from these hotels. I have copied more info from USTR below on these options.

After Leads are accommodated in these 21 rooms at the Lansdowne, there will be several (3 or 4 tbc) that we will be able to offer to some of you. While I do accept bribes of chocolate, it will be easiest to allocate the spare rooms to whoever is going to be in Leesburg for the full round. [The added complication will be different department travel approval/booking rules, as the rooms at the Lansdowne have to be held with a credit card and a 50% (refundable to a point) deposit. But we’ll cross that bridge when we come to it.]

For the **Homewood Suites** and **the Marriot**, it is first in gets the rooms (no allocating), and the Homewood Suites booking link is available below. The Marriott link should be sent out early next week. I know travel booking rules will get in the way but I strongly advise you to books rooms at either of these hotels, or start making plans for other hotels in the area and hiring a car which may be the best option for departments sending more than 1 person (or combine the two needs and get a Winnebago, as I understand Team DIISRTE are considering). Leesburg, Dulles Town Centre, and even Dulles Airport hotels are options if you have a car. I would not suggest relying on taxis as I’m not sure that they will be plentiful, at short notice, for relatively short hops around the suburbs.

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I will send through any further information I get from the US as soon as I get it.

Cheers

---

Investment Policy & Trans-Pacific Partnership Section  
 Goods & Investment Branch | Office of Trade Negotiations  
 Department of Foreign Affairs and Trade

[Lansdowne](#)

Room Rate: **\$185**, includes wireless internet

Main meeting space

Has 4 restaurants on site

**Courtyard Dulles Town Center (Marriott)**

Room Rate: **\$108**, includes wireless internet

Located within 5 miles of Lansdowne

It is located adjacent to the [Dulles Town Center](#), which has restaurants and a shopping mall.

BOOKING LINK: TBA

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Located within 5 miles of Lansdowne

Has kitchens in rooms/suites

1 mile from the downtown historic district

Across a highway bypass from the Leesburg Premium Outlet Mall

BOOKING LINK: [http://homewoodsuites.hilton.com/en/hw/groups/personalized/W/WASLDHW-TPP-20120905/index.jhtml?WT.mc\\_id=POG](http://homewoodsuites.hilton.com/en/hw/groups/personalized/W/WASLDHW-TPP-20120905/index.jhtml?WT.mc_id=POG)

<Attachment: LD\_Draft Schedule7192012\_revised.xlsx>

# TPP14 (Leesburg): Hotels and draft schedule [SEC=IN-CONFIDENCE] - Notes Memo

all redactions s47F

**From:** [REDACTED]  
**To:** [REDACTED]  
**Cc:** [REDACTED]  
**Sent:** 20-07-2012 06:04:41 AM

Dear Colleagues

As promised, an update on arrangements for Leesburg. First, attached is the first draft schedule – this has been circulated for comment today so it is subject to change.

Second, as I foreshadowed yesterday, the hotel arrangements are very challenging. There is not enough room at the venue – the [Lansdowne Resort](#) - to accommodate all delegates. As a result each country has been allocated 21 rooms for each night of the round, with other rooms available at the **Courtyard Marriott Dulles Town Centre** and the **Homewood Suites in Leesburg**. USTR will run buses – all day and evening – to/from these hotels. I have copied more info from USTR below on these options.

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I will send through any further information I get from the US as soon as I get it.

Cheers

---

Investment Policy & Trans-Pacific Partnership Section  
 Goods & Investment Branch | Office of Trade Negotiations  
 Department of Foreign Affairs and Trade

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BOOKING LINK: TBA

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1 mile from the downtown historic district

Across a highway bypass from the Leesburg Premium Outlet Mall

BOOKING LINK: [http://homewoodsuites.hilton.com/en/hw/groups/personalized/W/WASLDHW-TPP-20120905/index.jhtml?WT.mc\\_id=POG](http://homewoodsuites.hilton.com/en/hw/groups/personalized/W/WASLDHW-TPP-20120905/index.jhtml?WT.mc_id=POG)

<Attachment: LD\_Draft Schedule7192012\_revised.xlsx>

**RE: TPP14 (Leesburg): Hotels and draft schedule [SEC=IN-CONFIDENCE] - Notes Memo**

**From:** [Redacted]  
**To:** [Redacted]  
**Cc:** [Redacted]  
**Sent:** 25-07-2012 11:18:31 PM

exemptions under ss 33 and 47F

Morning All

No update yet on the Homewood Suites but the link for the Courtyard Marriott is as copied. Note the booking link will open to US staff on Monday so get in quick:

Below is the link for the Courtyard Dulles Town Center. The deadline to make room Reservations is August 13<sup>th</sup>.  
[Redacted]  
[Redacted]

If you would like to reserve a room with a **King Size bed** at our special rate, type **TPPTPPA** in the "Group Code" slot  
If you would like to reserve a room with **two Queen beds**, type **TPPTPPB** in the "Group Code" slot  
Your room should come out to **\$108.00**/night with internet and parking included.

[Redacted]

If you would like to call the hotel, you can call 1-888-236-2427:

Ask for the Trans Pacific Partnership Room Block at the Courtyard Dulles Town Center and give the password: [Redacted]  
[Redacted]

---

**From:** [Redacted]  
**Sent:** Friday, 20 July 2012 4:54 PM

**To:** [Redacted]  
[Redacted]  
[Redacted]  
[Redacted]  
[Redacted]  
[Redacted]  
[Redacted]  
[Redacted]  
[Redacted]

**Subject:** RE: TPP14 (Leesburg): Hotels and draft schedule [SEC=IN-CONFIDENCE]

Hi All  
Eagle-eyed [Redacted] has picked up that the Homewood Suites link is wrong " it takes you to book at a Homewood Suites which is different to the one USTR is describing, so hold fire on booking there. I have alerted the US so we can sort out which Homewood Suites they actually mean!  
[Redacted]

---

**From:** [Redacted]  
**Sent:** Friday, 20 July 2012 4:05 PM

**To:** [Redacted]  
[Redacted]

'brendan.bourke@ipaustralia.gov.au'; [REDACTED]

exemptions under ss 33 and 47F

**Subject:** TPP14 (Leesburg): Hotels and draft schedule [SEC=IN-CONFIDENCE]

Dear Colleagues

As promised, an update on arrangements for Leesburg. First, attached is the first draft schedule – this has been circulated for comment today so it is subject to change.

Second, as I foreshadowed yesterday, the hotel arrangements are very challenging. There is not enough room at the venue – the [Lansdowne Resort](#) - to accommodate all delegates. As a result each country has been allocated 21 rooms for each night of the round, with other rooms available at the **Courtyard Marriott Dulles Town Centre** and the **Homewood Suites in Leesburg**. USTR will run buses – all day and evening – to/from these hotels. I have copied more info from USTR below on these options.

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I will send through any further information I get from the US as soon as I get it.

Cheers

[REDACTED]

---

Investment Policy & Trans-Pacific Partnership Section  
Goods & Investment Branch | Office of Trade Negotiations  
Department of Foreign Affairs and Trade

<< File: LD\_Draft Schedule7192012\_revised.xlsx >>

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Located within 5 miles of Lansdowne

Has kitchens in rooms/suites

1 mile from the downtown historic district

Across a highway bypass from the Leesburg Premium Outlet Mall

BOOKING LINK: [http://homewoodsuites.hilton.com/en/hw/groups/personalized/W/WASLDHW-TPP-20120905/index.jhtml?WT.mc\\_id=POG](http://homewoodsuites.hilton.com/en/hw/groups/personalized/W/WASLDHW-TPP-20120905/index.jhtml?WT.mc_id=POG)

**TPP14: Logistics - credentials require a photo (action by COB Monday 6 August) [SEC=UNCLASSIFIED] - Notes Memo**

**From:** [REDACTED]  
**To:** [REDACTED]  
**Cc:** [REDACTED]   
**Sent:** 26-07-2012 08:08:39 AM exemptions under ss 33 and 47F

Dear Colleagues

[REDACTED]  
[REDACTED]

There will not be an independent website for registration (it will be handled directly through the virtual secretariat) and this time around **credentials with photos** will be issued to delegates.

Based on past registrations I have the personal details required the registration list, however you will **all need to submit a colour passport-style photo** electronically. **Please ensure the file is a .jpeg and the file name includes your name.** There are no further specifications on file size (but I have asked the US to confirm that and will advise if there are).

Please submit your photo to [REDACTED] by COB Monday 6 August. This is to meet a US deadline which they advise is not flexible. We will send reminders about this, given that some of you may need to get photos taken.

Kind regards

[REDACTED]

---

Investment Policy & Trans-Pacific Partnership Section  
Goods & Investment Branch | Office of Trade Negotiations  
Department of Foreign Affairs and Trade

[REDACTED]

s33 exemption

s33 exemption



**RE: TPP14 (Leesburg): Hotels and draft schedule [SEC=IN-CONFIDENCE] - Notes Memo**

**From:** [Redacted]  
**To:** [Redacted]  
**Cc:** [Redacted]  
**Sent:** 26-07-2012 11:58:08 PM

exemptions under ss 33 and 47F

Hi Everyone

Update from USTR on the Homewood Suites:

**HOMEWOOD SUITES:**

\* In fact, this is not the Homewood suites that I had advertised. It was a miscommunication with our staff. However, this Homewood Suites is still a short distance away, and we will provide a shuttle service as well. Sorry for the confusion!

[http://homewoodsuites.hilton.com/en/hw/groups/personalized/W/WASLDHW-TPP-20120905/index.jhtml?WT.mc\\_id=POG](http://homewoodsuites.hilton.com/en/hw/groups/personalized/W/WASLDHW-TPP-20120905/index.jhtml?WT.mc_id=POG)

\$108 + Tax = includes internet, breakfast, light dinner Mon-Thursday 5-7 PM, all suites have a kitchen

**Deadline: August 13**

---

**From:** [Redacted]  
**Sent:** Thursday, 26 July 2012 9:19 AM  
**To:** [Redacted]  
[Redacted]  
'brendan.bourke@ipaustralia.gov.au'; [Redacted]  
[Redacted]  
[Redacted]  
[Redacted]  
[Redacted]

**Subject:** RE: TPP14 (Leesburg): Hotels and draft schedule [SEC=IN-CONFIDENCE]

Morning All

No update yet on the Homewood Suites but the link for the Courtyard Marriott is as copied. Note the booking link will open to US staff on Monday so get in quick:

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If you would like to reserve a room with a **King Size bed** at our special rate, type **TPPTPPA** in the "Group Code" slot

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Your room should come out to **\$108.00/night** with internet and parking included.

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Ask for the Trans Pacific Partnership Room Block at the Courtyard Dulles Town Center and give the password: [Redacted]

From: [REDACTED]

exemptions under ss 33 and 47F

Sent: Friday, 20 July 2012 4:54 PM

To: [REDACTED]

'brendan.bourke@ipaaustralia.gov.au'; [REDACTED]

**Subject:** RE: TPP14 (Leesburg): Hotels and draft schedule [SEC=IN-CONFIDENCE]

Hi All

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---

From: [REDACTED]

Sent: Friday, 20 July 2012 4:05 PM

To: [REDACTED]

'brendan.bourke@ipaaustralia.gov.au'; [REDACTED]

**Subject:** TPP14 (Leesburg): Hotels and draft schedule [SEC=IN-CONFIDENCE]

Dear Colleagues

As promised, an update on arrangements for Leesburg. First, attached is the first draft schedule â€œ this has been circulated for comment today so it is subject to change.

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Cheers

exemptions under ss 33 and 47F

---

Investment Policy & Trans-Pacific Partnership Section  
Goods & Investment Branch | Office of Trade Negotiations  
Department of Foreign Affairs and Trade

<< File: LD\_Draft Schedule7192012\_revised.xlsx >>

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**RE: TPP14: Logistics - credentials require a photo (action by COB Monday 6 August) [SEC=UNCLASSIFIED] - Notes Memo**

**From:** [Redacted]  
**To:** [Redacted]  
**Cc:** [Redacted]  
**Sent:** 31-07-2012 06:04:37 AM

**exemptions under ss 33 and 47F**

Hi Everyone

Thanks to all those who have submitted their photo, and a friendly reminder to those that haven't we need your mugshots by **COB Monday August 6** so we can register you for Leesburg. Please send though to [Redacted]

[Redacted]

Kind regards

[Redacted]

---

**From:** [Redacted]  
**Sent:** Thursday, 26 July 2012 6:09 PM

**To:** [Redacted]  
[Redacted]  
'brendan.bourke@ipaustralia.gov.au'; [Redacted]  
[Redacted]  
[Redacted]  
[Redacted]  
[Redacted]  
[Redacted]  
[Redacted]  
[Redacted]  
[Redacted]  
[Redacted]

**Subject:** TPP14: Logistics - credentials require a photo (action by COB Monday 6 August) [SEC=UNCLASSIFIED]

**Importance:** High

Dear Colleagues

[Redacted]  
[Redacted]

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Based on past registrations I have the personal details required the registration list, however you will **all need to submit a colour passport-style photo** electronically. **Please ensure the file is a .jpeg and the file name includes your name.** There are no further specifications on file size (but I have asked the US to confirm that and will advise if there are).

Please submit your photo to [Redacted] by COB Monday 6 August. This is to meet a US deadline which they advise is not flexible. We will send reminders about this, given that some of you may need to get photos taken.

Kind regards

[Redacted]

Goods & Investment Branch | Office of Trade Negotiations

Department of Foreign Affairs and Trade



exemptions under ss 33 and 47F

s33 exemption

s33 exemption

**TPP14: Updated schedule [SEC=IN-CONFIDENCE:FTA] - Notes Memo**

**From:** [Redacted]  
**To:** [Redacted]  
**Cc:** [Redacted]   
**Sent:** 05-08-2012 11:23:45 PM **exemptions under ss 33 and 47F**

Hi Everyone  
Another "œfinal" schedule but hopefully not too disruptive " I think some Leads will be aware of changes due to ongoing discussions in their groups. Let me know if any change is impossible for us to accommodate.  
Differences:

[Redacted]  
[Redacted]  
[Redacted]  
[Redacted]  
[Redacted]  
[Redacted]  
[Redacted]

---

Investment Policy & Trans-Pacific Partnership Section  
Goods & Investment Branch | Office of Trade Negotiations  
Department of Foreign Affairs and Trade  
[Redacted]

<Attachment: LD\_Final Schedule8012012.xlsx>

s33 exemption

s33 exemption



<Attachment: LD\_Final Schedule8062012.xlsx>

s33 exemption

s33 exemption

**TPP14: Final, final, final schedule [SEC=IN-CONFIDENCE] - Notes Memo**

**From:** [REDACTED]  
**To:** [REDACTED]  
**Cc:** [REDACTED]   
**Sent:** 08-08-2012 11:19:37 PM

Hi All  
Only one change this time â€“ [REDACTED].

Kind regards  
[REDACTED]

exemptions under ss 33 and 47F

---

Investment Policy & Trans-Pacific Partnership Section  
Goods & Investment Branch | Office of Trade Negotiations  
Department of Foreign Affairs and Trade  
[REDACTED]

<Attachment: LD\_Final Schedule 8\_08\_2012.pdf>

s33 exemption

s33 exemption

s33 exemption

s33 exemption

all redactions s47F

CONFIRMATION_NO	FULL_NAME	ARRIVAL	DEPARTURE	ROOM TYPE	NIGHTS
8104956					
8248203					
8248204					
8248205					
8248206					
8248207					
8248208					
8248210					
8248211					
8248212					
8248213					
8248214					
8248215					
8248217					
8248218					
8248219					
8248220					
8248221					
8248222					
8248223					
8248224					
8248225					
8264702					
8265202					

**RE: TRIM Electronic Object : D12/680109 : Australia Rooming List  
[SEC=UNCLASSIFIED] - Notes Memo**

**From:** [REDACTED]  
**To:** [REDACTED]  
**Cc:** [REDACTED] "Brendan.Bourke@ipaaustralia.gov.au"  
<Brendan.Bourke@ipaaustralia.gov.au>  
**Sent:** 13-08-2012 1:22:12 PM

all redactions s47F

Good Morning,

Brendan Bourke is all set for checking out on the [REDACTED]. Attached is the current rooming list. Let me know if I can help you with anything else. Have a great day!

[REDACTED] | GROUP ROOM COORDINATOR  
Lansdowne Resort | 44050 Woodridge Parkway | Lansdowne, VA 20176  
Office: [REDACTED]

- Aspen . Austin . Boston . Chapel Hill . Charleston . Chicago . Cle Elum . Del Mar . Denver
- Eugene . Florham Park . Houston . Kirkland . Lake Tahoe . Leesburg . Los Angeles . Maui
- Palm Springs . Palos Verdes . Phoenix . Portland . San Diego . Santa Fe . Seattle . Snowmass Village
- Stowe . Sunriver . Tampa . Tarrytown . Telluride . Tempe . Vail . Washington, DC

Visit [www.destinationhotels.com](http://www.destinationhotels.com) to join Destination Delivers and plan your next travel experience

-----Original Message-----

**From:** [REDACTED]  
**Sent:** Thursday, August 09, 2012 7:34 PM  
**To:** [REDACTED]  
**Cc:** [REDACTED] Brendan.Bourke@ipaaustralia.gov.au  
**Subject:** TRIM Electronic Object : D12/680109 : Australia Rooming List [SEC=UNCLASSIFIED]

Dear [REDACTED]

Please amend the check- out date for Brendan Bourke (highlighted) to depart on the [REDACTED]

Grateful for your assistance. Please send me an amended list.

Kind regards,

[REDACTED]

-----< TRIM Record Information >-----

Record Number : D12/680109  
Title : Australia Rooming List

<Attachment: Australia Rooming List.xlsx>

s33 exemption

Re: TPP: International Exhaustion of trade marks[SEC=UNCLASSIFIED] - Notes Reply

From: Michael.Arblaster@ipaaustralia.gov.au
To: Brendan Bourke/OU=CBR/IPAustralia@IP\_Australia
Cc: Kumudu Ramasundara/OU=CBR/IPAustralia@IP\_Australia, Robyn Foster/OU=CBR/IPAustralia@IP\_Australia
Sent: 19-08-2011 6:07:36 PM

We need to be very careful about what we mean when we talk about exhaustion - it is used in two different ways.

There are two questions:

Trade marks are territorial and there is exhaustion.

- [Redacted]
• [Redacted]
[Redacted]
[Redacted]
[Redacted]
[Redacted]
[Redacted]
[Redacted]
[Redacted]
[Redacted]

Michael Arblaster
Assistant General Manager
Trade Marks and Designs Hearings
IP Australia

all exemptions s33



P + 61 2 6283 2779 | F + 61 2 6283 7999 | E michael.arblaster@ipaaustralia.gov.au
A 47 Bowes Street, Woden ACT 2606 | PO Box 200, Woden ACT Australia 2606

Visit us at http://www.ipaustralia.gov.au

Please consider the environment before printing this email

Brendan Bourke---19/08/2011 05:07:03 PM---The Trans-Pacific Partnership (TPP) Agreement is a proposed plurilateral free trade agreement (FTA)

From: Brendan Bourke/CAustralia
To: Michael Arblaster/CAustralia@IP\_Australia, Kumudu Ramasundara/CAustralia@IP\_Australia
Cc: Robyn Foster/CAustralia@IP\_Australia
Date: 19/08/2011 05:07 PM
Subject: TPP: International Exhaustion of trade marks[SEC=UNCLASSIFIED]

The Trans-Pacific Partnership (TPP) Agreement is a proposed plurilateral free trade agreement (FTA) currently involving 9 of the 21 Australian Pacific Economic Cooperation (APEC) members. Negotiations commenced in March 2010 and are ongoing. Negotiating participants are Australia, Brunei, Chile, Malaysia, New Zealand, Singapore, Peru, the United States of America (US), and Vietnam.

[Redacted]
[Redacted]
[Redacted]

[Redacted content]

Would welcome any views, [Redacted] preferably be end of next week (26 September)

Thanks

all exemptions s33

**Brendan Bourke**  
Assistant Director  
International Policy & Cooperation  
Business Development & Strategy Group  
IP Australia



P + 61 2 6283 2148 | F + 61 2 6283 7999 | E [brendan.bourke@ipaustalia.gov.au](mailto:brendan.bourke@ipaustalia.gov.au)  
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Visit us at <http://www.ipaustalia.gov.au>

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**TPP: International Exhaustion of trade marks[SEC=UNCLASSIFIED] - Notes Memo**

**From:** [Brendan.Bourke@ipaaustralia.gov.au](mailto:Brendan.Bourke@ipaaustralia.gov.au)  
**To:** Michael Arblaster/OU=CBR/IPAustralia@IP\_Australia, Kumudu Ramasundara/OU=CBR/IPAustralia@IP\_Australia  
**Cc:** Robyn Foster/OU=CBR/IPAustralia@IP\_Australia  
**Sent:** 19-08-2011 5:07:09 PM

all exemptions s33

The Trans-Pacific Partnership (TPP) Agreement is a proposed plurilateral free trade agreement (FTA) currently involving 9 of the 21 Australian Pacific Economic Cooperation (APEC) members. Negotiations commenced in March 2010 and are ongoing. Negotiating participants are Australia, Brunei, Chile, Malaysia, New Zealand, Singapore, Peru, the United States of America (US), and Vietnam.

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

Would welcome any views, [Redacted] . preferably be end of next week (26 September)

Thanks

**Brendan Bourke**

Assistant Director

International Policy & Cooperation

Business Development & Strategy Group

IP Australia



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From: [Brendan Bourke@ipaaustralia.gov.au](mailto:Brendan.Bourke@ipaaustralia.gov.au)  
To: [REDACTED]  
Cc: [REDACTED] s47F, Matthew Forno/OU=CBR/IPAustralia@IP\_Australia, Constantine Nikolakopoulos/OU=CBR/IPAustralia@IP\_Australia  
Sent: 18-11-2011 5:35:34 PM

all other exemptions s33

Attached are comments on the exhaustion table. There was some weird formatting stuff happening that I couldn't sort out, so sorry about that.

[REDACTED]

<Attachment: Exhaustion of rights chart - IPA input.docx>

**Brendan Bourke**  
Assistant Director  
International Policy & Cooperation  
Business Development & Strategy Group  
IP Australia

s47F 15/11/2011 11:04:36 AM [REDACTED]



P + 61 2 6283 2148 | F + 61 2 6283 7999 [REDACTED]  
E [brendan.bourke@ipaaustralia.gov.au](mailto:brendan.bourke@ipaaustralia.gov.au)  
A 47 Bowes Street, Woden ACT 2606 | PO Box 200, Woden ACT Australia 2606  
Visit us at <http://www.ipaaustralia.gov.au>

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From: [REDACTED]  
To: "Brendan Bourke (brendan.bourke@ipaaustralia.gov.au)" <brendan.bourke@ipaaustralia.gov.au>  
Date: 15/11/2011 11:04 AM  
Subject: FW: Interseasonal Work/TPP Confidential [SEC=IN-CONFIDENCE:FTA]

So it's all starting to come through now [REDACTED]

I'd be most grateful if you could have a look and let me know what should be fed in, due date back to Luz is 22 November (next Tuesday).

Many thanks, M

s47F  
FTA Commitments & Implementation Section  
Office of Trade Negotiations  
Department of Foreign Affairs & Trade  
Tel: [REDACTED]  
Fax: 02 6112 3773 s47F

[REDACTED]

s33 exemption

Re: TPP KL - [REDACTED] [SEC=IN-CONFIDENCE] - Notes Reply

From: [Brendan Bourke](mailto:Brendan.Bourke@ipaaustralia.gov.au)  
To: Matthew Forno/OU=CBR/IP=Australia@IP\_Australia, Constantine Nikolakopoulos/OU=CBR/IP=Australia@IP\_Australia  
Sent: 01-12-2011 10:03:19 AM

s47F

[REDACTED]

All other redactions s33

Brendan Bourke  
Assistant Director  
International Policy & Cooperation  
Business Development & Strategy Group  
IP Australia

s47F

17/11/2011 04:10:06 PM--Hi Brendan [REDACTED]



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From: "Brendan Bourke (brendan.bourke@ipaaustralia.gov.au)" <brendan.bourke@ipaaustralia.gov.au>  
To: [REDACTED]  
Date: 17/11/2011 04:10 PM  
Subject: TPP KL [REDACTED] [SEC=IN-CONFIDENCE.FTA]

Hi Brendan, [REDACTED]

Let me know what you think when you get a chance.

Many thanks, M.

[REDACTED]  
FTA Commitments & Implementation Section  
Office of Trade Negotiations  
Department of Foreign Affairs & Trade  
To: [REDACTED]

s47F

RE: TPP KL - [REDACTED]  
Notes Memo

[SEC=IN-CONFIDENCE] -

**From:** [REDACTED]  
**To:** "Brendan.Bourke@ipaustrialia.gov.au" <Brendan.Bourke@ipaustrialia.gov.au>  
**Cc:** "Matthew.Forno@ipaustrialia.gov.au" <Matthew.Forno@ipaustrialia.gov.au>, "Constantine.Nikolakopoulos@ipaustrialia.gov.au" <Constantine.Nikolakopoulos@ipaustrialia.gov.au>  
**Sent:** 01-12-2011 01:45:15 AM

That looks good, Brendan. I agree that this will be a useful conversation.  
M.

[REDACTED]

All other redactions s33

FTA Commitments & Implementation Section  
Office of Trade Negotiations  
Department of Foreign Affairs & Trade  
Tel: [REDACTED]  
Fax: 02 6112 3773

**From:** Brendan.Bourke@ipaustrialia.gov.au [mailto:Brendan.Bourke@ipaustrialia.gov.au]  
**Sent:** Thursday, 1 December 2011 10:03 AM  
**To:** [REDACTED]  
**Cc:** Matthew.Forno@ipaustrialia.gov.au; Constantine.Nikolakopoulos@ipaustrialia.gov.au  
**Subject:** Re: [REDACTED] [SEC=IN-CONFIDENCE]  
Hi [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

**Brendan Bourke**  
Assistant Director  
International Policy & Cooperation  
Business Development & Strategy Group  
IP Australia



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E [brendan.bourke@ipaustrialia.gov.au](mailto:brendan.bourke@ipaustrialia.gov.au)

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All other redactions s33

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From: [Redacted]

To: "Brendan Bourke ([brendan.bourke@ipaustralia.gov.au](mailto:brendan.bourke@ipaustralia.gov.au))" <[brendan.bourke@ipaustralia.gov.au](mailto:brendan.bourke@ipaustralia.gov.au)>

Date: 17/11/2011 04:10 PM

Subject: TPP KL - [Redacted] [SEC=IN-CONFIDENCE:FTA]

Hi Brendan, [Redacted]

Let me know what you think when you get a chance.

[Redacted]

Many thanks, M.

s47F

FTA Commitments & Implementation Section

Office of Trade Negotiations

Department of Foreign Affairs & Trade

Tel: s47F

Fax: 02 6112 3773

All other  
redactions s33

<Attachment: image001.gif>

TPP: Parallel Imports for Trade marks [SEC=UNCLASSIFIED] - Notes Memo

**From:** [Brendan.Bourke@ipaaustralia.gov.au](mailto:Brendan.Bourke@ipaaustralia.gov.au)  
**To:** Philip Noonan/OU=CBR/IPAustralia@IP\_Australia  
**Cc:** Kumudu Ramasundara/OU=CBR/IPAustralia@IP\_Australia, Terry Moore/OU=CBR/IPAustralia@IP\_Australia, Matthew Forno/OU=CBR/IPAustralia@IP\_Australia, Ian Goss/OU=CBR/IPAustralia@IP\_Australia  
**Sent:** 20-12-2011 10:26:23 AM

All redactions s33

Philip

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

I am seeking your views on this matter.

[Redacted]

Brendan

**Brendan Bourke**

Assistant Director

International Policy & Cooperation

Business Development & Strategy Group

IP Australia



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E [brendan.bourke@ipaaustralia.gov.au](mailto:brendan.bourke@ipaaustralia.gov.au)

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**Fw: TPP: Parallel Imports for Trade marks [SEC=UNCLASSIFIED] - Notes Memo**

**From:** [Philip.Noonan@ipaaustralia.gov.au](mailto:Philip.Noonan@ipaaustralia.gov.au)  
**To:** Fatima Beattie/OU=CBR/IPAustralia@IP\_Australia, Ian Goss/OU=CBR/IPAustralia@IP\_Australia, Robyn Foster/OU=CBR/IPAustralia@IP\_Australia  
**Cc:** Matthew Forno/OU=CBR/IPAustralia@IP\_Australia, Brendan Bourke/OU=CBR/IPAustralia@IP\_Australia, Terry Moore/OU=CBR/IPAustralia@IP\_Australia  
**Sent:** 21-12-2011 5:38:21 PM

All redactions s33

All

I have asked Brendan to set up a meeting, for after Robyn's return, to discuss [REDACTED]. Brendan will prepare a short briefing paper.

Philip

----- Forwarded by Philip Noonan/CBR/IPAustralia on 21/12/2011 05:36 PM -----

**From:** Brendan Bourke/CBR/IPAustralia  
**To:** Philip Noonan/CBR/IPAustralia@IP\_Australia  
**Cc:** Kumudu Ramasundara/CBR/IPAustralia@IP\_Australia, Terry Moore/CBR/IPAustralia@IP\_Australia, Matthew Forno/CBR/IPAustralia@IP\_Australia, Ian Goss/CBR/IPAustralia@IP\_Australia  
**Date:** 20/12/2011 10:26 AM  
**Subject:** TPP: Parallel Imports for Trade marks [SEC=UNCLASSIFIED]

Philip

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[Redacted]

[Redacted]

[Redacted]

I am seeking your views on this matter.

All other redactions s33

[Redacted]

Brendan

**Brendan Bourke**

Assistant Director

International Policy & Cooperation

Business Development & Strategy Group

IP Australia



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**FW: International Exhaustion Chart [SEC=UNCLASSIFIED] - Notes Memo**

**From:** [Redacted]  
**To:** [Redacted]  
**Cc:** "Brendan Bourke (brendan.bourke@ipaaustralia.gov.au)" <brendan.bourke@ipaaustralia.gov.au>  
**Sent:** 27-02-2012 12:15:04 AM

Good morning everyone,

[Redacted]

Regards,

[Redacted]

FTA Commitments & Implementation Section  
Office of Trade Negotiations  
Department of Foreign Affairs & Trade  
Tel: [Redacted]  
Fax: 02 6112 3773

all exemptions s33

[Redacted]

[Redacted]

s33 exemption

# TPP and international exhaustion/parallel importation [SEC=IN-CONFIDENCE] - Notes Memo

**From:** [Brendan.Bourke@ipaaustralia.gov.au](mailto:Brendan.Bourke@ipaaustralia.gov.au)  
**To:** Philip Noonan/OU=CBR/IPAustralia@IP\_Australia  
**Cc:** Fatima Beattie/OU=CBR/IPAustralia@IP\_Australia, Robyn Foster/OU=CBR/IPAustralia@IP\_Australia, Victor Portelli/OU=CBR/IPAustralia@IP\_Australia, Matthew Forno/OU=CBR/IPAustralia@IP\_Australia, Edwina Lewis/OU=CBR/IPAustralia@IP\_Australia,  More...  
**Sent:** 20-06-2012 2:54:10 PM

All redactions s33

Philip

[Redacted]

[Redacted]

[Redacted]

The issues addressed in the paper have previously been considered in a number of economic and legal reviews of the IP system and retailing in Australia over the last three decades that have considered parallel imports. [Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

I would welcome your (and others) comments.

<Attachment: Briefing Paper - Policy settings - Parallel Importation.doc>

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]



All other  
redactions s33

**Brendan Bourke**

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Re: TPP and international exhaustion/parallel importation [SEC=IN-CONFIDENCE] - Notes Reply

From: [Robyn.Foster@ipaaustralia.gov.au](mailto:Robyn.Foster@ipaaustralia.gov.au)  
To: Brendan Bourke/OU=CBR/IPAustralia@IP\_Australia  
Cc: Constantine Nikolakopoulos/OU=CBR/IPAustralia@IP\_Australia, Edwina Lewis/OU=CBR/IPAustralia@IP\_Australia, Fatima Beattie/OU=CBR/IPAustralia@IP\_Australia, Matthew Forno/OU=CBR/IPAustralia@IP\_Australia, Philip Noonan/OU=CBR/IPAustralia@IP\_Australia, [More...](#)  
Sent: 25-06-2012 12:26:24 PM

All redactions s33

Brendan

I am comfortable with your view in para 3 below [REDACTED]

Good paper.

Kind Regards

**Robyn Foster**

General Manager

Trade Marks and Designs

IP Australia



Ph 6283 2900, Fax 6285 4149

PO Box 200, Woden, ACT, 2606, Australia

[www.ipaustralia.gov.au](http://www.ipaustralia.gov.au)

Brendan Bourke---20/06/2012 02:54:10 PM---Philip At a meeting in April 2012, we discussed whether we could support provisions in the TPP that

From: Brendan Bourke/CBR/IPAustralia  
To: Philip Noonan/CBR/IPAustralia@IP\_Australia  
Cc: Fatima Beattie/CBR/IPAustralia@IP\_Australia, Robyn Foster/CBR/IPAustralia@IP\_Australia, Victor Portelli/CBR/IPAustralia@IP\_Australia, Matthew Forno/CBR/IPAustralia@IP\_Australia, Edwina Lewis/CBR/IPAustralia@IP\_Australia, Constantine Nikolakopoulos/CBR/IPAustralia@IP\_Australia  
Date: 20/06/2012 02:54 PM  
Subject: TPP and international exhaustion/parallel importation [SEC=IN-CONFIDENCE]

Philip

[REDACTED]

The issues addressed in the paper have previously been considered in a number of economic and legal reviews of the IP system and retailing in Australia over the last three decades that have considered parallel imports. [REDACTED]

[REDACTED]

[REDACTED]

I would welcome your (and others) comments.

<Attachment: Briefing Paper - Policy settings - Parallel Importation.doc>

[Redacted]

[Redacted]

All other redactions s33

[Redacted]

[Redacted]

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Re: TPP and international exhaustion/parallel importation [SEC=IN-CONFIDENCE] - Notes Reply

From: Victor.Portelli@ipaaustralia.gov.au
To: Brendan Bourke/OU=CBR/IPAustralia@IP\_Australia
Cc: Constantine Nikolakopoulos/OU=CBR/IPAustralia@IP\_Australia, Edwina Lewis/OU=CBR/IPAustralia@IP\_Australia, Fatima Beattie/OU=CBR/IPAustralia@IP\_Australia, Matthew Forno/OU=CBR/IPAustralia@IP\_Australia, Philip Noonan/OU=CBR/IPAustralia@IP\_Australia, More...
Sent: 28-06-2012 1:42:06 PM

Brendan,
I am happy with the direction on parallel imports.
Victor

All redactions s33

Brendan Bourke---20/06/2012 02:54:10 PM---Philip At a meeting in April 2012, we discussed whether we could support provisions in the TPP that

From: Brendan Bourke/CBR/IPAustralia
To: Philip Noonan/CBR/IPAustralia@IP\_Australia
Cc: Fatima Beattie/CBR/IPAustralia@IP\_Australia, Robyn Foster/CBR/IPAustralia@IP\_Australia, Victor Portelli/CBR/IPAustralia@IP\_Australia, Matthew Forno/CBR/IPAustralia@IP\_Australia, Edwina Lewis/CBR/IPAustralia@IP\_Australia, Constantine Nikolakopoulos/CBR/IPAustralia@IP\_Australia
Date: 20/06/2012 02:54 PM
Subject: TPP and international exhaustion/parallel importation [SEC=IN-CONFIDENCE]

Philip

[Redacted]

The issues addressed in the paper have previously been considered in a number of economic and legal reviews of the IP system and retailing in Australia over the last three decades that have considered parallel imports.

[Redacted]

[Redacted]

I would welcome your (and others) comments.

<Attachment: Briefing Paper - Policy settings - Parallel Importation.doc>

[Redacted]

[Redacted]

[Redacted]

[Redacted]

**Brendan Bourke**

Assistant Director  
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Business Development & Strategy Group  
IP Australia



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Re: TPP and international exhaustion/parallel importation [SEC=IN-CONFIDENCE] - Notes Reply

From: Philip.Noonan@ipaaustralia.gov.au  
To: Brendan Bourke/OU=CBR/IPAustralia@IP\_Australia  
Cc: Fatima Beattie/OU=CBR/IPAustralia@IP\_Australia, Robyn Foster/OU=CBR/IPAustralia@IP\_Australia, Celia Poole/OU=CBR/IPAustralia@IP\_Australia  
Sent: 25-07-2012 4:25:19 PM

All redactions s33

Brendan

I am fine with this paper thanks. Sorry for taking so long.

Philip

Brendan Bourke---20/06/2012 02:54:10 PM---Philip At a meeting in April 2012, we discussed whether we could support provisions in the TPP that

From: Brendan Bourke/CBR/IPAustralia  
To: Philip Noonan/CBR/IPAustralia@IP\_Australia  
Cc: Fatima Beattie/CBR/IPAustralia@IP\_Australia, Robyn Foster/CBR/IPAustralia@IP\_Australia, Victor Portelli/CBR/IPAustralia@IP\_Australia, Matthew Forno/CBR/IPAustralia@IP\_Australia, Edwina Lewis/CBR/IPAustralia@IP\_Australia, Constantine Nikolakopoulos/CBR/IPAustralia@IP\_Australia  
Date: 20/06/2012 02:54 PM  
Subject: TPP and international exhaustion/parallel importation [SEC=IN-CONFIDENCE]

Philip

[Redacted text block]

The issues addressed in the paper have previously been considered in a number of economic and legal reviews of the IP system and retailing in Australia over the last three decades that have considered parallel imports. [Redacted text block]

[Redacted text block]

[Redacted text block]

I would welcome your (and others) comments.

[attachment "Briefing Paper - Policy settings - Parallel Importation.doc" deleted by Philip Noonan/CBR/IPAustralia]

[Redacted text block]

[Redacted text block]

[Redacted text block]

[Redacted text block]

**Brendan Bourke**

Assistant Director  
International Policy & Cooperation  
Business Development & Strategy Group  
IP Australia



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**RE: TPP: Traditional knowledge, traditional cultural expressions and genetic resources [SEC=IN-CONFIDENCE] - Notes Memo**

**From:** [Redacted]  
**To:** [Redacted]  
**Cc:** "Brendan Bourke" <brendan.bourke@ipaaustralia.gov.au>  
**Sent:** 19-04-2012 11:10:40 AM

All other redactions s47F

IN-CONFIDENCE

Hi [Redacted]

s33

Happy to discuss later today.

[Redacted]

Principal Legal Officer  
Copyright and Digital Economy | Civil Law Division | Civil Justice and Legal Services Group  
Attorney-General's Department  
3-5 National Circuit, BARTON ACT 2600  
ph: [Redacted]

---

**From:** [Redacted]  
**Sent:** Wednesday, 18 April 2012 3:21 pm  
**To:** [Redacted]  
**Subject:** RE: TPP: Traditional knowledge, traditional cultural expressions and genetic resources [SEC=IN-CONFIDENCE]  
Thanks [Redacted] that's great. Do you have any initial views to share before the meeting? We could discuss by phone if that helps?

---

**From:** [Redacted]  
**Sent:** Wednesday, 18 April 2012 2:30 PM  
**To:** [Redacted]  
**Subject:** RE: TPP: Traditional knowledge, traditional cultural expressions and genetic resources [SEC=IN-CONFIDENCE]

IN-CONFIDENCE

Hi [Redacted] I will attend.

[Redacted]

Principal Legal Officer  
Copyright and Digital Economy | Civil Law Division | Civil Justice and Legal Services Group  
Attorney-General's Department  
3-5 National Circuit, BARTON ACT 2600  
ph: [Redacted]

---

**From:** [Redacted]  
**Sent:** Wednesday, 18 April 2012 8:43 am  
**To:** [Redacted]  
[Redacted]

**Subject:** FW: TPP: Traditional knowledge, traditional cultural expressions and genetic resources

Dear [REDACTED]

I hope this finds you well.

s33

It would be great to see you at the meeting tomorrow – please let me know if you can make it.

Kind regards

[REDACTED]

All other redactions s47F

**From:** [REDACTED]

**Sent:** Saturday, 7 April 2012 6:39 PM

**To:** [REDACTED]

'brendan.bourke@ipaaustralia.gov.au'; [REDACTED]

**Cc:** [REDACTED] 'Edwina.Lewis@ipaaustralia.gov.au'; [REDACTED]  
[REDACTED]

**Subject:** TPP: Traditional knowledge, traditional cultural expressions and genetic resources [SEC=IN-CONFIDENCE:FTA]

Dear Colleagues

I am writing to propose a meeting at DFAT on **Thursday 19 April from 3-4pm**

s33

s33

For information, [REDACTED] and I (and Brendan) will be attending an IP intersessional in Chile this week, returning to work Tuesday 17 April.

Please let us know if you are able to make a meeting at this time and if anyone else from your team will be attending. We look forward to seeing you soon.

With thanks and kind regards

[REDACTED]

[REDACTED]

A/g Director

International Intellectual Property Section

Office of Trade Negotiations

Australian Department of Foreign Affairs & Trade

Tel: [REDACTED]

Fax: +61 2 6112 2347

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s33 exemption

# TPP: Brief: Traditional knowledge, traditional cultural expressions and genetic resources [SEC=IN-CONFIDENCE:FTA] - Notes Memo

**From:** [Redacted]  
**To:** [Redacted] [Brendan.Bourke@ipaaustralia.gov.au](mailto:Brendan.Bourke@ipaaustralia.gov.au)  
 <[Brendan.Bourke@ipaaustralia.gov.au](mailto:Brendan.Bourke@ipaaustralia.gov.au)>,  
 [Redacted]  
**Cc:** [Redacted]   
 "Edwina.Lewis@ipaaustralia.gov.au" <[Edwina.Lewis@ipaaustralia.gov.au](mailto:Edwina.Lewis@ipaaustralia.gov.au)>,  
 "Constantine.Nikolakopoulos@ipaaustralia.gov.au" <[Constantine.Nikolakopoulos@ipaaustralia.gov.au](mailto:Constantine.Nikolakopoulos@ipaaustralia.gov.au)>,  
 [Redacted]  More...  
**Sent:** 30-04-2012 06:12:14 AM

All other redactions s47F

Dear Colleagues

s33

As discussed at our recent meeting, we've prepared a draft brief for the upcoming Dallas round incorporating your views (I've deleted some parts to shorten where possible) – see attached. We would be grateful for clearance of the brief by **COB Thursday 3 May**.

Many thanks again for your help, and don't hesitate to contact me if you would like to discuss.

Kind regards

[Redacted]

[Redacted]  
 Executive Officer  
 International Intellectual Property Section  
 Office of Trade Negotiations  
 Australian Department of Foreign Affairs & Trade

Tel: [Redacted]  
 Fax: +61 2 6112 2347

s33

s33 exemption

s33 exemption

s33 exemption

Re: TPP: Brief: Traditional knowledge, traditional cultural expressions and genetic resources [SEC-IN-CONFIDENCE] - Notes Reply

From: [Brendan Bourke@ipaustalia.gov.au](mailto:Brendan.Bourke@ipaustalia.gov.au)  
To: [Redacted]  
Cc: [Redacted]  
Sent: 01-05-2012 3:26:51 PM

Thanks [Redacted]

From our perspective the brief looks good, with some minor revisions as follows:

s33

Regards

**Brendan Bourke**  
Assistant Director  
International Policy & Cooperation  
Business Development & Strategy Group  
IP Australia



P + 61 2 6283 2148 | F + 61 2 6283 7999 | [Redacted]  
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Please consider the environment before printing this email

From: [Redacted] <[Brendan.Bourke@ipaustalia.gov.au](mailto:Brendan.Bourke@ipaustalia.gov.au)> <"Brendan.Bourke@ipaustalia.gov.au">  
[Redacted]  
[Redacted] <[Edwina.Lewis@ipaustalia.gov.au](mailto:Edwina.Lewis@ipaustalia.gov.au)>  
[Redacted] <[Peter.Komocki@dfat.gov.au](mailto:Peter.Komocki@dfat.gov.au)>  
Date: 30/04/2012 04:12 PM  
Subject: TPP: Brief: Traditional knowledge, traditional cultural expressions and genetic resources [SEC-IN-CONFIDENCE:FTA]

Dear Colleagues

s33

[Redacted] As discussed at our recent meeting, we've prepared a draft brief for the upcoming Dallas round incorporating your views (I've deleted some parts to shorten where possible) – see attached. We would be grateful for clearance of the brief by **COB Thursday 3 May**.

Many thanks again for your help, and don't hesitate to contact me if you would like to discuss.

Kind regards

[Redacted]

[Redacted]  
Executive Officer  
International Intellectual Property Section  
Office of Trade Negotiations  
Australian Department of Foreign Affairs & Trade

Tel: [Redacted]  
Fax: +61 2 6112 2347

[attachment "TPP\_IP - joint NZ Peru proposal on TK TCEs GRs - revised comments.docx" deleted by Brendan Bourke/CBR/IPAustralia]

all other redactions s47F

[Redacted] 30/04/2012 04:12:33 PM [Redacted] s33

s33 exemption

s33 exemption

s33 exemption

Re: TPP: IP: TK, TCEs and GRs: [REDACTED] [SEC=IN-CONFIDENCE] - Notes Reply

From: [ian.goss@ipaaustralia.gov.au](mailto:ian.goss@ipaaustralia.gov.au)  
To: Brendan Bourke/OU=CBR/IPAustralia@IP\_Australia  
Sent: 19-06-2012 3:36:53 PM

Brendan

all redactions s33

my comments in track change, pretty straight forward.

regards

[REDACTED]

**Ian Goss**  
General Manager  
Business Development and Strategy Group  
IP Australia  
PO Box 200 Woden ACT 2606  
Australia

Phone: (02) 6283 2950 Fax: (02) 6285 4149  
Email: [ian.goss@ipaaustralia.gov.au](mailto:ian.goss@ipaaustralia.gov.au)  
website: [www.ipaaustralia.gov.au](http://www.ipaaustralia.gov.au)

Brendan Bourke---18/06/2012 02:18:55 PM---Ian, Robyn, Victor [REDACTED]

From: Brendan Bourke/CAustralia  
To: Ian Goss/CAustralia@IP\_Australia, Robyn Foster/CAustralia@IP\_Australia, Victor Portelli/CAustralia@IP\_Australia  
Cc: Edwina Lewis/CAustralia@IP\_Australia, Steven Bailie/CAustralia@IP\_Australia, Matthew Forno/CAustralia@IP\_Australia, Fatima Beattie/CAustralia@IP\_Australia, Constantine Nikolakopoulos/CAustralia@IP\_Australia  
Date: 18/06/2012 02:18 PM  
Subject: TPP: IP: TK, TCEs and GRs: [REDACTED] [SEC=IN-CONFIDENCE]

Ian, Robyn, Victor

[REDACTED]

[REDACTED]

[REDACTED]

- [REDACTED]
- [REDACTED]
- [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Victor, if there is anyone specifically in patents you would like to look at this, please pass it on and/or let me know.

[REDACTED]

[REDACTED]

----- Forwarded by Brendan Bourke/CBR/IPAustralia on 18/06/2012 01:08 PM -----

From: [REDACTED]  
[REDACTED]  
[REDACTED] "Brendan.Bourke@ipaustalia.gov.au" <Brendan.Bourke@ipaustalia.gov.au>,  
"Steven.Bailie@ipaustalia.gov.au" <Steven.Bailie@ipaustalia.gov.au>, "Constantine.Nikolakopoulos@ipaustalia.gov.au" <Constantine.Nikolakopoulos@ipaustalia.gov.au>,  
"Edwina.Lewis@ipaustalia.gov.au" <Edwina.Lewis@ipaustalia.gov.au>  
Cc: [REDACTED]  
Date: 12/06/2012 11:21 AM  
Subject: TPP: IP: TK, TCEs and GRs: Dallas debrief [SEC=IN-CONFIDENCE:FTA]

Dear All

As discussed, you are invited to a debrief **tomorrow (Wednesday) at 4pm** at DFAT [REDACTED]

[REDACTED] Grateful if you could confirm your attendance so we can arrange passes. We look forward to seeing you then.

Kind regards

[REDACTED]

all other redactions s33

[REDACTED]  
Executive Officer  
International Intellectual Property Section  
Office of Trade Negotiations  
Australian Department of Foreign Affairs & Trade

Tel: [REDACTED]  
Fax: +61 2 6112 2347

[REDACTED]

all redactions s33

## Talking points

### *Why the Raising the Bar Bill should not be amended to ban gene patents*

- Gene patents have been the subject of a number of recent inquiries.
- Last year the Senate Legal and Constitutional Affairs Committee inquired into the Private Members' Bill, the Patent Amendment (Genes and Biological Materials) Bill 2010, which was seeking to ban patents for genes and biological materials.
- The majority report recommended that the Bill not be passed.
- In November last year the Government released its response to the Senate Community Affairs References Committee's report into Gene Patents.
- The Committee also did not recommend a ban on gene patents, and the Government agreed with this recommendation.
- What the Committee did recommend was raising patent standards and introducing a research exemption.
- Both of these recommendations are implemented by the Raising the Bar Bill.
- These recommendations have widespread support from stakeholders, the research community and industry.
- Passage of this Bill will give the innovation community long awaited and substantial improvements to the IP system.
- In their response to the Community Affairs Committee's recommendations the Government also agreed to further measures to address concerns about gene patents.
- These are a review of compulsory licensing provisions and consultation on rewording of the legislative tests for patent eligible subject matter.
- We should wait to see the outcomes of this work before deciding whether, or what further amendments might be necessary to the patent system where there are remaining concerns about gene patents.

## Talking points

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- These are a review of compulsory licensing provisions and consultation on rewording of the legislative tests for patent eligible subject matter.
- We should wait to see the outcomes of this work before deciding whether, or what further amendments might be necessary to the patent system where there are remaining concerns about gene patents.

**Parliamentary Secretary:** Information  
**Cc:** Minister Combet and Minister Evans

**Brief No:** "Brief No"  
**Division/Agency:** IP Australia

## DEBATE OF THE RAISING THE BAR BILL AND GENE PATENTS

**Timing:** For consideration by Tuesday 7 February 2012. (Approved by Philip Noonan, Director General, IP Australia.)

<b>Recommendation/s:</b>	<b>Approved/Noted</b>
1. That you note the attached talking points.	Yes / No
<b>Parliamentary Secretary's signature:</b>	<b>Date:</b>

### Key Points

- The Government's Intellectual Property Laws Amendment (Raising the Bar) Bill 2011 (the 'Raising the Bar Bill') implements key IP reforms developed during extensive public consultation over the last two years. The Raising the Bar Bill is widely supported by business, universities and the IP profession.
- It is scheduled for debate in the Senate on 7 February 2012 and may be debated in the House of Representatives shortly after.

### Issues/sensitivities

- There is an ongoing public debate over the patenting of isolated gene sequences. It is possible that some parliamentarians may move amendments seeking to ban gene patents during the debate of the Raising the Bar Bill.
- The issue of gene patents has been investigated by the Australian Law Reform Commission (2004), the Advisory Council on Intellectual Property (2010), and the Senate Community Affairs References Committee (2010). None of these reports recommended a ban on the patenting of isolated gene sequences. The Government accepted the majority of the recommendations made in these reports, including not banning gene patents and the reforms to the patent system proposed in the Raising the Bar Bill.
- The Raising the Bar Bill does not ban gene patents. Instead the Bill includes technology-neutral measures to raise patent thresholds and to introduce a statutory exemption from patent infringement for research activities.
- Talking points addressing an amendment banning gene patents are at **Attachment A**.

### Consultation

- NIL

Philip Noonan  
Director General  
IP Australia  
(02) 6283 2000 /  
2 February 2012

s47F

Contact Officer:  
Terry More  
(02) 6283 2632

**Attachments**

Attachment A: Talking points if an amendment banning gene patents is proposed.

## Background

### *The Raising the Bar Bill*

In March 2009, IP Australia commenced public consultation on IP rights reforms aimed at improving the Australian IP system. The reforms aimed to bring together recommendations made in reviews of the innovation and IP systems (including the ALRC report into gene patents), and ideas developed by IP Australia. There were three rounds of public consultation, culminating in an exposure draft bill. IP Australia received over 180 submissions from industry, universities, the IP profession and members of the public. Since the Bill has been introduced Medicines Australia, the Walter and Eliza Hall Institute, CropLife, the BioMelbourne network and the Licensing Executives Society of Australia and New Zealand have publicly supported the Bill.

A number of the reform proposals implement recommendations made by the Senate Community Affairs Committee in its Gene Patents report. These include raising standards for inventive step and disclosure in patent applications, requiring that patent specifications disclose a specific, substantial and credible use of inventions and introducing a statutory exemption from infringement for research activities. However, the Bill is technology-neutral and does not deal with gene-specific issues, rather it seeks to raise patentability standards across all technologies.

### *Gene patents*

Public concerns about gene technology and the patenting of genes, and the potential impacts on health access and costs, have been periodically raised over the last fifteen years. The debate centres on whether Australia should allow the patenting of isolated gene sequences, particularly in the context of private ownership and control of inventions that have human health implications. The current patent law allows medical and other industrial inventions isolated from nature to be patented as long as a practical use has been identified. This is a long standing aspect of the Australian law, which has enabled the development and access to important drugs, diagnostics and medical treatments, and other industrial products and processes.

On 23 November 2011, the Government provided a combined response addressing the Senate Community Affairs References Committee's 2010 report *Gene Patents*, the Australian Law Reform Commission's 2004 report *Genes and Ingenuity: Gene Patenting and Human Health*, and the Advisory Council on Intellectual Property's 2011 report *Review of Patentable Subject Matter*. Some of the key recommendations agreed to by the Government are:

- a review of the existing compulsory licensing safeguards to address concerns that gene patents may hinder public access to patented diagnostic tests and treatments,
- in principle agreement to reword, using contemporary language, the legislative test for subject matter that is eligible for patent protection, subject to public consultation on the draft legislative provisions, and
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This third element is a key focus of the Raising the Bar Bill.

On 24 November 2010, Senators Heffernan, Coonan, Xenophon and Siewert introduced the Patent Amendment (Human Genes & Biological Materials) Bill 2010 into the Senate (with a corresponding Bill introduced into the House of Representatives on 21 February 2011). The private member's Bill would prevent patents being granted over biological materials which are identical or substantially identical to what exists in nature. The Senate Legal and Constitutional Affairs Committee released its report on the Private Member's Bill on 21 September 2011. The majority report recommended the Bill not be passed. A dissenting report was released by the Senators on the Committee who sponsored the Bill.



**DIISR-IN-CONFIDENCE**

**BRIEF**

**Parliamentary Secretary:** Information  
**Cc:** Minister **Combet** and Minister Evans

**Brief No:** B12/368  
**Division/Agency:** IP Australia

**DEBATE OF THE RAISING THE BAR BILL AND GENE PATENTS**

**Timing:** For consideration by Tuesday 7 February 2012. (Approved by Philip Noonan, Director General, IP Australia.)

<b>Recommendation/s:</b>	<b>Approved/Noted</b>
1. That you note the attached talking points.	Yes / No
<b>Parliamentary Secretary's signature:</b>	<b>Date:</b>

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**Consultation**

- NIL

***Slipstream Version 3 February 2012***

Philip Noonan  
Director General  
IP Australia  
(02) 6283 2000 /  
2 February 2012

s47F

Contact Officer:  
Terry More  
(02) 6283 2632

**Attachments**

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**DIISR-IN-CONFIDENCE**

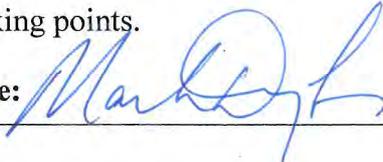
**BRIEF**

**Parliamentary Secretary:** Information  
**Cc:** Minister Combet and Minister Evans

**Brief No:** B12/368  
**Division/Agency:** IP Australia

**DEBATE OF THE RAISING THE BAR BILL AND GENE PATENTS**

**Timing:** For consideration by Tuesday 7 February 2012. (Approved by Philip Noonan, Director General, IP Australia.)

Recommendation/s:	Approved/Noted
1. That you note the attached talking points.	<input checked="" type="radio"/> Yes / <input type="radio"/> No
<b>Parliamentary Secretary's signature:</b> 	<b>Date:</b> 9/2/12

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**Consultation**

- NIL

*Slipstream Version 3 February 2012*

Philip Noonan  
Director General  
IP Australia  
(02) 6283 2000  
2 February 2012

s47F

Contact Officer:  
Terry More  
(02) 6283 2632

**Attachments**

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**Talking points**

*Why the Raising the Bar Bill should not be amended to ban gene patents*

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# Information Brief - Debate of the Raising the Bar Bill and Gene Patents [SEC=IN-CONFIDENCE] - Notes Memo

**From:** [Andrea.Blazsev@ipaaustralia.gov.au](mailto:Andrea.Blazsev@ipaaustralia.gov.au)  
**To:** mlobriefs@innovation.gov.au, kaye.fisk@innovation.gov.au  
**Cc:** Terry.Moore@ipaaustralia.gov.au, Brett.Massey@ipaaustralia.gov.au  
**Sent:** 03-02-2012 09:00:48 AM

MLO

Please find attached an information brief titled "Debate of the Raising the Bar Bill and Gene Patents". Please note this was emailed to the Parliamentary Secretary's Office last night due to the tight timeframes. It has been cleared by Philip Noonan, Director General, IP Australia.

<Attachment: 12-02-02 IB Debate of Raising the Bar Bill and Gene Patents.doc> <Attachment: 12-02-02 IB Attachment A - Debate of Raising the Bar Bill and Gene Patents.doc>

Kind Regards,

K

## **Kostas Arvanitis**

Assistant Director  
Strategy, Research and Ministerial Support  
IP Australia

P + 61 2 6283 2044 | F + 61 2 6281 1235 | E [kostas.arvanitis@ipaaustralia.gov.au](mailto:kostas.arvanitis@ipaaustralia.gov.au)  
A 47 Bowes Street, Woden ACT 2606 | PO Box 200, Woden ACT Australia 2606

Visit us at <http://www.ipaaustralia.gov.au>



Please consider the environment before printing this email

**Parliamentary Secretary:** Information  
**Cc:** Minister Combet and Minister Evans

**Brief No:** "Brief No"  
**Division/Agency:** IP Australia

**DEBATE OF THE RAISING THE BAR BILL AND GENE PATENTS**

**Timing:** For consideration by Tuesday 7 February 2012. (Approved by Philip Noonan, Director General, IP Australia.)

<b>Recommendation/s:</b>	<b>Approved/Noted</b>
1. That you note the attached talking points.	Yes / No
<b>Parliamentary Secretary's signature:</b>	<b>Date:</b>

**Key Points**

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**Consultation**

- NIL

Philip Noonan  
Director General  
IP Australia  
(02) 6283 2000 /  
2 February 2012

s47F

Contact Officer:  
Terry More  
(02) 6283 2632

**Attachments**

Attachment A: Talking points if an amendment banning gene patents is proposed.

## Background

### *The Raising the Bar Bill*

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*Patents Act 1990 – Proposed amendments to 18(2) and 18(4)*

<b>Bill</b>	<b>Proposed Amendments</b>
<p>Patent Amendment (Human Genes and Biological Materials) Bill 2010</p> <p><b>Person/s proposing amendments</b> Senators the Hon Helen Coonan, Senator the Hon Bill Heffernan, Senator Rachel Siewert and Senator Nick Xenophon</p>	<p>ss. 18(2) - Repeal the subsection, substitute</p> <p>(2) The following are not patentable inventions:</p> <p>(a) human beings, and the biological processes for their generation; and</p> <p>(b) <b><i>biological materials</i></b> including their components and derivatives, whether isolated or purified or not and however made, which are identical or substantially identical to such materials as they exist in nature.</p> <p>After ss. 18(4) - Insert</p> <p>(5) In this section: <b><i>biological materials</i></b> includes DNA, RNA, proteins, cells and fluids.</p>
<p>Patent Amendment (Human Genes and Biological Materials) Bill 2010 [No. 2]</p> <p><b>Person/s proposing amendments</b> Professor Luigi Palombi</p>	<p>ss. 18(2) - Repeal the subsection, substitute</p> <p>(2) The following are not patentable inventions:</p> <p>(a) human beings, and the biological processes for their generation; and</p> <p>(b) <b><i>biological materials</i></b>, whether isolated or purified or not and however made, which are <b><i>identical</i></b> to such materials as they exist in nature.</p> <p>After ss. 18(4) - Insert</p> <p>(5) In this section: <b><i>biological materials</i></b>, in section 18, includes DNA, RNA, proteins, cells and fluids and their components. <b><i>identical</i></b>, in section 18, means a biological material which is structurally and functionally identical and where any structural change or difference is immaterial to its function.</p>
<p>Patent Amendment (Human Genes and Biological Materials) Bill 2010 [No. 2]</p> <p><b>Person/s proposing amendments</b> Cancer Council of Australia</p>	<p>ss. 18(2) – Repeal the subsection, substitute with:</p> <p>(2) The following are not patentable inventions:</p> <p>(a) human beings, and the biological processes for their generation; and</p> <p>(b) <b><i>biological materials</i></b>, whether isolated or not and however made, which are <b><i>identical</i></b> to such materials as they exist in nature.</p> <p>After ss.18(4) replace with</p> <p>(5) In this section: <b><i>biological materials</i></b>, in section 18, includes DNA, RNA, proteins, cells and fluids including their components. and add <b><i>identical</i></b>, in section 18, means a biological material which is structurally and functionally identical and where any structural change or difference is immaterial to its function.</p>
<p>Patent Amendment (Human Genes and Biological Materials) Bill 2010 [No 2]</p> <p><b>Person/s proposing amendments</b> Senator the Hon Bill Heffernan Tabled 28 April 2011</p>	<p>ss. 18(2) - Repeal the subsection, substitute</p> <p>(2) The following are not patentable inventions:</p> <p>(a) human beings, and the biological processes for their generation; and</p> <p>(b) <b><i>biological materials</i></b>, whether isolated or not and however made, which are <b><i>identical</i></b> to such materials as they exist in nature.</p> <p>After ss. 18(4) - Insert</p> <p>(5) In this section: <b><i>biological materials</i></b>, in section 18, includes DNA, RNA, proteins, cells and fluids and their components. <b><i>identical</i></b>, in section 18, means a biological material which is structurally and functionally identical.</p>

**Parliamentary Secretary:** Information  
Cc: Minister

**Brief No:** B12/489  
**Division/Agency:** IP Australia

**GENE PATENTS – MEETING WITH IAN OLVER AND LUIGI PALOMBI**

**Organisation:** Professor Ian Olver CEO, Cancer Council and Dr Luigi Palombi, ANU

**Date:** 29 February 2012

**Time:** 12.20-1.00 pm

**Venue:** Parliamentary Secretary Mark Dreyfus' Office, Parliament House RG 87

**Attendees:** Mr Jim Round, Parliamentary Secretary Dreyfus' Chief of Staff; Professor Ian Olver CEO, Cancer Council; Dr Luigi Palombi, Australian National University; Ms Fatima Beattie Deputy Director General, IP Australia; Ms Terry Moore Director, IP Australia.

Recommendation	Approved/Noted
1. That you note the information provided.	Yes / No
<b>Parliamentary Secretary's signature:</b>	<b>Date:</b>

**Purpose of the meeting:** To discuss gene patents.

**Issues/sensitivities:**

- Professor Olver and Dr Palombi strongly oppose the patenting of isolated gene sequences. Both have provided submissions to recent inquiries into gene patents and proposed amendments to the *Patents Act 1990* which they have modified numerous times in the course of the gene patent debate.
- None of the gene patents inquiries concluded that banning gene patents is appropriate.
- The inquiries have recommended other measures for addressing concerns about gene patents. These include raising patent standards and introducing a statutory research exemption; which are elements of the *Intellectual Property Laws Amendment (Raising the Bar) Bill 2011*. The Bill is scheduled for debate in the current Parliamentary sittings.
- Professor Olver and Dr Palombi have publicly stated that they will continue to press for changes to patent law to ban gene patents despite the findings of the inquiries.

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17 February 2012

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**Attachments:**

- Attachment A: Attendees - Biographies for Professor Olver and Dr Palombi
- Attachment B: Australian newspaper article on gene patents
- Attachment C: Examples of amendments seeking to ban gene patents
- Attachment D: Talking points
- Attachment E: Government Response

## **Background**

There have been a number of inquiries into gene patents over recent years. Three main issues of concern with gene patents have emerged from these enquiries, that: gene sequences are inherently unpatentable; it is immoral to patent genetic material; and that gene patents adversely impact medical research and access to new medical technologies.

- *Gene sequences are inherently unpatentable*

Some argue, including Professor Olver and Dr Palombi, that isolated gene sequences are inherently unpatentable because they are naturally occurring materials patented in respect of their natural properties. Most countries, including Australia and its major trading partners regard isolated gene sequences as patent eligible subject matter. The basic requirements for patent eligibility are that an invention represents an artificial state of affairs with a practical use. Isolated gene sequences represent an artificial state of affairs as they have been chemically or physically excised from the chromosomes within which they naturally exist. A patent specification must also disclose a practical use for the isolated gene sequence, for example, its use to diagnose cancer, in order to be considered patent eligible. To actually qualify for a patent, other patentability criteria such as novelty and inventive step need to also be satisfied.

- *It is immoral to patent gene sequences*

The only subject matter-specific exclusion in the *Patents Act 1990* is the exclusion of human beings and the processes for their generation. This exclusion falls within Art 27.2 of the World Trade Organization Agreement on Trade Related Aspects of Intellectual Property (TRIPS) which permits exclusion from patentability of inventions the prevention of commercial exploitation of which is necessary to protect morality. None of the advocates for banning of gene patents have stated that they wish to prevent commercial exploitation of gene sequences. The Government Response to the Senate Community Affairs Committee has accepted the recommendation to include a morality exclusion in the Australian Patents Act.

- *Gene patents adversely impact research and the development of new technologies*

Reviews of gene patents have specifically considered this issue. Each time the conclusion has been that there is no evidence that gene patents have systemically adversely impacted research, the development of new technologies or access to healthcare. However, the reviews noted consistent concerns about the grant of overly broad and speculative patents and the need for researchers to have certainty about where they have freedom to operate. The Raising the Bar Bill addresses these concerns by raising the standards that need to be met for grant of a patent and introducing a statutory research exemption.

## **Chronology of reviews and actions by Professor Olver and Dr Palombi**

- *2002 – 2004 – Australian Law Reform Commission review of gene patenting*

In 2002 the Australian Law Reform Commission (ALRC) commenced a broad inquiry into the patenting laws and practices related to genes and genetics and related technologies, including the impact of gene patents on human health and cost effective provision of

healthcare. The inquiry concluded in 2004 with the release of the Commission's final report: *Genes and Ingenuity: Gene patenting and human health*.<sup>1</sup>

Cancer Council Australia (CCA), of which Professor Ian Olver is currently Chief Executive Officer (CEO), and Dr Luigi Palombi both provided submissions to the ALRC report. The submissions did not propose special rules for gene patents, but argued that genetic material was inherently unpatentable; being a discovery, rather than an invention. Both also recommended higher standards for the level of disclosure in patent applications.

The Committee's report did not recommend banning gene patents: it recommended that genetic materials and technologies be assessed against the same legislative criteria as other technologies. It did, however, recommend a range of general improvements to the patent system, including raising patent standards and introducing a statutory research exemption.

- **2008 – 2010 – *The Senate Community Affairs Committee inquiry into gene patents***

In 2008 an Australian company, Genetic Technologies Limited (GTL), as the exclusive licensee of the United States company Myriad's breast cancer gene (BRCA) patent, threatened Australian hospitals and clinical laboratories with infringement proceedings reneging on its 2003 public commitment not to enforce its exclusive licence (having gifted it to the public).

Although GTL subsequently refrained from pursuing its enforcement action, the company's actions reignited concerns about gene patents and their impact on access to healthcare. In response to these concerns, in November 2008 the Senate directed the Senate Community Affairs Committee to inquire into the impacts of gene patents on healthcare and the development of medical technologies.

Professor Olver, representing CCA, and Dr Palombi both provided submissions and appeared before the Committee. The CCA submission raised concerns that there was no adequate legal protection to ensure genetic testing remains accessible and at a reasonable cost to the health system and consumers. The submission argued that gene sequences are inherently unpatentable, but suggested that special rules for gene patents might be the only course of action. Dr Palombi's submission also argued that gene sequences are inherently unpatentable, suggesting that under existing law IP Australia should not be granting patents for isolated genetic material. Dr Palombi also recommended that the provision in the *Patents Act 1990* (the Act) defining patent eligible subject matter be amended to more clearly delineate between invention and discovery.

The Committee released its report (the Gene Patents report) in November 2010.<sup>2</sup> The report did not recommend banning gene patents: instead it recommended maintaining a watching brief on the impact of gene patents. The report found that the available evidence did not show that gene patents were systematically leading to adverse impacts on healthcare and medical research. Consistent with the ALRC report, the Gene Patents report also recommended raising patent standards and introducing a research exemption.

<sup>1</sup> <http://www.alrc.gov.au/publications/report-99>

<sup>2</sup> [http://aph.gov.au/senate/committee/clac\\_ctte/gene\\_patents\\_43/report/index.htm](http://aph.gov.au/senate/committee/clac_ctte/gene_patents_43/report/index.htm)

- **2010 – 2011 - The Senate Legal and Constitutional Affairs Committee’s inquiry into the Patent Amendment (Human Genes and Biological Materials) Bill 2010**

In November 2010, immediately prior to release of the Gene Patents report, Senators Coonan, Heffernan, Siewert and Xenophon introduced the *Patent Amendment (Human Genes and Biological Materials) Bill 2010* (the Private Members’ Bill) into the Senate. The Bill proposed amending the Act to exclude gene sequences (whether isolated or not) and biological materials from patent eligibility. The Bill was referred to the Senate Legal and Constitutional Affairs Committee for inquiry. In February 2011, an equivalent Bill was introduced into the House of Representatives by Members Dutton, Oakeshott, Forrest and Turnbull.

CCA and Dr Palombi both provided submissions to the inquiry and appeared before the Committee. Both supported the Bill but acknowledged that amendments might be necessary to address concerns raised during the inquiry. A number of amendments were proposed by Senator Heffernan, CCA and Dr Palombi. These amendments sought to better define the terms ‘biological material’ and to narrow the scope of the exemption to genes and biological materials identical to such materials as they exist in nature.

In September 2011 the Committee released its report on the Private Members’ Bill.<sup>3</sup> The majority of the Committee recommended that the Bill not be passed. The Committee expressed concern at the broad scope of the proposed exemption and the imprecise wording of the Bill. The Committee noted concerns expressed in submissions about the risk to investment in biotechnology if the Bill were passed and to compliance with international trade agreements, such as TRIPS.

The Committee also noted that amendments proposed in the Raising the Bar Bill would address some of the concerns about gene patents. The Committee said

*“The proposed amendment contained in the Raising the Bar bill also illustrate that other technology neutral changes to requirements in the Patents Act are viable. These amendments would tighten requirements for grant of patents in all fields of technology through proposals to raise the standards for inventive step, usefulness and the disclosure of inventions. In the view of the Committee, these proposals should contribute to improving the quality of inventions which are granted patents.”*

The Committee also noted that a number of submitters commented that the amendments proposed by Senator Heffernan, CCA and Dr Palombi did not resolve the lack of clarity or broad scope of the Bill.

Senators Heffernan, Siewert and Xenophon released a dissenting report recommending that an amended version of the Bill be passed.

- **2008 - 2011 – The Advisory Council on Intellectual Property report on Patentable Subject Matter**

In February 2011 the Advisory Council on Intellectual Property (ACIP) released its report into Patentable Subject matter.<sup>4</sup> This was an inquiry into the types of inventions that should and should not be patent eligible. Both Professor Olver and Dr Palombi provided submissions recommending introducing specific exclusions for gene patents and biological materials. The

<sup>3</sup> [http://aph.gov.au/senate/committee/legcon\\_ctte/patent\\_amendment/index.htm](http://aph.gov.au/senate/committee/legcon_ctte/patent_amendment/index.htm)

<sup>4</sup> <http://www.acip.gov.au/library/ACIP%20PSM%20final%20report%204%20Feb%202011.pdf>

report recommended rewording the existing requirements for patent eligibility using contemporary language but not changing the test itself.

- **2011 – The Government response to the Senate Community Affairs Committee’s Gene Patents report**

In November 2011 the Government released its response to the Gene Patents report (**Attachment E**). Consistent with the recommendation in the report, the response included a response to the ALRC and ACIP reports. The Government agreed with the majority of recommendations in the reports, including recommendations not to ban gene patents, to raise patent standards and introduce a research exemption; recognising that raising standards and the research exemption are elements of the Raising the Bar Bill. The Government also agreed to a review of compulsory licensing provisions, improving education and awareness of existing Crown Use provisions and consultation on rewording the existing legislative test for patent eligible subject matter using contemporary language.

- ***Legal action relating to the Myriad BRCA patent***

The BRCA patent that prompted the 2008 Senate Community Affairs Committee inquiry is currently the subject of court proceedings in Australia. In June 2010 Cancer Voices Australia filed an application in the Federal Court for revocation of the patent. The case is scheduled to be heard from 20 to 24 February 2012.

The BRCA patent has also been the subject of legal proceedings in the United States, where the American Civil Liberties Union has challenged Myriad’s US BRCA patent. The US Court of Appeal for the Federal Circuit, in its decision issued on 29 July 2011, upheld the validity of the challenged patent claims on isolated genetic material. On 7 December 2011 the American Civil Liberties Union appealed to the United States Supreme Court to hear the case and overturn the decision of the Court of Appeal. The Supreme Court has yet to decide whether to hear the case.

- ***The Anti-Counterfeiting Trade Agreement***

Dr Palombi has also criticised the Anti-Counterfeiting Trade Agreement (ACTA) which is due for public hearings by the Joint Standing Committee of Treaties on 27 February 2012. Dr Palombi argues that ratification of ACTA will require changes to existing patent laws to provide criminal procedures and penalties for patent infringement. The Government does not agree with this view. ACTA sets a minimum standard, providing for parties to apply civil penalties ‘at least’ in respect of wilful trademark counterfeiting and copyright piracy on a commercial scale. It does not reflect any obligation or ambition for parties to apply these standards to patents.

### **Contentious issues**

- Professor Olver and Dr Palombi have publicly stated that they will continue to press for changes to patent law to ban gene patents. They are likely to again raise this issue at the meeting. They may also propose additional amendments to the amendments proposed in the Private Members’ Bill. **Attachment C** provides the amendment in the Private Members’ Bill and the variations on that amendment proposed by Senator Heffernan, Professor Olver and Dr Palombi in their submissions on the Private Members’ Bill.
- Talking points are provided at **Attachment D** suggesting that further action should not be considered at this stage; that this would ignore the recommendations made in the Gene Patents report. The best course of action would be to first implement the

recommendations from the Gene Patents report and the reforms in Raising the Bar and wait to see the outcome of the BRCA court proceedings.



**Australian Government**  
**Department of Industry, Innovation, Science,**  
**Research and Tertiary Education**

**DIISRTE IN-CONFIDENCE**  
**MEETING BRIEF**

**Parliamentary Secretary:** Information  
**Cc:** Minister Combet

**Brief No:** B12/489  
**Division/Agency:** IP Australia

**GENE PATENTS – MEETING WITH IAN OLVER AND LUIGI PALOMBI**

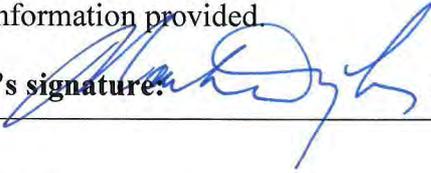
**Organisation:** Professor Ian Olver CEO, Cancer Council and Dr Luigi Palombi, ANU

**Date:** 29 February 2012

**Time:** 12.20-1.00 pm

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**Attendees:** Mr Jim Round, Parliamentary Secretary Dreyfus' Chief of Staff; Professor Ian Olver CEO, Cancer Council; Dr Luigi Palombi, Australian National University; Ms Fatima Beattie Deputy Director General, IP Australia; Ms Terry Moore Director, IP Australia.

Recommendation	Approved/Noted
1. That you note the information provided.	Yes / No
Parliamentary Secretary's signature: 	Date: 29/2/12

**Purpose of the meeting:** To discuss gene patents.

**Issues/sensitivities:**

- Professor Olver and Dr Palombi strongly oppose the patenting of isolated gene sequences. Both have provided submissions to recent inquiries into gene patents and proposed amendments to the *Patents Act 1990* which they have modified numerous times in the course of the gene patent debate.
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- The inquiries have recommended other measures for addressing concerns about gene patents. These include raising patent standards and introducing a statutory research exemption; which are elements of the *Intellectual Property Laws Amendment (Raising the Bar) Bill 2011*. The Bill is scheduled for debate in the current Parliamentary sittings.
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 17 February 2012

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 Terry Moore  
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**Attachments:**

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**DIISRTE IN-CONFIDENCE**  
**MEETING BRIEF**

**Background**

There have been a number of inquiries into gene patents over recent years. Three main issues of concern with gene patents have emerged from these enquiries, that: gene sequences are inherently unpatentable; it is immoral to patent genetic material; and that gene patents adversely impact medical research and access to new medical technologies.

- *Gene sequences are inherently unpatentable*

Some argue, including Professor Olver and Dr Palombi, that isolated gene sequences are inherently unpatentable because they are naturally occurring materials patented in respect of their natural properties. Most countries, including Australia and its major trading partners regard isolated gene sequences as patent eligible subject matter. The basic requirements for patent eligibility are that an invention represents an artificial state of affairs with a practical use. Isolated gene sequences represent an artificial state of affairs as they have been chemically or physically excised from the chromosomes within which they naturally exist. A patent specification must also disclose a practical use for the isolated gene sequence, for example, its use to diagnose cancer, in order to be considered patent eligible. To actually qualify for a patent, other patentability criteria such as novelty and inventive step need to also be satisfied.

- *It is immoral to patent gene sequences*

The only subject matter-specific exclusion in the *Patents Act 1990* is the exclusion of human beings and the processes for their generation. This exclusion falls within Art 27.2 of the World Trade Organization Agreement on Trade Related Aspects of Intellectual Property (TRIPS) which permits exclusion from patentability of inventions the prevention of commercial exploitation of which is necessary to protect morality. None of the advocates for banning of gene patents have stated that they wish to prevent commercial exploitation of gene sequences. The Government Response to the Senate Community Affairs Committee has accepted the recommendation to include a morality exclusion in the Australian Patents Act.

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Reviews of gene patents have specifically considered this issue. Each time the conclusion has been that there is no evidence that gene patents have systemically adversely impacted research, the development of new technologies or access to healthcare. However, the reviews noted consistent concerns about the grant of overly broad and speculative patents and the need for researchers to have certainty about where they have freedom to operate. The Raising the Bar Bill addresses these concerns by raising the standards that need to be met for grant of a patent and introducing a statutory research exemption.

**Chronology of reviews and actions by Professor Olver and Dr Palombi**

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healthcare. The inquiry concluded in 2004 with the release of the Commission's final report: *Genes and Ingenuity: Gene patenting and human health*.<sup>1</sup>

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In 2008 an Australian company, Genetic Technologies Limited (GTL), as the exclusive licensee of the United States company Myriad's breast cancer gene (BRCA) patent, threatened Australian hospitals and clinical laboratories with infringement proceedings reneging on its 2003 public commitment not to enforce its exclusive licence (having gifted it to the public).

Although GTL subsequently refrained from pursuing its enforcement action, the company's actions reignited concerns about gene patents and their impact on access to healthcare. In response to these concerns, in November 2008 the Senate directed the Senate Community Affairs Committee to inquire into the impacts of gene patents on healthcare and the development of medical technologies.

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The Committee released its report (the Gene Patents report) in November 2010.<sup>2</sup> The report did not recommend banning gene patents: instead it recommended maintaining a watching brief on the impact of gene patents. The report found that the available evidence did not show that gene patents were systematically leading to adverse impacts on healthcare and medical research. Consistent with the ALRC report, the Gene Patents report also recommended raising patent standards and introducing a research exemption.

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CCA and Dr Palombi both provided submissions to the inquiry and appeared before the Committee. Both supported the Bill but acknowledged that amendments might be necessary to address concerns raised during the inquiry. A number of amendments were proposed by Senator Heffernan, CCA and Dr Palombi. These amendments sought to better define the terms 'biological material' and to narrow the scope of the exemption to genes and biological materials identical to such materials as they exist in nature.

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The Committee also noted that amendments proposed in the Raising the Bar Bill would address some of the concerns about gene patents. The Committee said

*"The proposed amendment contained in the Raising the Bar bill also illustrate that other technology neutral changes to requirements in the Patents Act are viable. These amendments would tighten requirements for grant of patents in all fields of technology through proposals to raise the standards for inventive step, usefulness and the disclosure of inventions. In the view of the Committee, these proposals should contribute to improving the quality of inventions which are granted patents."*

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The BRCA patent that prompted the 2008 Senate Community Affairs Committee inquiry is currently the subject of court proceedings in Australia. In June 2010 Cancer Voices Australia filed an application in the Federal Court for revocation of the patent. The case is scheduled to be heard from 20 to 24 February 2012.

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Dr Palombi has also criticised the Anti-Counterfeiting Trade Agreement (ACTA) which is due for public hearings by the Joint Standing Committee of Treaties on 27 February 2012. Dr Palombi argues that ratification of ACTA will require changes to existing patent laws to provide criminal procedures and penalties for patent infringement. The Government does not agree with this view. ACTA sets a minimum standard, providing for parties to apply civil penalties ‘at least’ in respect of wilful trademark counterfeiting and copyright piracy on a commercial scale. It does not reflect any obligation or ambition for parties to apply these standards to patents.

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- Talking points are provided at **Attachment D** suggesting that further action should not be considered at this stage; that this would ignore the recommendations made in the Gene Patents report. The best course of action would be to first implement the

recommendations from the Gene Patents report and the reforms in Raising the Bar and wait to see the outcome of the BRCA court proceedings.

# Meeting Brief B12/489 - Gene Patents, Meeting with Professor Ian Olver and Dr Luigi Palombi [SEC=IN-CONFIDENCE] - Notes Memo

**From:** [Andrea.Blazsev@ipaaustralia.gov.au](mailto:Andrea.Blazsev@ipaaustralia.gov.au)  
**To:** mlobriefs@innovation.gov.au, kaye.fisk@innovation.gov.au  
**Cc:** Terry.Moore@ipaaustralia.gov.au  
**Sent:** 17-02-2012 1:15:20 PM

MLO

Please find attached meeting brief B12/489 - Gene Patents, meeting with Professor Ian Olver and Dr Luigi Palombi. It has been cleared by Fatima Beattie, Deputy Director General, IP Australia.

<Attachment: 12-02-17 B12-489 MB - Gene Patents - meeting with Ian Olver and Luigi Palombi.doc> <Attachment: 12-02-17 B12-489 Attachment A - Attendees.doc> <Attachment: 12-02-17 B12-489 Attachment B - Newspaper article.doc> <Attachment: 12-02-17 B12-489 Attachment C - Examples of amendments seeking to ban gene patents.doc> <Attachment: 12-02-17 B12-489 Attachment D - Talking points.doc> <Attachment: 12-02-17 B12-489 Attachment E - Govt response to Gene Patents report.doc>

Kind Regards,

## Ministerial Support Team

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## ATTENDEES

Name	Professor Ian Olver
Title	CEO
Organisation	Cancer Council Australia
Background	<p>CEO for the Cancer Council since 2006, when he was also appointed Clinical Professor in the Department of Medicine at the University of Sydney and an Honorary Associate with the Department of Medical Oncology at the Royal Prince Alfred Hospital.</p> <p>He trained in medical oncology at Peter MacCallum Cancer Institute, the Alfred Hospital in Melbourne and the University of Maryland Cancer Centre in Baltimore.</p> <p>He has previously served as:</p> <ul style="list-style-type: none"> <li>• Clinical Director at the Royal Adelaide Hospital Cancer Centre</li> <li>• Cancer Council SA Professor of Cancer Care at the University of Adelaide</li> <li>• Chair of the Medical Oncology Group of Australia from 2004-2006</li> </ul> <p>Currently serves on:</p> <ul style="list-style-type: none"> <li>• Australian Health Ethics Committee of the NHMRC</li> <li>• Board of Cancer Australia</li> <li>• Chairs the Board of the National Breast and Ovarian Cancer Centre</li> </ul> <p>While at the University of Adelaide, he established the first oncology clinic in Alice Springs and developed a telemedicine link for multidiscipline cancer care between Adelaide and Darwin. He also trained the first oncologist for the Christian Medical College Hospital in Vellore, India.</p> <p>In 2011, was appointed to the Order of Australia for service to medical oncology as a clinician, researcher, administrator and mentor, and to the community through leadership roles with cancer control organisations.</p>

Name	Dr Luigi Palombi
Title	Project Director of the Genetic Sequence Right Project
Organisation	Australian National University
Background	<p>Since 2006, Dr Palombi has headed the Genetic Sequence Right Project. The ANU website states that the purpose of the project “<i>is to formulate a sui generis alternative to the patent system with respect to technologies that involve either isolated biological materials or processes leading to the production of biological materials that are substantially identical to naturally occurring biological materials.</i>”</p> <p>He practiced law between 1982 and 1997. He was a partner at Davies Collision Cave, one of Australia’s larger patent attorney firms, before co-founding a boutique IP firm in 1995.</p> <p>Prior to leaving Australia in 1997, he acted for International Murex Technologies Inc in challenging Chiron Corp’s patent of isolated HCV (hepatitis C virus) genetic sequences.</p> <p>He returned to Australia in 2002 when the Australian Law Reform Commission commenced the first inquiry into gene patents. In 2005 he was awarded his PhD on “The Patenting of Biological Materials in the Context of TRIPS”.</p> <p>In 2008 he worked with the Cancer Council Australia on a campaign against BRCA gene patents, leading to the 2008 Senate inquiry into gene patents. Dr Palombi wrote the terms of reference for that inquiry.</p> <p>He has authored a number of papers on gene patents, and a book ‘Gene cartels: biotech patents in the age of free trade’ in 2009.</p>

# The Australian

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## Senate patently at odds over genes

- by: Leigh Dayton, Science writer
- From: The Australian
- October 01, 2011 12:00AM



Bill Heffernan, left, and Luigi Polombi are hopeful the bill will gain widespread support. Picture: Alan Pryke  
Source: The Australian

**BILL Heffernan is surprisingly philosophical. "It's just the reality of politics," he says of a Senate committee's call last week to dump his private member's bill to ban gene patenting.**

But along with proponents of his Patent Amendment (Human Genes and Biological Materials) Bill 2010, such as Australian National University patent law expert Luigi Polombi, the Liberal senator has not given up. "The fight has just begun," Heffernan tells Weekend Health.

The battle lines are drawn. On one side sit industry bodies such as Medicines Australia and the Institute of Patent and Trade Mark Attorneys, biotech and pharma industry groups and a handful of research institutes seeking funding through patents.

In Heffernan and Polombi's camp sit clinicians and advocacy groups such as Cancer Voices Australia and Cancer Council Australia.

The fundamental dispute is about whether naturally occurring, unaltered biological materials such as genes and proteins should be patentable. The bill introduced in the Senate last November by Heffernan would prohibit the practice. Its supporters argue it is essential to protect competitive research by eliminating commercial monopolies over such biological materials, as well as helping ensure that diagnostic tests based on, for instance, genes such as BRCA1 and BRCA2, which are associated with breast and cervical cancer, remain available in public laboratories.

Palombi points to the position adopted by the US government, following the decision of Myriad Genetics -- holder of patents on BRCA1 and BRCA2 -- to appeal an adverse District Court ruling to the Federal Circuit.

Last December, administration officials reinforced the "administration-wide" position that "isolated genes are not patentable subject matter".

Opponents of Heffernan's bill counter that gene patenting is critical. It takes time and money to commercialise drugs and biomedical products. Patent royalties cover costs. As Medicines Australia chief executive Brendan Shaw says, "Patents drive innovation, and innovation is the engine of growth."

Complicating the dispute is the Intellectual Property Laws Amendment (Raising the Bar) Bill 2011, released in draft form by Innovation, Industry, Science and Research Minister Kim Carr. The bill seeks to sidestep gene patenting by guaranteeing free access to "patented inventions for research and regulatory activities".

Not surprisingly, Carr's bill is backed by industry, including umbrella group the Licensing Executives Society of Australia and New Zealand. It favours enactment of the bill because it "includes the new exemptions that will operate to provide appropriate access to patented technologies".

Opponents of gene patenting, including Cancer Council chief executive Ian Olver, disagree.

"The Raising the Bar bill does not do nearly enough to prevent what almost occurred in 2008, the commercial monopolisation of genetic tests for breast and ovarian cancer risk that should be available in public laboratories," Olver says.

Meanwhile, the ruckus has spread beyond human biological material to plants and animals. "I've been contacted by the Cattle Council and the Grains Research and Development Corporation," Heffernan says. "I'll be instigating questions in the Senate. We've got to continue to discuss this."

Olver agrees: "What we need is a round-table meeting of the major stakeholders . . . with guidance from independent legal experts, so we can redevelop the [Heffernan] bill in a way that protects the public interest from gene monopolies while allaying concerns about research investment."

## Talking points

### *If the case for further amendments to ban gene patents is argued*

- It would be premature to take any further action on gene patents at this stage.
- This would ignore the recommendations made in the recent review of gene patents.
- The Government has agreed to a review of compulsory licensing provision and consultation on rewording the legislative test for patent eligible subject matter.
- The Raising the Bar Bill proposes changes, such as the research exemption and raising patent standards, that address some of the concerns raised in the gene patents debate.
- There is also the BRCA court case that will answer the important question of whether isolated genetic material is patent eligible subject matter.
- We should wait to see the outcomes of this work before deciding whether, or what further amendments might be necessary to the patent system where there are remaining concerns about gene patents.

### *If asked what is being done to implement the recommendations from the Gene Patents report*

- IP Australia is currently considering options for who might do the review of compulsory licensing and will advise the Minister shortly.
- IP Australia is also developing an information package on Crown Use provisions targeted to the research, medical and clinical professions.
- Work on amendments to the *Patents Act* will commence once the compulsory licensing review is underway. There will be extensive public consultation on any proposed amendment.



**Australian Government Response**

**to**

**Senate Community Affairs References Committee**

**Gene Patents Report**

**November 2011**

## Introduction

On 11 November 2008 the Senate referred matters relating to the patenting of human genes and genetic materials to the Senate Community Affairs References Committee (the Senate Committee) for inquiry and report. The Senate Committee tabled its report (the Senate Gene Patents Report) on 24 November 2010.

The terms of reference for the inquiry directed the Senate Committee to inquire into:

The impact of the granting of patents in Australia over human and microbial genes and non-coding sequences, proteins, and their derivatives, including those materials in an isolated form, with particular reference to:

- (a) the impact which the granting of patent monopolies over such materials has had, is having, and may have had on:
  - (i) the provision and costs of healthcare;
  - (ii) the provision of training and accreditation for healthcare professionals;
  - (iii) the progress in medical research; and
  - (iv) the health and wellbeing of the Australian people;
- (b) identifying measures that would ameliorate any adverse impacts arising from the granting of patents over such materials, including whether the *Patents Act 1990* should be amended, in light of any matters identified by the inquiry; and
- (c) whether the *Patents Act 1990* should be amended so as to expressly prohibit the grant of patent monopolies over such materials.

The Senate Gene Patents Report contains 16 recommendations directed, in part, to:

- establishing mechanisms for monitoring the implications of gene patents and the operation of the patent system;
- increasing legal requirements for the grant of a patent;
- improving patent law and practice concerning the exploitation of gene patents, including in relation to a new research defence to claims of patent infringement, Crown use, and compulsory licensing of patents; and
- introducing measures to assist in the interpretation and application of the *Patents Act 1990*.

Recommendation 4 of the Senate Gene Patents Report also recommended that the Government provide a combined response to:

- the Senate Gene Patents Report;
- the 2011 Advisory Council on Intellectual Property's Patentable Subject Matter Report (ACIP PSM Report);
- the 2004 Australian Law Reform Commission's Report No. 99, *Genes and Ingenuity: Gene Patenting and Human Health* (ALRC 99 Report); and
- the review of Australia's patent system by IP Australia.

The Government accepts this recommendation. This Government response addresses the recommendations of the above three reports. The review of Australia's patent system by IP Australia does not involve any public recommendations for Government response. However, the relevant outcomes of this review are outlined in the responses to the recommendations of the three reports.

***ALRC 99 Report***

On 17 December 2002 the then Australian Government Attorney-General, the Hon Daryl Williams MP, asked the Australian Law Reform Commission (ALRC) to inquire into and report on the laws and practices governing intellectual property rights over genetic materials and related technologies, with a particular focus on human health issues. The ALRC's report, *Genes and Ingenuity: Gene Patenting and Human Health*, (ALRC 99, 2004) was tabled on 31 August 2004.

The terms of reference for the inquiry directed the ALRC to consider – with a particular focus on human health issues – the impact of current patenting laws and practices related to genes and genetic and related technologies on:

- the conduct of research and its subsequent application and commercialisation;
- the Australian biotechnology sector; and
- the cost-effective provision of healthcare in Australia.

The terms of reference also requested the ALRC to consider what changes, if any, may be required to address any problems identified in current laws and practices with the aim of encouraging the creation and use of intellectual property to further the health and economic benefits of genetic research and genetic and related technologies.

The ALRC 99 report contains 50 recommendations directed to:

- improving patent law and practice concerning the patenting of genetic materials and technologies, including through amendments to the *Patents Act 1990* and changes in the practices and procedures of IP Australia, patent examiners and the courts;
- improving patent law and practice concerning the exploitation of gene patents, including in relation to a new research defence to claims of patent infringement, Crown use, and compulsory licensing of gene patents;
- ensuring that publicly funded research, where commercialised, results in appropriate public benefit, including through the adoption of appropriate patent practices;
- encouraging universities and other research organisations to raise the awareness of researchers about patenting issues and the commercialisation of research;
- ensuring that Australian research organisations and biotechnology companies are adequately skilled to deal with issues concerning commercialisation and the licensing of patented inventions;
- establishing mechanisms for monitoring the implications of gene patents for research and healthcare so that governments have the ability to intervene where gene patents are considered to have an adverse impact, either in specific cases or systemically;
- clarifying the application of competition law to the exploitation of intellectual property rights, including patented genetic materials and technologies; and

- clarifying the scope and practical application of exceptions to copyright infringement in relation to research.

***ACIP PSM Report***

In 2008 the Minister for Innovation, Industry, Science and Research, Senator the Hon Kim Carr, requested that the Advisory Council on Intellectual Property (ACIP) conduct a review of patentable subject matter, including the appropriateness and adequacy of the 'manner of manufacture' test as the threshold requirement for patentable subject matter under Australian law, and the historical requirement that an invention must not be 'generally inconvenient'. Instigation of the review was informed by recommendation 6-2 of the ALRC 99 Report. ACIP released its report on patentable subject matter (ACIP PSM Report) on 16 February 2011.

The ACIP PSM Report contains 11 recommendations directed to various changes to the *Patents Act 1990* including:

- introducing a statement of objectives;
- defining patentable subject matter requirements using clear and contemporary language; and
- removing some of the current exclusions to patentable subject matter and introducing a morality exclusion.

The Government thanks the Senate Committee, the ALRC and ACIP for their reports. The Government's response to the recommendations of these reports is set out below.

**Government Response to Recommendations<sup>1</sup>**

Legend:

- The Senate Community Affairs Committee report, *Gene Patents* – November 2010 (**SGP Report**)
- The Advisory Council on Intellectual Property report, *Patentable Subject Matter* – December 2010 (**ACIP PSM Report**)
- The Australian Law Reform Commission report, *Genes and Ingenuity: Gene Patenting and Human Health*, (ALRC 99, 2004) – June 2004 (**ALRC 99 Report**)

<b>SGP Report</b>
<b>Recommendation 1</b> 3.156 The Committee recommends that the Government support and expand on the collection of data, research and analysis concerning genetic testing and treatment in Australia, in line with recommendation 19-1 of the 2004 Australia Law Reform Commission report <i>Genes and ingenuity</i> .
<b>ALRC 99 Report</b>
<b>Recommendation 19–1</b> The Australian Health Ministers’ Advisory Council (AHMAC) should establish processes for: (a) economic evaluation of medical genetic testing and other new genetic medical technologies; and (b) examination of the financial impact of gene patents on the delivery of healthcare services in Australia.

**Response**

The Government accepts these recommendations in principle.

The report and the Government response to the Review of Health Technology Assessment in Australia (HTA Review), which had been conducted as a Better Regulation Ministerial Partnership, were released by the Minister for Health and Ageing and the Minister for Finance and Deregulation in February 2010. In implementing the recommendations of the HTA Review that were accepted by Government, the Department of Health and Ageing has established the Health Technology Assessment Access Point to coordinate the provision of comprehensive advice to Government regarding co-dependent technologies, such as where the cost-effective use of a drug may be dependent on the result of a genetic test, and to determine the appropriate methodology for assessing such technologies.

The Government considers that the Medical Services Advisory Committee (MSAC) is the appropriate body to undertake evaluations of medical genetic tests (including their cost-effectiveness) based on available evidence. MSAC undertakes evaluations on eligible medical services on application from non-government bodies, on referral from Government, and as requested by the Australian Health Ministers’ Advisory Committee (AHMAC). The National Health and Medical Research Council

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<sup>1</sup> Given the overlap and similar areas covered by many of the recommendations, the Government has provided a single response to multiple recommendations of the reports where appropriate.

(NHMRC) can also provide advice on technical or ethical aspects of genetic testing if requested by MSAC to assist in its deliberations.

The Government considers that there is insufficient need at this time to establish a specific process for examination of the financial impact of gene patents in the delivery of healthcare. The economic value and impact of patents continues to be an area of research interest both in Australia and internationally. A number of intellectual property organisations, including the World Intellectual Property Organization (WIPO), have recently included on their staff economists for this purpose. In Australia such research is undertaken by a number of universities and institutes including the Intellectual Property Research Institute of Australia (IPRIA). IP Australia also maintains a watching brief on developments in this regard.

<b>SGP Report</b>
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<b>Recommendation 2</b>
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3.157 The Committee recommends that the Government conduct a public consultation and feasibility study regarding establishing a transparency register for patent applications and other measures to track the use of patents dealing with genes and genetic materials.
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<b>ALRC 99 Report</b>
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<b>Recommendation 9-1</b>
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IP Australia should develop and regularly update a searchable online database comprising patents and published patent applications. The database should: (a) be accessible to the public through IP Australia’s website; (b) provide user-friendly access and search capabilities on a wide variety of bases; and (c) as soon as practicable, provide full-text searching of all complete specifications of published Australian patent applications and granted patents.
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**Response**

The Government accepts Recommendation 9-1 of the ALRC 99 Report and notes that IP Australia has developed and implemented the AusPat search system to provide ready access to Australian patent information including full-text searching of complete specifications back to 1904 (commencement of the first Commonwealth Patents Act<sup>2</sup>). AusPat is a world standard database of patent applications enabling searches to be conducted across 28 different data fields including applicant/inventor name, technology, etc.. The functionality of the system caters for the novice to the advanced searcher including on-line support through a feedback mechanism.

In addition the system includes an ‘eDossier’ facility which means that the public will be able to readily see any objections raised by the patent examiner and the responses, amendments, etc. submitted by the patent applicant to overcome those and result in grant of a patent. This facility provides access to patent application files open to public inspection (which occurs 18 months from filing) from 2006.

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<sup>2</sup> *Patents Act 1903* (Cth).

The Government will continue to explore web-based technology to make patent data more readily accessible and understood by the Australian community as part of continuous improvement of existing capabilities.

The Government accepts Recommendation 2 of the SGP Report as it relates to patent applications rather than how it relates to the 'use' of patents. The Government notes that the Intellectual Property Research Institute of Australia (IPRIA), which is partly funded by Government, has in the past and continues to conduct research on the use of patents. This includes research on patent enforcement and assignment.

<b>SGP Report</b>
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<b>Recommendation 3</b>
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4.137 The Committee recommends that the Senate refer the Patent Amendment (Human Genes and Biological Materials) Bill 2010 to the relevant Senate committee for inquiry and report.
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**Response**

This recommendation is a matter for the Senate.

<b>SGP Report</b>
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<b>Recommendation 4</b>
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5.161 The Committee recommends that the Government provide a combined response addressing the Committee's inquiry into gene patents; the 2004 report on gene patents by the Australian Law Reform Commission; the review of patentable subject matter by the Australian Council on Intellectual Property (ACIP); and the review of Australia's patent system by IP Australia. The Committee recommends that the response be provided not later than mid-2011 or three months after the release of the findings of all reviews.
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**Response**

The Government accepts this recommendation.

<b>SGP Report</b>
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<b>Recommendation 5</b>
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5.162 The Committee recommends that, at an appropriate time following the release of the ACIP review of patentable subject matter and the IP Australia review of the patent system, the Community Affairs References Committee be tasked with inquiring into the Government's response to, and implementation of, the recommendations of those reviews, as well as the recommendations of the Committee's report on gene patents.
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**Response**

This recommendation is a matter for the Senate.

**SGP Report**

**Recommendation 6**

5.172 The Committee recommends that the *Patents Act 1990* be amended so that the test for obviousness in determining inventive step is that a claimed invention is obvious if it was 'obvious for the skilled person to try a suggested approach, alternative or method with a reasonable expectation of success'.

**Response**

The Government accepts this recommendation in principle.

The Government acknowledges the need to raise Australia's patent standard for inventive step (which is used to determine whether or not the claimed invention is obvious). The Intellectual Property Laws Amendment (Raising the Bar) Bill 2011 which has been the subject of extensive public consultations over a two year period provides for a number of changes to raise the standards for grant of a patent thereby realigning Australia's patent law with global trends regarding standards for patentability. The various changes proposed under the Bill will in combination strengthen the inventive step requirements and increase the quality of patents that are granted. The test "obvious for the skilled person to try a suggested approach, alternative or method with a reasonable expectation of success" is but one of a number of legal tests which can be used by examiners and the courts to determine obviousness.

**SGP Report**

**Recommendation 7**

5.173 The Committee recommends that the *Patents Act 1990* be amended to remove the limitation that 'common general knowledge' be confined to that existing in Australia at the time a patent application is lodged (that is, that 'common general knowledge' anywhere in the world be considered).

**Response**

The Government accepts this recommendation.

Amendments to implement this recommendation are contained in the Intellectual Property Laws Amendment (Raising the Bar) Bill 2011. The Bill has been the subject of extensive public consultations over a two year period and provides for a number of changes to raise the standards for grant of a patent thereby realigning Australia's patent law with global trends regarding standards for patentability. The various changes proposed under the Bill will in combination increase the quality of patents that are granted.

**SGP Report**

**Recommendation 8**

5.174 The Committee recommends that the *Patents Act 1990* be amended to remove the requirement that 'prior art information' for the purposes of determining inventive step must be that which could reasonably have been expected to be 'ascertained' (that is, that the 'prior art base' against which inventive step is assessed not be restricted to information that a skilled person in the relevant field would have actually looked for and found (ascertained)).

**Response**

The Government accepts this recommendation.

Amendments to implement this recommendation are contained in the Intellectual Property Laws Amendment (Raising the Bar) Bill 2011. The Bill has been the subject of extensive public consultations over a two year period and provides for a number of changes to raise the standards for grant of a patent thereby realigning Australia's patent law with global trends regarding standards for patentability. The proposed amendments would also remove the requirement that prior art for the purposes of assessing the inventive step of an invention is restricted to only that information that would be 'understood and regarded as relevant' by a skilled person in the art. The requirements that prior art be 'understood' and 'regarded as relevant' are implicit in the pre-existing tests for inventive step. The various changes proposed under the Bill will in combination increase the quality of patents that are granted.

**SGP Report**

**Recommendation 9**

5.175 The Committee recommends that the *Patents Act 1990* be amended to introduce descriptive support requirements, including that the whole scope of the claimed invention be enabled and that the description provide sufficient information to allow the skilled addressee to perform the invention without undue experimentation.

**Response**

The Government accepts this recommendation.

Amendments to implement this recommendation are contained in the Intellectual Property Laws Amendment (Raising the Bar) Bill 2011. The Bill has been the subject of extensive public consultations over a two year period and provides for a number of changes to raise the standards for grant of a patent thereby realigning Australia's patent law with global trends regarding standards for patentability. The various changes proposed under the Bill will in combination increase the quality of patents that are granted.

<b>SGP Report</b>
<p><b>Recommendation 10</b></p> <p>5.179 The Committee recommends that the <i>Patents Act 1990</i> be amended to provide that an invention will satisfy the requirement of 'usefulness' in section 18(1) only in such cases as a patent application discloses a 'specific, substantial and credible' use; the Committee recommends that such amendments incorporate the full set of recommendations on this issue from the Australian Law Reform Commission's 2004 report, <i>Genes and ingenuity</i> (Recommendations 6-3 to 6-4).</p>
<b>ACIP PSM Report</b>
<p><b>Recommendation 5</b></p> <p>Amend the <i>Patents Act 1990</i> (Cth) so that the requirement of usefulness in paragraphs 18(1)(c) and 18(1A)(c) encompasses the requirement for utility that is currently an aspect of the manner of manufacture requirement, and is a ground for examination of a standard patent and an innovation patent.</p>
<b>ALRC 99 Report</b>
<p><b>Recommendation 6-3</b></p> <p>The Commonwealth should amend the <i>Patents Act 1990</i> (Cth) (<i>Patents Act</i>) to:</p> <p>(a) include 'usefulness' as a requirement in the examination of an application for a standard patent and in the certification of an innovation patent;</p> <p>(b) provide that an invention will satisfy the requirement of 'usefulness' only if the patent application discloses a specific, substantial and credible use;</p> <p>(c) require the Commissioner of Patents to be satisfied on the balance of probabilities that the requirement of 'usefulness' is made out in order to accept an application for a standard patent or to certify an innovation patent; and</p> <p>(d) include 'lack of usefulness' as a basis upon which an accepted application for a standard patent may be opposed, in addition to its current role as a ground for revocation. (See also Recommendation 8-3.)</p> <p><b>Recommendation 6-4</b></p> <p>IP Australia should develop guidelines, consistent with the <i>Patents Act</i>, the <i>Patents Regulations 1991</i> (Cth) and existing case law, to assist patent examiners in applying the 'usefulness' requirement. The guidelines should outline factors relevant to determining whether a use disclosed in a patent application is specific, substantial and credible to a person skilled in the relevant art.</p>

## Response

The Government accepts these recommendations.

With regard to Recommendation 6-3(d) of the ALRC 99 Report, the *Patents Act 1990* was amended in 2004 to include paragraphs 18(1)(c) and 18(1)(d) as grounds of opposition under section 59. The introduced grounds of opposition are that the claimed invention:

- must be useful (paragraph 18(1)(c)); and
- must not have been secretly used in Australia before the priority date of the claim by, or on behalf of, or with the authority of, the patentee or nominated person or the predecessor in title to the invention (paragraph 18(1)(d)).

With regard to Recommendation 6-4 of the ALRC 99 Report, IP Australia has commenced work in developing such guidelines. The date for completion of the guidelines to implement this recommendation will depend on the timing of the

legislative changes required to implement all other elements of these recommendations.

Amendments to implement all other elements of these recommendations are contained in the Intellectual Property Laws Amendment (Raising the Bar) Bill 2011. The Bill has been the subject of extensive public consultations over a two year period and provides for a number of changes to raise the standards for grant of a patent thereby realigning Australia's patent law with global trends regarding standards for patentability. The various changes proposed under the Bill will in combination increase the quality of patents that are granted.

<b>SGP Report</b>
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<b>Recommendation 11</b>
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5.185 The Committee recommends that the <i>Patents Act 1990</i> be amended to clarify the circumstances in which the Crown use provisions may be employed; and that the Government develop clear policies for the use of the Crown use provisions. The Committee recommends that the Government adopt the Australian Law Reform Commission's recommendations on this issue from its 2004 report, <i>Genes and ingenuity</i> (Recommendations 26-1 to 26-3)
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<b>ALRC 99 Report</b>
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<b>Recommendation 26-1</b>
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The Australian Health Ministers' Advisory Council should develop a policy regarding the circumstances in which it may be appropriate for the Commonwealth or a State to exploit a patented invention under the Crown use provisions of the <i>Patents Act 1990</i> (Cth) ( <i>Patents Act</i> ) for the purposes of promoting human health. Similarly, the Department of Health and Ageing should develop a policy regarding the circumstances in which it may be appropriate for the Commonwealth to acquire a patent for the purposes of promoting human health. Decisions about Crown use in specific cases must be made on their individual merits.
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<b>Recommendation 26-2</b>
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The Commonwealth should amend the <i>Patents Act</i> to clarify that, for the purposes of the Crown use provisions, an invention is exploited 'for the services of the Commonwealth or of a State' if the exploitation of the invention by a Commonwealth or State authority (or by an authorised person) is for the provision of healthcare services or products to members of the public.
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<b>Recommendation 26-3</b>
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The Commonwealth should amend the <i>Patents Act</i> to provide that, when a patent is exploited under the Crown use provisions, the remuneration that is to be paid by the relevant authority must be paid promptly and must be just and reasonable having regard to the economic value of the use. Similarly, the Act should be amended to provide that, when a patent is acquired under the Crown acquisition provisions, compensation must be paid promptly and must be just and reasonable having regard to the economic value of the patent.
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**Response**

The Government notes these recommendations.

The Advisory Council on Intellectual Property (ACIP) investigated and reported on the Crown use provisions (see 2005 ACIP Report, *Review of Crown Use Provisions for Patents and Designs*).

The Government decided that there was insufficient evidence to support any legislative changes to the current provisions. As a result of the ACIP Review, the Minister for Innovation, Industry, Science and Research wrote to relevant Commonwealth, State and Territory Ministers in March 2009 to raise awareness of government rights and obligations under the provisions. IP Australia also developed a public information sheet highlighting the Crown's rights and obligations and the rights of intellectual property owners under the provisions.

The Government does not see a need at present to develop a health-specific policy on the circumstances in which Crown use provisions should be exploited as the provisions are available for all Commonwealth, State and Territory services. The Government agrees that the circumstances in which a patented invention should be exploited pursuant to the Crown use provisions should be considered on a case-by-case basis.

<p><b>SGP Report</b></p> <p><b>Recommendation 12</b></p> <p>5.190 The Committee recommends that the Government amend the <i>Patents Act 1990</i> to clarify the scope of the 'reasonable requirements of the public' test, taking into account the recommendation of the Australian Law Reform Commission on this issue in its 2004 report, <i>Genes and ingenuity</i> (Recommendation 27-1); the Committee recommends that the Government review the operation of the competition based test for the grant of a compulsory licence, with particular reference to its interaction with the <i>Trade Practices Act 1974</i>.</p>
<p><b>ALRC 99 Report</b></p> <p><b>Recommendation 27-1</b></p> <p>The Commonwealth should amend the provisions of the <i>Patents Act 1990</i> (Cth) relating to compulsory licences by:</p> <p>(a) inserting the competition-based test recommended by the Intellectual Property and Competition Review Committee as an additional ground for the grant of a compulsory licence; and</p> <p>(b) clarifying the scope of the 'reasonable requirements of the public test'.</p>

**Response**

The Government accepts these recommendations.

As the SGP Report notes, the Government introduced a competition-based test as an additional ground for the grant of a compulsory licence in the *Intellectual Property Laws Amendment Act 2006*. Specifically, the provision provides for a compulsory licence to be available as a remedy if a person has contravened any anti-competitive conduct provision under Part IV of the *Competition and Consumer Act 2010*. The Government will review the operation of the compulsory licence provisions of the *Patents Act 1990* including measures to raise awareness of these provisions.

**SGP Report****Recommendation 13**

5.195 The Committee recommends that the *Patents Act 1990* be amended to include a broad research exemption.

**ALRC 99 Report****Recommendation 13–1**

The Commonwealth should amend the *Patents Act 1990* (Cth) (Patents Act) to establish an exemption from patent infringement for acts done to study or experiment on the subject matter of a patented invention; for example, to investigate its properties or improve upon it. The amendment should also make it clear that:

- (a) the exemption is available only if study or experimentation is the sole or dominant purpose of the act;
- (b) the existence of a commercial purpose or objective does not preclude the application of the exemption; and
- (c) the exemption does not derogate from any study or experimentation that may otherwise be permitted under the Patents Act.

**Response**

The Government accepts these recommendations.

Amendments to introduce an exemption from infringement for acts done for experimental purposes are contained in the Intellectual Property Laws Amendment (Raising the Bar) Bill 2011. The Bill has been the subject of extensive public consultations over a two year period and provides for a number of changes to raise the standards for grant of a patent thereby realigning Australia's patent law with global trends regarding standards for patentability. The proposed amendments include a broad research exemption as well as an exemption for acts connected with obtaining regulatory approval (such as the conduct of trials to provide data necessary for obtaining regulatory approval). The exemption is technology neutral applying to research in any technology field and regulatory approval of any technology. The various changes proposed under the Bill will in combination increase the quality of patents that are granted and provide the sought after certainty for researchers.

**SGP Report****Recommendation 14**

5.197 The Committee recommends that, to assist courts and patent examiners with the interpretation and application of the *Patents Act 1990*, the Government consider amending the Act to include anti-avoidance provisions.

**Response**

The Government does not accept this recommendation.

The Government has considered the submissions and examples put forward to the Senate inquiry and in the SGP Report relating to this recommendation.

The Government is of the view that existing measures including: the ability for third parties to make submissions during examination of a patent application (section 27 of the *Patents Act 1990*), pre-grant opposition (Chapter 5 and 9A Part 3 of the *Patents Act 1990*), re-examination (Chapter 9 and 9A Part 2 of the *Patents Act 1990*), internal quality audits, and external administrative and judicial processes, provide for compliance and quality.

These measures will be enhanced further with improved access to patent information through the new eDossier system. The eDossier provides on-line, free of charge, public access to relevant documents and correspondence on the patent application prosecution file. The improved access to this information will increase the transparency of the patent system and enable members of the public to address any concerns they may have about perceived misuse of the system through these existing measures.

Furthermore, the Intellectual Property Laws Amendment (Raising the Bar) Bill 2011 which has been the subject of extensive public consultations over a two year period provides for a number of changes to raise the standards for grant of a patent thereby realigning Australia's patent law with global trends regarding standards for patentability. Specifically, the Bill seeks to change the burden of proof to 'balance of probabilities' for all patentability criteria which with the addition of a statement of objectives to the *Patents Act 1990* (in accordance with Recommendation 15 of the SGP Report and Recommendation 1 of the ACIP PSM Report) will further assist the courts and patent examiners with the interpretation and application of the *Patents Act 1990*. The various changes proposed under the Bill will in combination increase the quality of patents that are granted.

<b>SGP Report</b>
<p><b>Recommendation 15</b></p> <p>5.198 The Committee recommends that, to assist courts and patent examiners with the interpretation and application of the <i>Patents Act 1990</i>, the Government consider amending the Act to include objects provisions.</p>
<b>ACIP PSM Report</b>
<p><b>Recommendation 1</b></p> <p>Include a statement of objectives in the <i>Patents Act 1990</i> (Cth) describing the purposes of the legislation.</p> <p><b>Recommendation 2</b></p> <p>The statement of objectives to be included in the <i>Patents Act 1990</i> (Cth) should describe the purposes of the legislation as being to provide an environment that promotes Australia's national interest and enhances the well-being of Australians by balancing the competing interests of patent rights holders, the users of technological knowledge, and Australian society as a whole.</p>

**Response**

The Government accepts these recommendations.

The Government recognises that a statement of objectives in the *Patents Act 1990* would provide a clear statement of legislative intent. The Government will develop legislation to give effect to these recommendations and its intention that patents should not lead to patients being denied reasonable access to healthcare. The legislation will be the subject of the same considered and comprehensive public consultation process as the Intellectual Property Laws Amendment (Raising the Bar) Bill 2011 including public exposure of the legislation drafting instructions and the draft legislative provisions.

<b>SGP Report</b>
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<b>Recommendation 16</b>
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5.202 The Committee recommends that the Government establish a patent audit committee.
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**Response**

The Government notes this recommendation.

The Government notes that the objective of the patent audit committee is to provide assurance to Government that the patent system is working as intended. The Government notes that the Advisory Council on Intellectual Property (ACIP) which is comprised of expert members appointed by the Minister for Innovation, Industry Science and Research already has the powers to undertake quality reviews where directed by the Minister and to co-opt temporary members with expertise in the relevant subject area of a review. The Government will consider varying ACIP's membership to ensure industry, research and community/consumer interests are sufficiently represented. ACIP can be tasked with providing advice to the Minister on matters such as:

- whether the patent system appropriately balances economic considerations with the needs of the community (including benefits to the community);
- emerging technologies and access issues; and
- compulsory licensing.

The Government also notes that any such reviews would be in addition to existing avenues to assure the quality of individual patents in Australia including substantive patent examination, re-examination, pre-grant opposition procedures, third party notification under section 27 of the *Patents Act 1990*, the administrative and judicial review system, and IP Australia's internal quality audits and transparency in the prosecution of patent applications through the eDossier facility (which provides on-line, free of charge, public access to relevant documents and correspondence on the patent application prosecution file). The Intellectual Property Research Institute of Australia (IPRIA) also has an active and varied research program looking at various topical patent issues, including issues of quality.

**ACIP PSM Report****Recommendation 3**

Define patentable subject matter in the *Patents Act 1990* (Cth), for the purposes of both a standard patent and an innovation patent, using clear and contemporary language that embodies the principles of inherent patentability as developed by the High Court in the NRDC case and in subsequent Australian court decisions.

**Recommendation 4**

Amend the *Patents Act 1990* (Cth) to enhance the clarity of the patentability requirements, and to remove overlap of the patentable subject matter provision with the provisions on novelty, inventive step and usefulness.

**ALRC 99 Report****Recommendation 6–2**

The responsible Minister should initiate an independent review of the appropriateness and adequacy of the ‘manner of manufacture’ test as the threshold requirement for patentable subject matter under Australian law, with a particular focus on the requirement that an invention must not be ‘generally inconvenient’.

**Response**

The Government accepts these recommendations in principle, and will develop legislation to define patentable subject matter using clear and contemporary language. The Government recognises the important role of patents in commercialising health research and the need to provide industry with certainty within the patent system. The development of this legislation will be subject to considered and comprehensive public consultation. This will enable an opportunity to consider benefits and impacts on the health sector. The legislation drafting instructions and the draft legislative provisions will be subject to the same considered and comprehensive public consultation process as the Intellectual Property Laws Amendment (Raising the Bar) Bill 2011.

The Government has already acted on Recommendation 6-2 of the ALRC 99 Report which has resulted in the ACIP PSM Report. The ‘manner of manufacture’ test has served the Australian intellectual property system well to date, but the Government recognised that as part of continuous improvement and international harmonisation it would be appropriate to review the test. However, due to the high degree of overlap between ‘manner of manufacture’ and other criteria for patentability, in order to be effective the scope of the review was broadened to encompass ‘patentable subject matter’. The terms of reference for the review were to conduct a review of patentable subject matter, including the appropriateness and adequacy of the ‘manner of manufacture’ test as the threshold requirement for patentable subject matter under Australian law, and the historical requirement that an invention must not be ‘generally inconvenient’.

The ACIP PSM Report is the result of extensive public consultation over a two and a half year period including written submissions and public forums. The Government recognises the complexities of providing incentives for creating innovations, enabling further innovation and cost effective access to innovations. Any changes must therefore have full regard to all these. This is particularly important with respect to health-related innovations where understandably there is strong public concern about affordable access to healthcare.

It is also important to note that the Intellectual Property Laws Amendment (Raising the Bar) Bill 2011 which has also been the subject of extensive public consultations over a two year period provides for a number of changes to raise the standards for grant of a patent thereby realigning Australia's patent law with global trends regarding standards for patentability. The higher standards for demonstrating novelty, inventive step and usefulness will provide for patenting of inventions that demonstrate a more substantial level of inventiveness and thereby raise the overall quality of patents granted in Australia. In that regard the changes proposed under the Bill will deal directly with broad and speculative patents which are understandably of public concern. The Bill also has provisions to provide researchers and innovators with the freedom to undertake research and regulatory approval activities without fear of infringing patents. All these proposed changes to the *Patents Act 1990*, in combination with existing safeguards of Crown use and compulsory licences, increase clarity over patentability requirements, provide incentives for creating innovations and making them available and establish mechanisms for responding to anti-competitive behaviour.

The Government will also continue to monitor international developments through its membership of various fora including the World Intellectual Property Organization (WIPO) and World Health Organization (WHO), and international and domestic patent-related jurisprudence to ensure that the balance of interests continues to be maintained.

<b>ACIP PSM Report</b>
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<b>Recommendation 6</b>
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Retain the specific exclusions set out in sub-sections 18(2) and 18(3) of the <i>Patents Act 1990</i> (Cth).
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**Response**

The Government accepts this recommendation.

<b>ACIP PSM Report</b>
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<b>Recommendation 7</b>
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Repeal section 50 of the <i>Patents Act 1990</i> (Cth), and the corresponding grounds for revocation of an innovation patent contained in section 101B of the <i>Patents Act 1990</i> (Cth).
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**Response**

The Government accepts this recommendation having regard to the response in relation to Recommendations 8, 9 and 10 of the ACIP PSM Report.

<b>ACIP PSM Report</b>
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<b>Recommendation 8</b>
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Include in the <i>Patents Act 1990 (Cth)</i> a patentability exclusion as permitted by Article 27(2) of the TRIPS Agreement.
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<b>Recommendation 9</b>
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Amend the <i>Patents Act 1990 (Cth)</i> so as to exclude from patentability an invention the commercial exploitation of which would be wholly offensive to the ordinary reasonable and fully informed member of the Australian public.
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<b>Recommendation 10</b>
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Amend the <i>Patents Act 1990 (Cth)</i> to provide the Commissioner of Patents with an explicit power to seek advice, from any person the Commissioner considers appropriate, to assist the Commissioner in applying the general patentability exclusion proposed in ACIP Recommendation 8 and in ACIP Recommendation 9.
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<b>ALRC 99 Report</b>
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<b>Recommendation 7-1</b>
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The <i>Patents Act 1990 (Cth)</i> should <i>not</i> be amended:
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(a) to exclude genetic materials and technologies from patentable subject matter;
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(b) to exclude methods of diagnostic, therapeutic or surgical treatment from patentable subject matter; or
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(c) to expand the existing circumstances in which social and ethical considerations may be taken into account in decisions about granting patents.
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Rather, social and ethical concerns should be addressed primarily through direct regulation of the use or exploitation of a patented invention.
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**Response**

The Government accepts Recommendation 7-1 (a) in principle and (b) in full but not (c) of the ALRC 99 Report in recognition of the more recent proposals in the ACIP PSM Report.

The Government recognises the need for the patent system to reflect contemporary community expectations and therefore accepts Recommendations 8, 9 and 10 of the ACIP PSM Report but notes that the specific amendments to the *Patents Act 1990* will need to be consistent with Australia's international obligations. The Government will develop legislation to give effect to these recommendations. The legislation will be subject of the same considered and comprehensive public consultation process as the Intellectual Property Laws Amendment (Raising the Bar) Bill 2011 including public exposure of the legislation drafting instructions and the draft legislative provisions.

<b>ACIP PSM Report</b>
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<b>Recommendation 11</b>
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Amend the <i>Patents Act 1990</i> (Cth) to require the Commissioner of Patents to be satisfied that an invention is a patentable invention before accepting an application for a standard patent or certifying an innovation patent.
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<b>ALRC 99 Report</b>
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<b>Recommendation 8–3</b>
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The Commonwealth should amend the <i>Patents Act</i> to require patent examiners to be satisfied on the balance of probabilities when assessing all statutory requirements for patentability that are relevant at the stage of examination. (See also Recommendation 6–3.)
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**Response**

The Government accepts these recommendations.

The amendments to give effect to these recommendations are contained in the Intellectual Property Laws Amendment (Raising the Bar) Bill 2011. The Bill has been the subject of extensive public consultations over a two year period and provides for a number of changes to raise the standards for grant of a patent thereby realigning Australia’s patent law with global trends regarding standards for patentability. The various changes in combination will increase the quality of patents granted in Australia.

<b>ALRC 99 Report</b>
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<b>Recommendation 5–1</b>
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IP Australia should:
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| (a) assess the impact of patent fees on the actual term of Australian patents; and<br>(b) periodically review the structure and quantum of patent fees to ensure that fees are set at levels appropriate to discourage patent holders from maintaining patents that lack real commercial value. |
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**Response**

The Government accepts this recommendation.

IP Australia sets fees consistent with:

- achievement of the following agency Outcome as agreed with Government:  
Increased innovation, investment and trade in Australia, and by Australians overseas, through the administration of the registrable intellectual property rights system, promoting public awareness and industry engagement, and advising Government;
- the *Australian Government Cost Recovery Guidelines 2005*;
- the *Financial Management and Accountability Act 1997*; and
- other Government policies and international obligations.

IP Australia employs a fee schedule structure where the renewal fees increase with the age of the patent and thereby discourage renewal of patents with no or little remaining commercial value. In developing the fee schedules, IP Australia takes into consideration a range of issues including the mean age of Australian patents, consistency in cost of like services across other intellectual property rights, international benchmarking and equality of access for patent holders of different

economic means. IP Australia completed a review of its fee structure in July 2010, having last reviewed its fees in 2006. It will continue to conduct regular reviews of its fee structure and will take all the relevant issues into account including assessing the impact of fees over the period of Australian patents as well as the need to consider disincentives for behaviour that could reduce innovation.

<b>ALRC 99 Report</b>
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<b>Recommendation 6-1</b>
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Patent applications relating to genetic materials and technologies should be assessed according to the same legislative criteria for patentability that apply to patent applications relating to any other type of technology.
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**Response**

The Government accepts this recommendation noting Australia's obligation under the World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) to maintain technology-neutral patentability criteria.

The Government is pursuing a number of changes to raise the standards for grant of a patent thereby realigning Australia's patent law with global trends regarding standards for patentability. These changes are contained in the Intellectual Property Laws Amendment (Raising the Bar) Bill 2011 which has been the subject of extensive public consultations over a two year period. The various changes proposed under the Bill will require more evidence that the invention can do what it claims to do and increase quality of the patents granted in Australia.

<b>ALRC 99 Report</b>
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<b>Recommendation 8-1</b>
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To ensure the ongoing competence of Australian patent examiners in examining patent applications, IP Australia should enhance its efforts to provide examiners with education and training in areas of technology relevant to their particular specialty. IP Australia should review and update its education and training programs regularly so that new developments can be incorporated as required.
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**Response**

The Government accepts this recommendation.

The Government recognises the importance of the skills of patent examiners in ensuring quality of decision making in the grant of Australian patents. To that end IP Australia has an active program of continuing professional training and development. Opportunities are available for examiners in the form of internal and external training courses, part-time university study and attendance at seminars, conferences (including international conferences), industrial visits and placements. The programs are subject to periodic reviews and improvements. In the 2009-10 financial year, IP Australia spent 3.4% of its expense budget on staff training and development. On average, \$5,900 was spent per patent examiner on training and development.

IP Australia also continues to recruit new staff with knowledge and experience in developing technologies. IP Australia requires all patent examiners to have tertiary qualifications. As at early 2010, 53% of patent examiners employed by IP Australia had postgraduate tertiary qualifications with 80% of these being science-based.

**ALRC 99 Report**

**Recommendation 8–2**

IP Australia should develop examination guidelines, consistent with the *Patents Act 1990* (Cth) (*Patents Act*), the *Patents Regulations 1991* (Cth) and existing case law, to explain how the criteria for patentability apply to inventions involving genetic materials and technologies.

**Response**

The Government accepts this recommendation.

The Government agrees that there should be clear examination guidelines for how the criteria for patentability apply to inventions for all technologies, including genetic materials. IP Australia has examination guidelines to give effect to this recommendation and these are contained in the publicly available *Australian Patent Office Manual of Practice and Procedure*<sup>3</sup> which is a controlled document under its externally certified ISO 9001 quality management system. The Government believes the current examination guidelines provide appropriate guidance on how these criteria apply to inventions involving genetic materials and technologies. IP Australia will continue to provide appropriate guidance as the law develops, and will update the examination guidelines as appropriate in consultation with stakeholders.

**ALRC 99 Report**

**Recommendation 9–2**

Information about patent litigation should be readily accessible to the public.

To this end:

- (a) the Commonwealth should amend the *Patents Act 1990* (Cth) (*Patents Act*) to require courts exercising jurisdiction under the Act to give written notice to the Commissioner of Patents when a legal proceeding to challenge or enforce a patent is commenced, and when a decision or judgment is given in any such proceeding;
- (b) the Commissioner of Patents should include information about any such notice in the file of a patent and make the information readily available, for example in the Official Journal of Patents and in the patents database on IP Australia's website; and
- (c) courts exercising jurisdiction under the Patents Act should amend their Rules of Court, as necessary, to give effect to this Recommendation.

**Response**

The Government accepts this recommendation noting however that a change to the *Patents Act 1990* is not necessary.

Section 139 of the *Patents Act 1990* and provisions contained in Rule 34.42 of the Federal Court Rules already require parties to provide information to the Commissioner of Patents. The Commissioner places this information on the file for the patent in question and this information is accessible using the e-Dossier facility in AusPat which allows online, public access to patent files.

Also, the Federal Court has implemented an internet inquiry system called 'Federal Law Search' which provides this information for patent-related proceedings. IP Australia will continue to work with the Federal Court to improve the existing

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<sup>3</sup> Available at [http://www.ipaustralia.gov.au/pdfs/patentsmanual/WebHelp/Patent\\_Examiners\\_Manual.htm](http://www.ipaustralia.gov.au/pdfs/patentsmanual/WebHelp/Patent_Examiners_Manual.htm)

notification process and visibility of proceedings via AusPat and the Federal Court's Federal Law Search system.

**ALRC 99 Report**

**Recommendation 10-1**

Courts exercising jurisdiction under the *Patents Act 1990* (Cth) (*Patents Act*) should continue to develop their practices and procedures for dealing with patent matters in order to promote the just, efficient and cost effective resolution of patent disputes.

**Response**

This recommendation is a matter for courts exercising jurisdiction under the *Patents Act 1990*.

**ALRC 99 Report**

**Recommendation 10-2**

Courts exercising jurisdiction under the *Patents Act* should continue to develop procedures and arrangements to allow judges to benefit from the advice of assessors or scientific advisors in litigation involving patents over genetic materials and technologies.

**Response**

This recommendation is a matter for courts exercising jurisdiction under the *Patents Act 1990*.

**ALRC 99 Report**

**Recommendation 11-1**

The Australian Research Council (ARC) and the National Health and Medical Research Council (NHMRC) should review the *National Principles of Intellectual Property Management for Publicly Funded Research* (National Principles) to ensure that publicly funded research, where commercialised, results in appropriate public benefit. (See also Recommendations 12-1 and 17-2.)

**Response**

The Government accepts this recommendation.

The National Health and Medical Research Council (NHMRC), in collaboration with the Australian Research Council (ARC) are convening a review of the *Principles of Intellectual Property Management for Publicly Funded Research*. The review will include consultation with interested stakeholders.

**ALRC 99 Report**

**Recommendation 11–2**

The ARC and NHMRC should develop guidelines to assist organisations receiving public funding for research in complying with the National Principles. The guidelines should, among other things:

- (a) provide guidance on what is meant by ‘public benefit’;
- (b) assist organisations in determining whether it is appropriate for particular research results to be commercialised; and
- (c) identify a range of approaches to the exploitation of intellectual property and the circumstances in which they might be used.

**Response**

The Government accepts this recommendation.

The Government supports the development of guidelines to assist organisations receiving public funding for research in complying with the *Principles of Intellectual Property Management for Publicly Funded Research* (National Principles), and supports such guidelines including the elements in the recommendation. The guidelines will be developed in consultation with interested stakeholders.

The Government notes that both the Australian Research Council (ARC) and the National Health and Medical Research Council (NHMRC) require compliance with the National Principles as an integral part of receiving ARC and NHMRC funding. Until December 2010 for the ARC this was facilitated through the Funding Agreement signed between the ARC and the Administering Organisation, and was required as part of any Multi-Institutional or Collaborative Agreement signed by the Administering Organisation with other parties involved with ARC funded research. From January 2011 compliance continues to be required and will be included in both the Funding Rules and the Funding Agreement. Currently for NHMRC, compliance is facilitated through the Deeds of Agreement signed between NHMRC and the Administering Institution. It is the responsibility of the Administering Organisation or Institution to provide further guidance and facilitate the mechanics of protecting intellectual property and/or commercialising research where appropriate.

**ALRC 99 Report**

**Recommendation 11–3**

In exceptional circumstances, where the public benefit would clearly be served by broad dissemination of the results of publicly funded research, the ARC and the NHMRC should consider attaching conditions to the grant of funding. These conditions might include a requirement that research results be placed in the public domain, or that a patented invention be widely licensed.

**Response**

The Government accepts the recommendation in principle.

The Government notes that the *Australian Code for the Responsible Conduct of Research* and the *National Principles of Intellectual Property Management for Publicly Funded Research* include guidance on the dissemination of research findings and management of intellectual property. Compliance is a condition under which ARC and NHMRC funding is awarded. Where suitable, strategies for achieving

impact from publicly funded research should be assessed on a case by case basis and publication should be consistent with appropriate IP management. Cooperative Research Centres (CRCs) are also required to comply with this code.

NHMRC believes that the results of government-supported health and medical research should be made widely available so that both the research community and the public are able to derive maximum benefit from these outputs. The ARC has always been supportive of the broad dissemination of research and in 2011 has introduced a new component to Funding Rules which will allow up to two per cent of awarded ARC funding (total or non-salary) to be used for publication and dissemination of Project outputs and outreach activity costs.

NHMRC has introduced a policy that requires all published outputs arising from NHMRC-supported research projects to be deposited in an open access institutional repository within 12 months of the date of publication. Similarly, the ARC strongly encourages publication in publicly accessible outlets and the depositing of data and any publications arising from a Project in an appropriate subject and/or institutional repository.

In addition, the ARC has introduced from 2011 new guidelines against which Final Reports will be evaluated including the need to justify why any publications from a Project have not been deposited in appropriate repositories within 12 months of publication, and the need to outline how data arising from the Project has been made publicly accessible where appropriate.

<b>ALRC 99 Report</b>
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<b>Recommendation 11–4</b>
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Research organisations should ensure that their policies on intellectual property ownership cover research undertaken by visiting researchers, students and staff—whether undertaken solely within the organisation or jointly with other bodies. (See also Recommendation 17–4.)
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**Response**

The Government accepts this recommendation in principle noting that its implementation is a matter for research organisations.

<b>ALRC 99 Report</b>
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<b>Recommendation 12–1</b>
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The Australian Research Council and the National Health and Medical Research Council, in implementing Recommendations 11–1 to 11–3, should recognise the public benefit in ensuring the wide dissemination of research tools.
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**Response**

The Government accepts the recommendation in principle.

The Government notes that the *Australian Code for the Responsible Conduct of Research*, jointly published by the ARC, the NHMRC and Universities Australia, includes guidance on the dissemination of research findings including manage research data and materials, how to publish and disseminate research findings, including proper attribution of authorship, how to conduct effective peer review and

how to manage conflicts of interest to promote integrity in research, and manage intellectual property. Compliance with the Code is a condition under which the ARC and the NHMRC funding is awarded. As noted, the ARC has a number of guidelines, requirements and funding opportunities available to support wide dissemination of research outputs.

**ALRC 99 Report**

**Recommendation 14–1**

Research organisations should continue to take steps to raise the awareness of researchers in health sciences and biotechnology about intellectual property issues and the commercialisation of research, and should provide relevant advice to researchers as required.

**Response**

The Government accepts this recommendation in principle noting that its implementation is a matter for research organisations.

The Government notes that the *Australian Code for the Responsible Conduct of Research*, jointly published by the Australian Research Council (ARC), the National Health and Medical Research Council (NHMRC) and Universities Australia, includes guidance on the responsibilities of institutions. This includes the promotion of responsible conduct of research, the establishment of good governance and management practices, provision of training for researchers, promotion of mentoring and ensuring researchers have a safe working environment, and management of intellectual property. Compliance with the Code is a condition under which the ARC and the NHMRC funding are awarded.

**ALRC 99 Report**

**Recommendation 14–2**

Universities should ensure that students undertaking degrees in health sciences or biotechnology are made familiar with intellectual property issues and the commercialisation of research.

**Response**

The Government accepts this recommendation in principle noting that its implementation is a matter for individual universities.

**ALRC 99 Report**

**Recommendation 14–3**

The responsible Minister should initiate a review of the grace period provisions in the *Patents Regulations 1991* (Cth) (*Patents Regulations*) to examine:

- (a) whether they are well understood by the research community; and
- (b) how they have affected the commercialisation of Australian research in Australia or overseas.

**Response**

The Government accepts this recommendation.

IP Australia completed a review of the grace period provisions and the final report was published (*Review of Patent Grace Period*, August 2005). This review was in

response to a Government commitment to review the grace period provisions two years after they were introduced (on 1 April 2002). The report recommended that no changes to the grace period provisions were required.

Since this review, the Government has identified some aspects of the drafting of the current grace period provisions that create uncertainty as to the requirements for use and scope of these provisions. Relevant amendments to remove this uncertainty are being pursued through the Intellectual Property Laws Amendment (Raising the Bar) Bill 2011. The Bill which has been the subject of extensive public consultations over a two year period provides for a number of changes to raise the standards for grant of a patent thereby realigning Australia's patent law with global trends regarding standards for patentability. The various changes proposed under the Bill will require more evidence that the invention can do what it claims to do and increase quality of the patents granted in Australia. The Government continues to engage in international fora in relation to a harmonised approach to grace periods. The Government will continue to monitor national and international developments and jurisprudence to ensure the grace period provision continues to serve the needs of the public and innovators.

<b>ALRC 99 Report</b>
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<b>Recommendation 14-4</b>
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Research organisations should ensure that their researchers are fully informed about the operation of the grace period provisions in the Patents Regulations, particularly in relation to:
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| (a) the effect of publication before filing a patent application; and   |
| (b) the effect of publication on the patentability of their inventions in countries that do not have equivalent provisions. |

**Response**

The Government accepts this recommendation in principle noting that its implementation is a matter for research organisations.

<b>ALRC 99 Report</b>
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<b>Recommendation 15-1</b>
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IP Australia should develop examination guidelines, consistent with the <i>Patents Act 1990</i> (Cth), the <i>Patents Regulations 1991</i> (Cth) and existing case law, to explain how the criteria for patentability apply to inventions involving stem cells and related technologies.
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**Response**

The Government accepts this recommendation.

IP Australia has developed examination guidelines to give effect to this recommendation and these are contained in the publicly available *Australian Patent Office Manual of Practice and Procedure* (available at [http://www.ipaustralia.gov.au/pdfs/patentsmanual/WebHelp/Patent\\_Examiners\\_Manual.htm](http://www.ipaustralia.gov.au/pdfs/patentsmanual/WebHelp/Patent_Examiners_Manual.htm)) which is a controlled document under its externally certified ISO 9001 quality management system. These guidelines will need to take account of any outcomes from the 2010 review of the *Research Involving Human Embryos Act 2002* and the *Prohibition of Human Cloning Act 2002*.

**ALRC 99 Report**

**Recommendation 15–2**

As part of the independent reviews to be conducted under the *Research Involving Human Embryos Act 2002* (Cth) and the *Prohibition of Human Cloning Act 2002* (Cth), the responsible Minister and the National Health and Medical Research Council should require an examination of the exploitation of intellectual property rights over stem cells when considering the establishment of a National Stem Cell Bank.

**Response**

This recommendation is no longer relevant.

The 2005 Legislation Review of the *Research Involving Human Embryos Act 2002* (and the *Prohibition of Human Cloning Act 2002*) recommended the establishment of a National Stem Cell Bank. The Government subsequently rejected this recommendation after commissioning a Report on Options for the Establishment of a National Stem Cell Bank (2007) and deciding that such a bank could not be justified for a number of reasons, including because the science is at an early stage and it would duplicate resources available overseas e.g. UK Stem Cell Bank. The National Health and Medical Research Council (NHMRC) will maintain a watching brief on developments in this area.

**ALRC 99 Report**

**Recommendation 17–1**

Biotechnology Australia, in conjunction with its member departments, should collaborate with the peak national bodies with an interest in technology transfer from the public sector:

- (a) to further develop and implement programs to assist technology transfer offices in research organisations in commercialising inventions involving genetic materials and technologies; and
- (b) to develop strategies to ensure widespread participation of technology transfer offices in these programs.

**Response**

The Government accepts this recommendation in principle, noting that Biotechnology Australia no longer exists.

The Advisory Council on Intellectual Property (ACIP) is currently conducting a review, titled *Collaborations between the Public and Private Sectors: The Role of Intellectual Property*, into how intellectual property acts as an enabler or disabler in collaborations between the public and private sectors. The Government will respond to the recommendations of this review in due course. The Australian Government has facilitated a number of collaborations between public and private entities such as through Commercialisation Australia, the Australian Research Council (ARC), the National Health and Medical Research Council (NHMRC) and Cooperative Research Centres (CRCs) and will monitor this issue.

<b>ALRC 99 Report</b>
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<b>Recommendation 17–2</b>
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The Australian Research Council (ARC) and the National Health and Medical Research Council (NHMRC), in implementing Recommendation 11–1, should recognise the importance of clear ownership of intellectual property resulting from collaborative or jointly funded research.
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**Response**

The Government accepts this recommendation and recognises the importance of clear ownership of intellectual property resulting from jointly funded research.

The Government notes that: the Australian Research Council (ARC) and the National Health and Medical Research Council (NHMRC) funding agreements currently require that institutions have policies and procedures in place for the management of intellectual property; and, where there is a requirement for matching funding by partner organisations, ARC funding agreements require that institutions not allow a research project to commence, nor funding to be expended, until the institutions and their collaborating partner organisations have entered into a written agreement that, among other things, includes arrangements for managing intellectual property. Within the relevant ARC Funding Rules and Funding Agreement documentation, the ARC is explicit that the ARC does not claim ownership of any intellectual property in a Proposal or a funded Project.

The Government agrees that the ARC, the NHMRC and Cooperative Research Centres (CRCs) should review those requirements in the light of the outcomes of the review of the *National Principles of Intellectual Property Management for Publicly Funded Research* which is currently being scoped. The review will include consultation with stakeholders.

The Government notes that the *Australian Code for the Responsible Conduct of Research*, jointly published by the ARC, the NHMRC and Universities Australia, includes guidance on establishing agreements for collaborations, managing conflicts of interest, access to research materials and intellectual property.

In implementing Recommendation 11-1 of the ALRC 99 Report, review of the National Principles, the Principles currently state that, ‘The ARC and the NHMRC do not wish to hold a stake in direct ownership of IP nor do they intend to benefit directly from commercial outcomes of the research funded through their financial support’ and ‘Recognising the Common Law rights of research institutions as employers, the ownership and the associated rights of all IP generated by the NHMRC and the ARC supported research will initially be vested in the research institutions administering the grants’.

**ALRC 99 Report**

**Recommendation 17–3**

The ARC and NHMRC, in implementing Recommendation 11–2, should:  
(a) provide guidance on ensuring clear ownership of intellectual property resulting from collaborative or jointly funded research; and  
(b) identify a range of approaches to ensuring clarity of ownership.

**Response**

The Government accepts this recommendation in principle, noting that while it is not appropriate for the Government to provide legal advice to third parties, it is common for issues of intellectual property ownership to be negotiated as part of contractual processes.

However, the Government notes that the *Australian Code for the Responsible Conduct of Research*, jointly published by the Australian Research Council (ARC), the National Health and Medical Research Council (NHMRC) and Universities Australia, recommends that organisations involved in joint research projects ensure that an agreement is reached with the partners on the management of the research including issues relating to intellectual property.

The Government also notes that with regard to Recommendation 11-2 of the ALRC 99 Report, the ARC continues to require compliance with the *National Principles of Intellectual Property Management for Publicly Funded Research* (National Principles) as an integral part of receiving ARC funding through Funding Rules and Funding Agreements. As noted above, this includes the requirement that compliance with the National Principles must be part of any Multi-Institutional or Collaborative Agreement signed by the Administering Organisation with other parties involved with ARC funded research.

The Government also notes that the Australian Council on Intellectual Property (ACIP) is currently conducting a review entitled *Collaborations between the Public and Private Sectors: The Role of Intellectual Property*.

**ALRC 99 Report**

**Recommendation 17–4**

Research organisations should ensure that their policies and practices address the problems of ownership of intellectual property resulting from collaborative or jointly funded research. (See also Recommendation 11–4.)

**Response**

The Government accepts this recommendation in principle noting that its implementation is a matter for individual research organisations.

The Government further notes that the *National Principles of Intellectual Property Management for Publicly Funded Research* would apply to research organisations where their research is government funded.

**ALRC 99 Report**

**Recommendation 17–5**

Biotechnology Australia, in conjunction with its member departments, should collaborate with the peak national bodies with an interest in technology transfer from the public sector to develop model materials transfer agreements for use by research organisations, along the lines of the models developed by the United States Association of University Technology Managers. (See also Recommendation 22–2.)

**Response**

The Government accepts this recommendation in principle, noting that Biotechnology Australia no longer exists.

The Government will investigate options for developing model materials transfer agreements for use by research organisations. A proposed process for developing model agreements will involve stakeholder consultation.

**ALRC 99 Report**

**Recommendation 18–1**

Biotechnology Australia, in conjunction with its member departments, and in consultation with state and territory governments and other stakeholders, should:

- (a) develop further programs to assist biotechnology companies in commercialising inventions involving genetic materials and technologies; and
- (b) develop strategies to ensure widespread participation of biotechnology companies in these programs.

**Response**

The Government accepts this recommendation in principle.

Although not specifically directed at biotechnology, these initiatives are available to biotechnology companies:

- Australia's Innovation Agenda, *Powering Ideas: an Innovation Agenda for the 21st Century*, was released on 12 May 2009. It sets a 10-year reform agenda to make Australia more productive and more competitive. *Powering Ideas* takes a holistic approach to developing a 10-year vision for the national innovation system (NIS) as it builds on the review of the NIS, other reviews, and investigation and policy work undertaken throughout 2008-09. *Powering Ideas* outlines actions taken to boost Australia's innovation system, as well as new proposals to improve innovation within the research, business and public sectors including reforms to the governance of the innovation system. It sets innovation priorities and strengthens coordination: to improve skills and expand research capacity; to increase incentives for innovation in business, government and the community sector; and to boost domestic and international collaboration over the next 10 years.;
- The R&D Tax Credit, which replaces the R&D Tax Concession from income years starting on or after 1 July 2011, supports business R&D and targets small innovative firms, including in the biotechnology sector. Legislation implementing the new program passed the Australian Parliament on 24 August 2011. The legislation awaits Royal Assent. The new R&D Tax Credit has two key components: (i) a 45 per cent refundable tax credit (equivalent to a 150 per cent

concession) will be available to firms with an aggregated turnover of \$20 million per annum; and (ii) a 40 per cent non-refundable tax credit (equivalent to a 133 per cent concession) will be available to all other firms. The new R&D Tax Credit is a broad-based and market-driven package. It increases the base rate of government assistance for R&D conducted by businesses of all sizes, with no limit to the amount of R&D expenditure for support. The new measure is simple, predictable and adopts the international practice of using a well-understood tax credit to support business R&D. To be available from 1 January 2014, a new element to the R&D Tax Credit, Quarterly Credits, will be open for small and medium enterprises (SMEs) in anticipation of receiving a tax offset under the R&D Tax Credit. Quarterly credits will further improve cash flow of SMEs and provide an added incentive to invest in R&D;

- Commercialisation Australia is a competitive, merit-based assistance program offering funding and resources to accelerate the business building process for Australian companies, entrepreneurs, researchers and inventors. Commercialisation Australia offers not only a range of funding options, but multi-layered networking opportunities to help applicants achieve business success; and
- The Innovation Investment Fund program targets new companies at the seed, start-up and early expansion stages of development to assist them to grow rapidly and to build upon their research and development capability. This is achieved by providing capital and business assistance from venture capital fund managers. Of the 13 current fund managers, three are specifically targeted at biotechnology while another six have an interest in the sector.

<b>ALRC 99 Report</b>
<b>Recommendation 19–2</b> AHMAC should examine options for using government funding and purchasing power to control the cost of goods and services that are subject to gene patents and used in the provision of healthcare.

**Response**

The Government does not accept this recommendation

The Government does not see a need at present for additional mechanisms to address the cost of medical goods and services. The Government has existing funding mechanisms, the Medicare Benefits and Pharmaceutical Benefits Schemes, which are aimed at providing Australians with access to appropriate and affordable and cost-effective medical services and medicines.

**ALRC 99 Report**

**Recommendation 19–3**

Where particular gene patent applications, granted patents or patent licensing practices are considered to have an adverse impact on medical research or the cost-effective provision of healthcare, Commonwealth, state and territory health departments should consider whether to exercise any existing legal options to facilitate access to the inventions. These options should be exercised only with appropriate legal or patent attorney advice, and include:

(a) challenging a patent application or granted patent by initiating proceedings to oppose a patent application; requesting re-examination of a patent; or applying for revocation of a patent under the *Patents Act 1990* (Cth) (*Patents Act*) (see Chapter 9);

(b) making a complaint to the Australian Competition and Consumer Commission where evidence arises of a potential breach of Part IV of the *Trade Practices Act 1974* (Cth) (see Chapter 24);

(c) exploiting or acquiring a patent under the Crown use and acquisition provisions of the *Patents Act* (see Chapter 26); or

(d) applying for the grant of a compulsory licence under the *Patents Act* (see Chapter 27).

**Response**

The Government accepts this recommendation in principle and notes that the National Health and Medical Research Council (NHMRC) has the capability to provide technical advice on the expected impact of patents and patent practices on medical research and the provision of healthcare. In line with the responses to Recommendations 19-1 of the ALRC 99 Report, the Government considers that the Medical Services Advisory Committee (MSAC) is the appropriate body to undertake economic evaluation of new health-related technologies.

With regard to Recommendation 19-3(c), the Advisory Council on Intellectual Property (ACIP) undertook a review of the use of Crown use provisions (see ACIP Report *Review of Crown Use Provisions for Patents and Designs*), following which the Minister for Innovation, Industry, Science and Research wrote to relevant Commonwealth and State Ministers in March 2009 to raise awareness of government rights and obligations under the provisions. IP Australia also developed a public information sheet highlighting the Crown's rights and obligations and the intellectual property owners' rights under the provision.

**ALRC 99 Report**

**Recommendation 19–4**

The proposed Human Genetics Commission of Australia (HGCA) should monitor the application of intellectual property laws to genetic materials and technologies, where these may have implications for medical research or human health, both generally and in specific cases. The HGCA should liaise with and provide advice to AHMAC, health departments, and other stakeholders about ways to facilitate access to inventions, in accordance with Recommendation 19–3. Pending the establishment of the HGCA, AHMAC should establish a mechanism to perform these functions.

**Response**

The Government notes this recommendation.

In response to the Human Genetics Commission of Australia (HGCA) recommendation in the Australian Law Reform Commission/Australian Health Ethics Committee Report, *Essentially Yours: The Protection of Human Genetic Information*, the Human Genetics Advisory Committee (HGAC) has been established as a principal committee of the National Health and Medical Research Council (NHMRC). HGAC advises the CEO of the NHMRC on high-level technical and strategic issues in human genetics, and on the broad social, ethical and legal implications of human genetics and related technologies. The Australian Health Ministers' Advisory Council (AHMAC) and other government stakeholders can request advice from HGAC via the NHMRC CEO. However, detailed monitoring of the application of intellectual property laws to genetic materials and technologies is outside HGAC's Terms of Reference and the *National Health and Medical Research Council Act 1992*.

The Crown use provisions were reviewed by the Advisory Council on Intellectual Property (ACIP) and their report issued in 2005 (see 2005 ACIP Report, *Review of Crown Use Provisions for Patents and Designs*), following which the Minister for Innovation, Industry, Science and Research wrote to relevant Commonwealth and State Ministers in March 2009 to raise awareness of government rights and obligations under the provisions. IP Australia also developed a public information sheet highlighting the Crown's rights and obligations and the intellectual property owners' rights under the provisions.

The Government also supports a review of the operation of the compulsory licensing provisions of the *Patents Act 1990* (see response to Recommendation 12 of the SGP Report and Recommendation 27-1 of the ALRC 99 Report) to ensure that the provisions are achieving their intended purpose as a safeguard to facilitate access to innovations where the reasonable requirements of the public are not being met. The review will also include measures to raise awareness of these provisions.

**ALRC 99 Report**

**Recommendation 22-1**

Biotechnology Australia, in conjunction with its member departments, should develop and implement programs to assist research organisations and biotechnology companies in licensing and commercialising inventions involving genetic materials and technologies. The programs should be developed in collaboration with state and territory governments, peak national bodies with an interest in licensing and commercialisation of intellectual property, and other relevant stakeholders. (See also Recommendations 17-1 and 18-1.)

**Response**

The Government accepts this recommendation in principle, noting that Biotechnology Australia no longer exists.

The Government notes that there are existing government and private sector initiatives that encourage the commercialisation of innovations from public sector research and biotechnology companies, as set out in the responses to Recommendations 17-1, 17-2 and 18-1 of the ALRC 99 Report.

**ALRC 99 Report**

**Recommendation 22-2**

AusBiotech Ltd, as the peak industry body in the biotechnology sector, should develop model agreements and interpretative guidelines for patent licences involving genetic materials and technologies. The model agreements should be developed in collaboration with Biotechnology Australia, state and territory governments, and other relevant stakeholders as a non-binding model of desirable licensing practices. (See also Recommendation 17-5.)

**Response**

The Government accepts this recommendation in principle, noting that Biotechnology Australia no longer exists.

The Government will investigate options for developing model agreements and interpretative guidelines for patent licences. A proposed process for undertaking these investigations will involve stakeholder consultation.

**ALRC 99 Report**

**Recommendation 22-3**

AusBiotech Ltd should consider whether additional industry initiatives are necessary or desirable to facilitate the licensing of patent rights over genetic materials and technologies.

**Response**

This recommendation is a matter for AusBiotech Ltd.

**ALRC 99 Report**

**Recommendation 24–1**

The Commonwealth should amend s 51(3) of the *Trade Practices Act 1974* (Cth) (*Trade Practices Act*) to clarify the relationship between Part IV of the Act and intellectual property rights.

**Recommendation 24–2**

The Australian Competition and Consumer Commission (ACCC) should develop guidelines to clarify the relationship between Part IV of the *Trade Practices Act* and intellectual property rights. The guidelines should address:

(a) when the licensing or assignment of intellectual property might be exempted under s 51(3) or might breach Part IV; and

(b) when conduct that would otherwise breach Part IV might be authorised under Part VII of the *Trade Practices Act*.

The guidelines should extend to the exploitation of intellectual property rights in genetic materials and technologies, including patent pools and cross-licensing.

**Response**

The Government notes the recommendations to amend section 51(3) of the *Competition and Consumer Act 2010* (CCA) and for the Australian Competition and Consumer Commission (ACCC) to subsequently produce guidance material.

As the agency responsible for the enforcement of the provisions of the CCA, the ACCC produces a wide range of publications that deal with its functions and the legislation for which it is responsible.

If subsection 51(3) of the CCA is amended to change the application of the competition laws to intellectual property in the future, the Government will ask the ACCC to consider issuing relevant guidance.

**ALRC 99 Report**

**Recommendation 24–3**

As the need arises, the ACCC should review the conduct of firms dealing with genetic materials and technologies protected by intellectual property rights, to determine whether their conduct is anti-competitive within the meaning of Part IV of the *Trade Practices Act*.

**Response**

The Government notes this recommendation.

The Australian Competition and Consumer Commission (ACCC) is an independent statutory authority charged with the responsibility for enforcing the *Competition and Consumer Act 2010* (CCA). Relevantly, subsection 29(1A) of the CCA prohibits the Minister giving directions to the ACCC about its performance of functions or exercise of powers under Part IV (prohibition of anti-competitive conduct) of the CCA.

The ACCC publishes guidelines on its enforcement and compliance policies, which are available on its website – [www.accc.gov.au](http://www.accc.gov.au). The Government expects that if any concerns arise, the ACCC will consider these issues in the same way as it would all suspected breaches of the CCA.

**ALRC 99 Report**

**Recommendation 24–4**

Commonwealth, state and territory health departments, and other stakeholders, should make use of existing complaint procedures under the *Trade Practices Act* where evidence arises of conduct that may breach Part IV and have an adverse impact on medical research or the cost-effective provision of healthcare.

**Response**

The Government accepts this recommendation in principle.

The Government notes that concerned parties should use the Australian Competition and Consumer Commission's (ACCC's) existing complaints mechanisms to raise any concerns that conduct is occurring which may breach the competition provisions of the *Competition and Consumer Act 2010*.

**ALRC 99 Report**

**Recommendation 25–1**

If evidence arises that the prices of patented genetic materials and technologies have adversely affected access to healthcare services in Australia, the responsible Minister should consider whether to:

(a) refer the matter to the Productivity Commission for a study or inquiry pursuant to the *Productivity Commission Act 1998* (Cth); or

(b) direct the Australian Competition and Consumer Commission, or another body, to conduct an inquiry pursuant to Part VIIA of the *Trade Practices Act 1974* (Cth).

**Response**

The Government notes this recommendation.

Part VIIA of the *Competition and Consumer Act 2010* provides for price inquiries where, in the view of the Minister, competitive pressures are not sufficient to achieve efficient prices and protect consumers. The Government will consider the need for such an inquiry if this evidence arises.

**ALRC 99 Report**

**Recommendation 28–1**

The Commonwealth should amend the *Copyright Act 1968* (Cth) (*Copyright Act*) to provide that research with a commercial purpose or objective is 'research' in the context of fair dealing for the purpose of research or study.

**Response**

The Government does not accept this recommendation.

The issue of whether the term 'research' in sections 40 and 103C of the *Copyright Act 1968* can include a commercial purpose has not been specifically considered by the courts. The wording in the provisions does not currently exclude research with a commercial purpose from the scope of the fair dealing exception. The reasoning of cases examining these provisions confirms that the terms 'research' and 'study' should be interpreted with their ordinary meanings. The ordinary meaning of

‘research’ connotes a broad meaning that does not distinguish whether the purpose is of a commercial or private nature.

The current wording of the *Copyright Act 1968* does not exclude research with a commercial purpose from falling under the fair dealing exception. Until a contrary finding is made under case law the Government sees no need for legislative amendments to be made to the *Copyright Act 1968*.

<b>ALRC 99 Report</b>
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<b>Recommendation 28–2</b>
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The Commonwealth should amend the <i>Copyright Act</i> to provide that, in relation to databases protected by copyright, the operation of the provisions relating to fair dealing for the purpose of research or study cannot be excluded or modified by contract.
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**Response**

The Government does not accept this recommendation.

The operation of the provisions relating to fair dealing for the purpose of research or study in relation to databases protected by copyright is a subset of the broader issue of the exclusion or modification by contract of the fair dealing exceptions. The views of the Australian Law Reform Commission (ALRC) are noted and provide valuable assistance to the Government. However, the Government does not propose to examine this broader issue at this time.

<b>ALRC 99 Report</b>
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<b>Recommendation 28–3</b>
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Prior to the implementation of art 17.4.7 of the Australia–United States Free Trade Agreement—which includes a prohibition on the circumvention of access control measures—the Australian Government should assess the need for an exception for researchers engaging in fair dealing for the purpose of research or study in relation to databases protected by copyright. Once the prohibition has been implemented, the Australian Government should periodically review the impact of the anti-circumvention provisions on the practical exercise of fair dealing for the purpose of research or study in copyright works.
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**Response**

The Government notes this recommendation.

The Government notes the views expressed by the Australian Law Reform Commission (ALRC) that the Government should assess the need for an exception to circumvention for researchers engaging in fair dealing for the purpose of research and study in relation to databases. However, the ALRC indicated that there did not appear to be any significant problems being experienced by Australian researchers in this regard.

The then Australian Government Attorney-General, the Hon Philip Ruddock MP, gave a reference to the House of Representatives Standing Committee on Legal and Constitutional Affairs to inquire into, and report on, possible additional exceptions to the technological protection measures liability scheme. The Committee concluded its

inquiry in March 2006. The Committee did not recommend an exception to allow circumvention by researchers engaging in fair dealing for the purpose of research and study in relation to databases.

In accordance with the Australia-United States Free Trade Agreement, amendments to the *Copyright Act 1968* set out the criteria for determining additional exceptions. Amongst other matters, proponents of an exception must credibly demonstrate that there is an actual or likely adverse impact on their non-infringing activities. Future reviews to determine the need for any additional exceptions will provide the opportunity for those affected by the liability scheme to demonstrate that the need exists for an exception to allow circumvention of technological protection measures for research and study in relation to databases.

### Ministerial Coversheet

<b>Date Due in MLO:</b>	20/02/2012	<b>Ministerial Item:</b>	B12/489
<b>Action Division:</b>	IP Aust	<b>Current Division:</b>	IP Aust
<b>Action:</b>	Engagement - Request MO Minister Office: Dreyfus		
<b>Signatories:</b>	DREYFUS QC MP, MARK		
<b>Subject:</b>	Gene Patents - meeting with Professor Ian Olver CEO, Cancer Council and Luigi Palombi, ANU		

<b>Ministerial Type:</b>	Engagement	<b>Attachments:</b>	N
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<b>Start Date:</b>	29/02/2012	<b>End Date:</b>	29/02/2012	<u>TIME</u>
<b>Venue:</b>	Parliamentary Secretary Mark Dreyfus's Office - Parliament House RG 87			12.30 - 1.0
<b>Present:</b>				
<b>Media Release:</b>	N			
<b>Speech:</b>	N			
<b>Dept. Officer to Attend:</b>	N			
<b>Adviser:</b>	Round, Jim (Dreyfus)			
<b>Talking Points:</b>	N			
<b>Special Arrangements:</b>				

<b>Instructions:</b>			
<b>Officer:</b>	Cartolano, Christine		
<b>Date:</b>	10 Feb 2012 15:21		
<b>Text:</b>	Suggested Action Officer: Baxter, Juile Requesting Adviser: Round, Jim (Dreyfus) Briefing on Gene Patents is requested		
<b>Officer:</b>			

**Parliamentary Secretary:** Decision  
**Cc:** Minister Combet

**Brief No:** "Brief No"  
**Division/Agency:** IP Australia

**DEBATE OF THE RAISING THE BAR BILL AND GENE PATENTS –  
REPLACEMENT SPEECHES AND TALKING POINTS**

**Timing:** For consideration by Thursday 15 March 2012. The second reading speech needs to be provided to the House of Representatives Tabling Office at least one day prior to debate. (Timing approved by Director General, Philip Noonan and discussed with your Office.)

<b>Recommendation/s:</b>	<b>Approved/Noted</b>
1. That you approve the attached replacement second reading and summing up speeches for the <i>Intellectual Property Laws Amendment (Raising the Bar) Bill 2011</i> .	Yes / No
2. That you note the attached talking points.	Yes / No
<b>Parliamentary Secretary's signature:</b>	<b>Date:</b>

**Key Points**

- You were previously briefed (**B12/368**) on the Raising the Bar Bill prior to its debate in the Senate. The Bill was passed by the Senate on 27 February 2012 and is scheduled for debate in the House of Representatives in the current sittings.
- The attachments to this brief amend the second reading and summing-up speeches, as discussed at your meeting with IP Australia officers on 7 March 2012. **Attachment C** provides talking points for discussions with your parliamentary colleagues.
- Once approved, IP Australia will provide copies of the replacement second reading speech to the House of Representatives Tabling Office.

**Issues/sensitivities**

- Gene patents may be raised during debate in the House of Representatives. The amended second reading and summing up speeches and talking points address this issue, both for the purposes of the Parliamentary debate and also for any discussions with your parliamentary colleagues.

Philip Noonan  
Director General  
IP Australia  
(02) 6283 2000 / s47F  
9 March 2012

Contact Officer:  
Terry Moore  
(02) 6283 2632

**Attachments**

Attachment A: Replacement Second Reading Speech  
Attachment B: Replacement Summing up Speech  
Attachment C: Replacement Talking points on gene patents



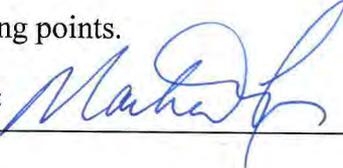
BRIEF

**Parliamentary Secretary:** Decision  
**cc:** Minister Combet  
 Minister Evans

**Brief No:** B12/827  
**Division/Agency:** IP Australia

**DEBATE OF THE RAISING THE BAR BILL AND GENE PATENTS –  
 REPLACEMENT SPEECHES AND TALKING POINTS**

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Recommendation/s:	Approved/Noted
1. That you approve the attached replacement second reading and summing up speeches for the <i>Intellectual Property Laws Amendment (Raising the Bar) Bill 2011</i> .	<input checked="" type="radio"/> Yes / No
2. That you note the attached talking points.	<input checked="" type="radio"/> Yes / No
<b>Parliamentary Secretary's signature:</b> 	<b>Date:</b> 16/3/12

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Philip Noonan  
 Director General  
 IP Australia  
 (02) 6283 2000 /  
 9 March 2012

s47F

Contact Officer:  
 Terry Moore  
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**Attachments**

- Attachment A: Replacement Second Reading Speech
- Attachment B: Replacement Summing up Speech
- Attachment C: Replacement Talking points on gene patents

*Slipstream version 9 March 2012*

**INTELLECTUAL PROPERTY LAWS AMENDMENT (RAISING THE BAR)  
BILL 2011**

**SECOND READING SPEECH**

**HOUSE OF REPRESENTATIVES**

The Intellectual Property Laws Amendment (Raising the Bar) Bill 2011 is a major reform of the intellectual property system. It is the culmination of two years of extensive consultation with interested parties. The bill will improve many parts of the intellectual property system, including the Patents, Trade Marks, Copyright, Designs and Plant Breeder's Rights Acts. The bill will ensure that Australia maintains a world class intellectual property system: an IP system that fosters Australian innovation in the modern global economy.

Australian innovation is critical to the resilience of the economy through changing times. Innovation makes our economy more competitive. But the extent of innovation necessary to keep our economy competitive can't happen on its own. In addition to requiring support and investment, innovation requires a strong intellectual property system.

A strong IP system underpins investment in innovation. This was recognised in *Powering Ideas*, the Government's innovation agenda for the 21<sup>st</sup> century. A strong IP system provides investors an opportunity to recoup the investments necessary to bring their ideas to the marketplace. The IP system also gives the public and innovators the tools necessary for further innovation, through published information about new technology.

As also recognised in *Powering Ideas* – “*The trick is to get the balance right: too little protection will discourage people from innovating because the returns are*

*uncertain; too much protection may discourage people from innovating because the pathways to discovery are blocked by other intellectual property owners”.*

The reforms set out in this Bill seek to improve that balance by addressing six key areas:

- Patent standards;
- Research freedom;
- Reducing delays in resolving patent and trade mark applications;
- Improvements to the attorney profession;
- Trade mark and copyright infringement; and
- Technical improvements to the IP system.

***Schedule 1 - Patent Standards***

First, the Bill seeks to raise patent standards. This addresses concerns that Australia’s standards are lower than standards elsewhere, which discourages export of the technology we develop and inhibits growth of Australian business. Lower Australian patent standards actually disadvantage Australian patent holders, who should be able to take their inventions overseas with confidence that they will qualify for patent protection in Australia’s major trading partners. Lower patent standards may also clutter the Australian innovation landscape with broad patents that would not meet the standards of our major trading partners, getting in the way of Australians who might otherwise be able to develop inventions in new areas.

A theme in this Bill is one of recalibrating and raising Australian standards, to align them more closely with those of other major trading partners around the world. Some patent standards around the world have developed to the point where there is an

aligned approach internationally. In such cases where there is an aligned global approach, the Bill raises Australian patenting standards to that common approach.

The Bill raises patent standards in three important areas.

First, it raises standards with respect to the information provided in patent applications and specifications. Disclosure is a cornerstone of the patent system.

Patents are an exchange between inventors and the public. In exchange for a 20 year monopoly on commercialisation, the innovator must tell the public how their idea works. This disclosure allows for potential follow-on innovators to build on initial work to produce even better innovations.

The Bill raises standards to require that the patent right is consistent with the information provided in the patent specification. There must be enough information disclosed for the public to make and use the invention. Also, a specific, substantial and credible use for the invention must also be disclosed and the scope of the claims for patent protection must not extend beyond what has been disclosed.

Importantly, the amended provisions mirror similar provisions in the United Kingdom and Europe. It is intended that Australian courts will have regard to developments in the law in the courts of these other jurisdictions when interpreting the new provisions, and will develop Australian law in a consistent fashion. This will help Australian exporters have the confidence that a patent granted in Australia is likely to be matched by a patent granted in major overseas markets.

Secondly, the Bill raises the standards for inventiveness. Raising the standards for inventiveness allows the patent system to better recognise the global innovation environment and reflect the modern economy's improved access to information. We must not grant a patent for something that has been done before. The Bill ensures that

the patent system takes into account all published information that is reasonably available and accessible to the public. It will also ensure that this information is assessed against the background of knowledge of the skilled person, regardless of where that person resides.

Thirdly, the Bill ensures that a consistent standard of proof is applied by the Commissioner of Patents in all decisions and expands the grounds that the Commissioner can consider during examination and re-examination. Someone who seeks a patent will bear the burden of showing that they are entitled to patent protection. The Bill requires the Commissioner to be satisfied, on the balance of probabilities, that a patent, if granted, will be valid.

Taken together, these changes ensure that only high quality patents are granted in Australia. They make sure that the scope of disclosure is commensurate with the monopoly granted. They will make sure that patents are only granted for innovations that warrant patent protection. They will also ensure that the Commissioner of Patents can apply robust standards when assessing whether or not a patent should be granted and whether or not a patent should be revoked.

### ***Schedule 2 – Research freedom***

The second category of reforms responds to concerns that patent rights can sometimes deter or block innovation by discouraging researchers from developing further innovations or spin-offs. We need to set our researchers free and ensure that the patent system encourages further innovation. The key reform in this category introduces an explicit provision permitting experimentation to be conducted without infringing patent rights. This amendment will give comfort to researchers in Australia, and is strongly supported by Australia's research sector.

The amendment strikes a balance between the rights of patentees and the rights of subsequent researchers. The exemption protects researchers and follow-on innovators as long as what they are doing is predominantly for research and experimental purposes. The exemption is intended to allow for some areas of commercial activity - for example, where the researchers are doing their work under contract, and are accepting payment to do experiments to improve on, or test a patented invention to see how it works. However, if the purpose is primarily commercial – such as where the researcher is seeking to commercialise the patented invention - the amendment protects the interests of patent owners because it will not apply where the main purpose is to commercialise the invention or manufacture it for sale.

A second reform introduces an amendment to exempt research activities necessary for gaining pre-market or pre-manufacturing regulatory approval from infringement. This ensures that a patent owner gets no more than the statutory period of protection. Such an exemption already exists for particular regulatory activities in the pharmaceutical industry. The amendment expands this exemption to apply to all technologies. Currently, a patentee can delay a competitor's entry into the market when the patentee's patent expires by threatening the competitor with infringement proceedings if they seek to do the work necessary to gain regulatory approval during the patent term. This gives the patentee a *de facto* extension on the term of their patent. The amendments will enable competitors to make the preparations necessary to enter the market as soon as a patent has ceased or expired. The amendments will not, however, allow the competitor to stockpile their product during the patent term, or make or use it in any way that detracts from the patentee's exclusive rights to commercial advantage from their invention during the term of the patent.

The amendments in schedules one and two also address some of the concerns raised in recent inquiries into gene patents.

In 2004 the Australian Law Reform Commissioner released its report, *Genes and Ingenuity: Gene patenting and human health*, following a two year inquiry into patenting laws and practices related to genetics and related technologies, including the impact of gene patents on human health and cost effective provision of healthcare. In 2010 the Senate Community Affairs Committee released its report, *Gene Patents*, following its inquiry into the impacts of gene patents on healthcare and medical research.

Both reports recommended technology-neutral changes to raise patent standards and introduce a research exemption. These changes are reflected in Schedules 1 and 2 of the Raising the Bar Bill.

The Government has committed to implement further recommendations from the reports. These include a review of existing compulsory licensing provisions and consultation on further reforms to patents legislation to reword, using contemporary language, the legislative test for patent eligible subject matter, and to introduce a morality exclusion.

### ***Schedule 3 - Reducing delays in resolving applications***

The third category of reforms is aimed at making the patent and trade mark application process more efficient. These changes will speed up the processes for determining applications for IP rights. They will also prevent tactical use of the system by those who profit from delay. The amendments target two key areas.

The first area is the process of opposing patent and trade mark applications.

Opposition processes permit any person who might be adversely impacted by issue of

an IP right to come forward and oppose it. Oppositions are intended to provide for a swift and efficient administrative resolution where a third party has concerns about the grant of an IP right. However, oppositions have become increasingly more complicated and protracted. The Bill introduces a series of reforms aimed at resolving opposition proceedings more efficiently while still ensuring a fair outcome, and ensuring that any delays are truly unavoidable ones.

The second area relates to what are called 'divisional' patent applications. Patent systems around the world permit a patent application to be divided into one or more divisional applications, primarily to account for circumstances where more than one invention is claimed in the original application. However, the provisions are not as clear as desirable and sometimes divisional applications are used to delay finalisation of a particular invention or frustrate a third party. The reforms tighten the provisions for divisional applications, particularly timeframes for making applications. This will reduce opportunities to delay finalisation of applications.

#### ***Schedule 4 - Improvements to the attorney profession***

A fourth category of reforms improves various aspects of Australia's intellectual property profession. If we expect more from intellectual property attorneys – to meet the higher standards provided for in the Bill, it is reasonable to extend to them the privileges available to other professions. The Bill makes two key changes to the patent and trade marks attorney professions in Australia.

The first change will permit patent and trade mark attorneys to conduct all aspects of their business through a corporate structure. Patent and trade mark attorneys are currently unable to do this, and this restriction is enforced through criminal sanctions. This is at odds with how other professions are regulated and are able to conduct their

businesses in Australia. The Bill amends the Patents and Trade Marks Acts to allow a company to act and describe itself as a patent attorney. The new provisions are modelled closely on corresponding provisions of the Model Law for the regulation of the legal profession around Australia, with some variations necessitated by the different function and structure of the two professions. This is a reform that has been long sought after by the patent attorney profession, and aligns that profession more closely with other professions in Australia.

The second change will extend the privilege that attaches to certain communications. At present, only certain communications to and from attorneys who are registered in Australia are privileged. In a globalised economy, in which IP rights are sought and prosecuted around the world, it is important that the privilege in Australia extends more broadly than only to Australian registered attorneys. The Bill extends privilege to overseas attorneys who are authorised to provide intellectual property advice and better aligns patent and trade mark attorney privilege with that attaching to communications to and from lawyers. Similar amendments, applying to privilege attaching to communications to and from legal practitioners, were introduced by this government through the *Evidence Amendment Act 2008*.

#### ***Schedule 5 - Trade mark and copyright infringement***

The fifth category of reforms introduced by the Bill will improve the ability of trade mark and copyright owners to enforce their rights. Trade mark rights will also be strengthened by improving the remedies available when the rights have been found to have been infringed. We are setting higher standards for the granting of intellectual

property rights. It is reasonable that, where rights are granted, that higher standards also apply to their enforcement. There are three areas for improvement.

The first relates to the criminal penalties available for infringements of registered trade marks. Criminal penalties play an important role in trade mark enforcement, by deterring infringements and punishing infringers. There have been concerns expressed that Australia's criminal penalties are too low to operate as an effective deterrent. The Bill addresses this concern by increasing the criminal penalties for existing offences. Higher penalties will be more effective in deterring infringement of trade mark rights. The changes also introduce some summary offences, but with lower fault elements and lower penalties. This will provide greater flexibility to law enforcement agencies when prosecuting trade mark crimes. These changes also bring the criminal penalties under the Trade Marks Act into closer alignment with those under the Copyright Act.

The second area of improvements to IP enforcement relates to the civil remedies available for infringements of trade marks. These amendments will introduce a further remedy in civil actions for trade mark infringement. At the moment, the trade mark owner can seek damages, an account of profits, or injunctive relief. This is out of step with the remedies available under other IP laws, which also allow the IP rights owner to obtain what are called 'additional' or 'exemplary' damages. The aim of awarding additional damages is to increase the deterrence for infringers. The Bill amends the Trade Marks Act to introduce exemplary damages as an additional remedy to trade mark infringement.

The third area of improvements relates to the powers of the Australian Customs and Border Protection Service to intercept goods that infringe copyrights or registered trade marks at the border. The Bill improves the existing arrangements by permitting

Customs officials to provide more information to copyright and trade mark owners about goods that are seized at the border. The Bill also requires that Customs only release seized goods if the importer lodges a claim for return, which must include the identity and address of the importer and be filed within a specified time period. These changes will help rights owners in deciding whether or not to commence an infringement action. And then they will also help in the commencement of infringement proceedings.

***Schedule 6 - Technical improvements to the IP system***

The sixth category of reforms is a collection of technical improvements and changes, clarifications and updates to the Patents, Trade Marks, Plant Breeder's Rights and Designs Acts. The measures implemented in this category share the common themes of modernising aspects of Australia's IP system, increasing transparency in the decision-making process, and generally making the system easier to use.

In particular the amendments include a number of changes that improve the flexibility of the IP rights system for users. Examples of changes in this area are the changes to improve processes for resolving ownership disputes. Current processes can be unduly complex, making it difficult for the Commissioner to resolve disputes and correct ownership details in the patent register. The changes proposed by the bill will give the Commissioner greater flexibility to decide disputes and correct the register, ensuring that the public has correct information about who a patent has been granted to.

Another example is extending the jurisdiction of the Federal Magistrates Court to hear trade mark and design matters. This provides innovators with the option of a less

formal, and more speedy and cost effective alternative for considering less complex trade mark and design matters.

This Bill represents a comprehensive package of improvements to the IP system. It is the most comprehensive package of reforms in the lifetime of the current Patents Act. These changes bolster support for innovation in Australia and better equip Australians to commercialise their innovations in the evolving modern economy.

***Summing up speech for second reading debate***

I ~~want~~ to thank Honourable Members for their contribution to the debate and ~~would like to make a few responses to the points they raise ....~~

I would also like to take a moment to thank all the stakeholders who contributed their thoughts and suggestions on this Bill. The proposals in this Bill have been the subject of extensive consultation – three separate rounds of public consultation stretching over the last two years. Innovators, researchers, small businesses, big businesses, academic experts, lawyers and patent and trade marks attorneys and users of the products of the IP system have all offered thoughtful comments. These have undoubtedly led to a better Bill. And, if the Bill is passed, they will lead to better law.

*there have been some suggestions*  
I note that ~~some members have suggested~~ that the Bill does not go far enough and that further amendments *might be* ~~are~~ required to address the issue of gene patents. Gene patents have been the subject of a number of recent inquiries by two Senate Committees, the Australian Law Reform Commission and the Advisory Council on Intellectual Property.

Most recently, the Senate Legal and Constitutional Affairs Committee inquired into the Patent Amendment (Genes and Biological Materials) Bill 2010. This was a Private Member's Bill which sought to ban patents for gene and biological materials. The majority report of the Committee recommended that the Private Member's Bill not be passed.

Before that the Senate Community Affairs References Committee conducted a comprehensive review into gene patents and their impacts on access to medical treatment and the research. Last November the Government released its response to the Committee's report. The Committee did not recommend a ban on gene patents and the Government agreed with this recommendation.

The Committee also recommended amending the *Patents Act* to raise patent standards and introduce a research exemption.

These amendments will be implemented through the Raising the Bar Bill. They have widespread support from stakeholders, the research community and industry; including those on both sides

of the gene debate, who see the changes as an important step in improving the patent system.

The Government also agreed to further measures recommended by the Committee to address concerns about gene patents.

Central to these are review of existing compulsory licensing provisions and amendments to patents legislation to reword the legislative test for patent eligible subject matter, using contemporary language, and to introduce a morality exclusion.

~~Work on these further measures will commence this year. This~~

*These measures*  
work will be the subject of the same considered and comprehensive full public consultation as the Raising the Bar Bill.

A strong intellectual property system is essential to drive the innovation and research that benefits so many Australians.

Robust patent standards ensure that broad patents don't clog the innovation landscape, preventing competition for better ideas and better inventions. By aligning standards with our major

trading partners the Bill makes it easier for Australian inventors to take their good ideas overseas. The Bill gives clarity and certainty to our researchers, so they can experiment free from the shadow of litigation. The Bill speeds up the process of resolving patent and trade mark applications, so that applicants and the public know where they are free to operate and innovate. The Bill assists the IP professionals that assist our innovators, making it easier for them to continue to provide quality advice. The Bill deters imitators and fakes with better border protection systems and stronger sanctions for counterfeiters. And finally the Bill simplifies the more technical aspects of the current IP system, so that innovators can spend less time prosecuting applications and more time producing innovation.

These measures raise the bar. They raise the quality of our innovation system and so raise the quality of the innovation that benefits all Australians. That is why we need this Bill.

***Talking points for discussion of gene patents and the Raising the Bar Bill with Parliamentary colleagues***

- In November last year the Government released its response to the Senate Community Affairs References Committee's inquiry into Gene Patents.
- The Government response agreed with the Committee's recommendations that there be no ban on gene patents at this stage. This followed the recommendation from the Senate Standing Committee on Legal and Constitutional Affairs that the private members bill on gene patents not be passed.
- The response also agreed that there are other changes that need to be made to the patent system to address concerns about gene patents.
- Some of these are in the Raising the Bar Bill. They raise patent standards and introduce a statutory exemption from infringement for research activities.
- They are supported by stakeholders from both sides of the gene patents debate, who see them as an important step in improving the patent system.
- Other work will get underway over the coming year.
- Central to this work are a review of the existing compulsory licensing provisions and changes to the *Patents Act* to reword the test for patent eligible subject in clearer language, introduce a morality exclusion and introduce a statement of objectives that reflects the intention that patents should not lead to patients being denied reasonable access to healthcare.
- This work will be the subject of the same considered and comprehensive full public consultation as the Raising the Bar Bill.

# Urgent Decision Brief - 'Debate of the Raising the Bar Bill and Gene Patents - Replacement Speeches and Talking Points' [SEC=IN-CONFIDENCE] - Notes Memo

**From:** [Andrea.Blazsev@ipaaustralia.gov.au](mailto:Andrea.Blazsev@ipaaustralia.gov.au)  
**To:** mlobriefs@innovation.gov.au, kaye.fisk@innovation.gov.au  
**Cc:** Terry.Moore@ipaaustralia.gov.au  
**Sent:** 09-03-2012 09:15:36 AM

Good morning MLO

Please find attached an urgent decision brief titled 'Debate of the Raising the Bar Bill and Gene Patents - Replacement Speeches and Talking Points'

It has been cleared by Philip Noonan, Director General, IP Australia and the timing has also been discussed with the Parliamentary Secretary's Office. Please note that we are also emailing this directly to Emo due to the short timeframe.

<Attachment: 12-03-09 DB Debate on Raising the Bar - Replacement speeches and talking points.doc> <Attachment: 12-03-09 Attachment A - Replacement Second Reading Speech.doc> <Attachment: 12-03-10 Attachment B Replacement Summing up Speech.doc>

<Attachment: 12-03-10 Attachment C - Talking points.doc>

Kind Regards,

## Ministerial Support Team

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**INTELLECTUAL PROPERTY LAWS AMENDMENT (RAISING THE BAR)**

**BILL 2011**

**SECOND READING SPEECH**

**HOUSE OF REPRESENTATIVES**

The Intellectual Property Laws Amendment (Raising the Bar) Bill 2011 is a major reform of the intellectual property system. It is the culmination of two years of extensive consultation with interested parties. The bill will improve many parts of the intellectual property system, including the Patents, Trade Marks, Copyright, Designs and Plant Breeder's Rights Acts. The bill will ensure that Australia maintains a world class intellectual property system: an IP system that fosters Australian innovation in the modern global economy.

Australian innovation is critical to the resilience of the economy through changing times. Innovation makes our economy more competitive. But the extent of innovation necessary to keep our economy competitive can't happen on its own. In addition to requiring support and investment, innovation requires a strong intellectual property system.

A strong IP system underpins investment in innovation. This was recognised in *Powering Ideas*, the Government's innovation agenda for the 21<sup>st</sup> century. A strong IP system provides investors an opportunity to recoup the investments necessary to bring their ideas to the marketplace. The IP system also gives the public and innovators the tools necessary for further innovation, through published information about new technology.

As also recognised in *Powering Ideas* – “*The trick is to get the balance right: too little protection will discourage people from innovating because the returns are*

*uncertain; too much protection may discourage people from innovating because the pathways to discovery are blocked by other intellectual property owners”.*

The reforms set out in this Bill seek to improve that balance by addressing six key areas:

- Patent standards;
- Research freedom;
- Reducing delays in resolving patent and trade mark applications;
- Improvements to the attorney profession;
- Trade mark and copyright infringement; and
- Technical improvements to the IP system.

#### ***Schedule 1 - Patent Standards***

First, the Bill seeks to raise patent standards. This addresses concerns that Australia’s standards are lower than standards elsewhere, which discourages export of the technology we develop and inhibits growth of Australian business. Lower Australian patent standards actually disadvantage Australian patent holders, who should be able to take their inventions overseas with confidence that they will qualify for patent protection in Australia’s major trading partners. Lower patent standards may also clutter the Australian innovation landscape with broad patents that would not meet the standards of our major trading partners, getting in the way of Australians who might otherwise be able to develop inventions in new areas.

A theme in this Bill is one of recalibrating and raising Australian standards, to align them more closely with those of other major trading partners around the world. Some patent standards around the world have developed to the point where there is an

aligned approach internationally. In such cases where there is an aligned global approach, the Bill raises Australian patenting standards to that common approach.

The Bill raises patent standards in three important areas.

First it raises standards with respect to the information provided in patent applications and specifications. Disclosure is a cornerstone of the patent system. Patents are an exchange between inventors and the public. In exchange for a 20 year monopoly on commercialisation, the innovator must tell the public how their idea works. This disclosure allows for potential follow-on innovators to build on initial work to produce even better innovations.

The Bill raises standards to require that the patent right is consistent with the information provided in the patent specification. There must be enough information disclosed for the public to make and use the invention. Also, a specific, substantial and credible use for the invention must also be disclosed and the scope of the claims for patent protection must not extend beyond what has been disclosed.

Importantly, the amended provisions mirror similar provisions in the United Kingdom and Europe. It is intended that Australian courts will have regard to developments in the law in the courts of these other jurisdictions when interpreting the new provisions, and will develop Australian law in a consistent fashion. This will help Australian exporters have the confidence that a patent granted in Australia is likely to be matched by a patent granted in major overseas markets.

Secondly, the Bill raises the standards for inventiveness. Raising the standards for inventiveness allows the patent system to better recognise the global innovation environment and reflect the modern economy's improved access to information. We must not grant a patent for something that has been done before. The Bill ensures that

the patent system takes into account all published information that is reasonably available and accessible to the public. It will also ensure that this information is assessed against the background of knowledge of the skilled person, regardless of where that person resides.

Thirdly, the Bill ensures that a consistent standard of proof is applied by the Commissioner of Patents in all decisions and expands the grounds that the Commissioner can consider during examination and re-examination. Someone who seeks a patent will bear the burden of showing that they are entitled to patent protection. The Bill requires the Commissioner to be satisfied, on the balance of probabilities, that a patent, if granted, will be valid.

Taken together, these changes ensure that only high quality patents are granted in Australia. They make sure that the scope of disclosure is commensurate with the monopoly granted. They will make sure that patents are only granted for innovations that warrant patent protection. They will also ensure that the Commissioner of Patents can apply robust standards when assessing whether or not a patent should be granted and whether or not a patent should be revoked.

### ***Schedule 2 – Research freedom***

The second category of reforms responds to concerns that patent rights can sometimes deter or block innovation by discouraging researchers from developing further innovations or spin-offs. We need to set our researchers free and ensure that the patent system encourages further innovation. The key reform in this category introduces an explicit provision permitting experimentation to be conducted without infringing patent rights. This amendment will give comfort to researchers in Australia, and is strongly supported by Australia's research sector.

The amendment strikes a balance between the rights of patentees and the rights of subsequent researchers. The exemption protects researchers and follow-on innovators as long as what they are doing is predominantly for research and experimental purposes. The exemption is intended to allow for some areas of commercial activity - for example, where the researchers are doing their work under contract, and are accepting payment to do experiments to improve on, or test a patented invention to see how it works. However, if the purpose is primarily commercial – such as where the researcher is seeking to commercialise the patented invention - the amendment protects the interests of patent owners because it will not apply where the main purpose is to commercialise the invention or manufacture it for sale.

A second reform introduces an amendment to exempt research activities necessary for gaining pre-market or pre-manufacturing regulatory approval from infringement. This ensures that a patent owner gets no more than the statutory period of protection. Such an exemption already exists for particular regulatory activities in the pharmaceutical industry. The amendment expands this exemption to apply to all technologies.

Currently, a patentee can delay a competitor's entry into the market when the patentee's patent expires by threatening the competitor with infringement proceedings if they seek to do the work necessary to gain regulatory approval during the patent term. This gives the patentee a *de facto* extension on the term of their patent. The amendments will enable competitors to make the preparations necessary to enter the market as soon as a patent has ceased or expired. The amendments will not, however, allow the competitor to stockpile their product during the patent term, or make or use it in any way that detracts from the patentee's exclusive rights to commercial advantage from their invention during the term of the patent.

The amendments in schedules one and two also address some of the concerns raised in recent inquiries into gene patents.

In 2004 the Australian Law Reform Commissioner released its report, *Genes and Ingenuity: Gene patenting and human health*, following a two year inquiry into patenting laws and practices related to genetics and related technologies, including the impact of gene patents on human health and cost effective provision of healthcare. In 2010 the Senate Community Affairs Committee released its report, *Gene Patents*, following its inquiry into the impacts of gene patents on healthcare and medical research.

Both reports recommended technology-neutral changes to raise patent standards and introduce a research exemption. These changes are reflected in Schedules 1 and 2 of the Raising the Bar Bill.

The Government has committed to implement further recommendations from the reports, and will commence work on these this year. These include a review of existing compulsory licensing provisions and consultation on further reforms to patents legislation to reword, using contemporary language, the legislative test for patent eligible subject matter, and to introduce a morality exclusion.

### ***Schedule 3 - Reducing delays in resolving applications***

The third category of reforms is aimed at making the patent and trade mark application process more efficient. These changes will speed up the processes for determining applications for IP rights. They will also prevent tactical use of the system by those who profit from delay. The amendments target two key areas.

The first area is the process of opposing patent and trade mark applications.

Opposition processes permit any person who might be adversely impacted by issue of

an IP right to come forward and oppose it. Oppositions are intended to provide for a swift and efficient administrative resolution where a third party has concerns about the grant of an IP right. However, oppositions have become increasingly more complicated and protracted. The Bill introduces a series of reforms aimed at resolving opposition proceedings more efficiently while still ensuring a fair outcome, and ensuring that any delays are truly unavoidable ones.

The second area relates to what are called ‘divisional’ patent applications. Patent systems around the world permit a patent application to be divided into one or more divisional applications, primarily to account for circumstances where more than one invention is claimed in the original application. However, the provisions are not as clear as desirable and sometimes divisional applications are used to delay finalisation of a particular invention or frustrate a third party. The reforms tighten the provisions for divisional applications, particularly timeframes for making applications. This will reduce opportunities to delay finalisation of applications.

#### ***Schedule 4 - Improvements to the attorney profession***

A fourth category of reforms improves various aspects of Australia’s intellectual property profession. If we expect more from intellectual property attorneys – to meet the higher standards provided for in the Bill, it is reasonable to extend to them the privileges available to other professions. The Bill makes two key changes to the patent and trade marks attorney professions in Australia.

The first change will permit patent and trade mark attorneys to conduct all aspects of their business through a corporate structure. Patent and trade mark attorneys are currently unable to do this, and this restriction is enforced through criminal sanctions. This is at odds with how other professions are regulated and are able to conduct their

businesses in Australia. The Bill amends the Patents and Trade Marks Acts to allow a company to act and describe itself as a patent attorney. The new provisions are modelled closely on corresponding provisions of the Model Law for the regulation of the legal profession around Australia, with some variations necessitated by the different function and structure of the two professions. This is a reform that has been long sought-after by the patent attorney profession, and aligns that profession more closely with other professions in Australia.

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#### ***Schedule 5 - Trade mark and copyright infringement***

The fifth category of reforms introduced by the Bill will improve the ability of trade mark and copyright owners to enforce their rights. Trade mark rights will also be strengthened by improving the remedies available when the rights have been found to have been infringed. We are setting higher standards for the granting of intellectual

property rights. It is reasonable that, where rights are granted, that higher standards also apply to their enforcement. There are three areas for improvement.

The first relates to the criminal penalties available for infringements of registered trade marks. Criminal penalties play an important role in trade mark enforcement, by deterring infringements and punishing infringers. There have been concerns expressed that Australia's criminal penalties are too low to operate as an effective deterrent. The Bill addresses this concern by increasing the criminal penalties for existing offences. Higher penalties will be more effective in deterring infringement of trade mark rights. The changes also introduce some summary offences, but with lower fault elements and lower penalties. This will provide greater flexibility to law enforcement agencies when prosecuting trade mark crimes. These changes also bring the criminal penalties under the Trade Marks Act into closer alignment with those under the Copyright Act.

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The third area of improvements relates to the powers of the Australian Customs and Border Protection Service to intercept goods that infringe copyrights or registered trade marks at the border. The Bill improves the existing arrangements by permitting

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In particular the amendments include a number of changes that improve the flexibility of the IP rights system for users. Examples of changes in this area are the changes to improve processes for resolving ownership disputes. Current processes can be unduly complex, making it difficult for the Commissioner to resolve disputes and correct ownership details in the patent register. The changes proposed by the bill will give the Commissioner greater flexibility to decide disputes and correct the register, ensuring that the public has correct information about who a patent has been granted to.

Another example is extending the jurisdiction of the Federal Magistrates Court to hear trade mark and design matters. This provides innovators with the option of a less

formal, and more speedy and cost effective alternative for considering less complex trade mark and design matters.

This Bill represents a comprehensive package of improvements to the IP system. It is the most comprehensive package of reforms in the lifetime of the current Patents Act. These changes bolster support for innovation in Australia and better equip Australians to commercialise their innovations in the evolving modern economy.

***Summing up speech for second reading debate***

I want to thank Honourable Members for their contribution to the debate and would like to make a few responses to the points they raise ....

*[Insert speaking notes for responding to other members' speeches during debate.]*

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I would also like to take a moment to thank all the stakeholders who contributed their thoughts and suggestions on this Bill. The proposals in this Bill have been the subject of extensive consultation – three separate rounds of public consultation stretching over the last two years. Innovators, researchers, small businesses, big businesses, academic experts, lawyers and patent and trade marks attorneys and users of the products of the IP system have all offered thoughtful comments. These have undoubtedly led to a better Bill. And, if the Bill is passed, they will lead to better law.

I note that some members have suggested that the Bill does not go far enough and that further amendments are required to address the issue of gene patents. Gene patents have been the subject of a number of recent inquiries by two Senate Committees, the Australian Law Reform Commission and the Advisory Council on Intellectual Property.

Most recently, the Senate Legal and Constitutional Affairs Committee inquired into the Patent Amendment (Genes and Biological Materials) Bill 2010. This was a Private Member's Bill which sought to ban patents for gene and biological materials. The majority report of the Committee recommended that the Private Member's Bill not be passed.

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The Committee also recommended amending the *Patents Act* to raise patent standards and introduce a research exemption.

These amendments will be implemented through the Raising the Bar Bill. They have widespread support from stakeholders, the research community and industry; including those on both sides

of the gene debate, who see the changes as an important step in improving the patent system.

The Government also agreed to further measures recommended by the Committee to address concerns about gene patents.

Central to these are review of existing compulsory licensing provisions and amendments to patents legislation to reword the legislative test for patent eligible subject matter, using contemporary language, and to introduce a morality exclusion.

Work on these further measures will commence this year. This work will be the subject of the same considered and comprehensive full public consultation as the Raising the Bar Bill.

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***Talking points for discussion of gene patents and the Raising the Bar Bill with Parliamentary colleagues***

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- The Government response agreed with the Committee's recommendations that there be no ban on gene patents at this stage. This followed the recommendation from the Senate Standing Committee on Legal and Constitutional Affairs that the private members bill on gene patents not be passed.
- The response also agreed that there are other changes that need to be made to the patent system to address concerns about gene patents.
- Some of these are in the Raising the Bar Bill. They raise patent standards and introduce a statutory exemption from infringement for research activities.
- They are supported by stakeholders from both sides of the gene patents debate, who see them as an important step in improving the patent system.
- Other work will get underway over the coming year.
- Central to this work are a review of the existing compulsory licensing provisions and changes to the *Patents Act* to reword the test for patent eligible subject in clearer language, introduce a morality exclusion and introduce a statement of objectives that reflects the intention that patents should not lead to patients being denied reasonable access to healthcare.
- This work will be the subject of the same considered and comprehensive full public consultation as the Raising the Bar Bill.

### Ministerial Coversheet

<b>Date Due in MLO:</b>	28/03/2012	<b>Ministerial Item:</b>	C12/910
<b>Action Division:</b>	IP Aust	<b>Current Division:</b>	IP Aust
<b>Action:</b>	Reply by Parliamentary Sec	<b>Minister Office:</b>	Dreyfus
<b>Signatories:</b>	DREYFUS QC MP, MARK		
<b>Subject:</b>	Patents Amendment Genetic Materials Bill		

<b>Ministerial Type:</b>	Correspondence	<b>Attachments:</b>	N
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<b>Corro Date:</b>	13/03/2012	<b>Interim Reply:</b>	N
<b>MO Received Date:</b>	13/03/2012		
<b>Complexity:</b>	NON-COMPLEX	<b>MP Rep Constituent:</b>	N
<b>Campaign:</b>			

**Instructions:**

**Officer:** Cartolano, Christine  
**Date:** 14 Mar 2012 11:39  
**Text:** Briefing requested on how the office address the concerns of Melissa Parke MP

**Officer:**



The Hon. Mark Dreyfus QC MP  
Parliamentary Secretary for Industry and Innovation  
Parliamentary Secretary for Climate Change and Energy Efficiency  
Australian Parliament House  
Canberra ACT

13 March 2012

Dear Minister,

**Patents Amendment (Genetic Materials) Bill**

For the past three years I have been engaged within the caucus committee process regarding the issue of gene patents. It has been a matter of deep concern to me and many within the Australian community that patents are being granted over human genes and diagnostic tests when (a) there is no invention involved, which is after all supposed to be the point of the patent system; (b) this is impacting on health research and diagnosis because scientists, researchers and health professionals are not able to access basic genetic information without fear of infringing a patent; and (c) unjustified patent monopolies are stifling competition and adding massively to the cost of our PBS.

Given the concerns outlined above, which have not been addressed in the Intellectual Property Amendment (Raising the Bar) Bill, I intend to introduce a private members Bill, *the Patents Amendment (Genetic Materials) Bill*, which would exclude from patentability:

1. Genetic materials that exist in nature (including 'isolated' genetic materials) where there has been no invention; and
2. Tests that involve mere comparisons of genetic sequences without any invention.

I seek the Government's support for this Bill, and will be taking it through the caucus committee process to seek Caucus approval. I am also sending a copy of this letter to Ministers Tanya Plibersek, Greg Combet, and Nicola Roxon. Please find enclosed a copy of the Bill and a draft explanatory memorandum.

Yours sincerely,

Melissa Parke MP  
Federal Labor Member for Fremantle

C12/910

<b>Parliamentary Secretary for Industry and Innovation</b>	
Division: <b>IPA AUSTRALIA</b>	DLO: <b>EMO</b>
Subject:	
<b>RECEIVED 13 MAR 2012</b>	
<input checked="" type="checkbox"/> Covering Brief	<input type="checkbox"/> Departmental Reply
<input type="checkbox"/> VIP Reply	<input type="checkbox"/> Appropriate Action
<input type="checkbox"/> <del>Stakeholder Engagement</del>	<input type="checkbox"/> For Information (NFA)
<input type="checkbox"/> <del>CoS/Adviser</del>	<input type="checkbox"/> Campaign
<input type="checkbox"/> CoS/Adviser	<input type="checkbox"/> Refer to:.....

Briefing also requested on how the office can address the concerns of Melissa Parke MP

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Aubin Grc  
Ban  
Beaconsfi  
Bee  
Bibra Lc  
Bict  
Cockburn Cen  
Coog  
Coolbell  
East Fremar  
Fremar  
Hamilton  
Hammond Pr  
Henders  
Hit  
Jandal  
Kardin  
Muns  
Naval Bc  
North Coog  
North Fremar  
North Lc  
O'Conn  
Parks  
Rotman 120  
Sams  
South Fremar  
South Lc  
Spencer

2010-2011-2012

The Parliament of the  
Commonwealth of Australia

HOUSE OF REPRESENTATIVES

*Presented and read a first time*

**Patents Amendment (Genetic Materials)  
Bill 2012**

**No.     , 2012**

*(Ms Parke)*

**A Bill for an Act to amend the *Patents Act 1990* to  
prevent the patenting of genetic materials existing  
in nature, and for related purposes**

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<b>Schedule 1—Amendments</b>		<b>3</b>
	<i>Patents Act 1990</i>	3

1     **A Bill for an Act to amend the *Patents Act 1990* to**  
2     **prevent the patenting of genetic materials existing**  
3     **in nature, and for related purposes**

4     The Parliament of Australia enacts:

5     **1 Short title**

6                     This Act may be cited as the *Patents Amendment (Genetic*  
7                     *Materials) Act 2012*.

8     **2 Commencement**

9                     This Act commences on the day after this Act receives the Royal  
10                    Assent.

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1     **3 Schedule(s)**

2             Each Act that is specified in a Schedule to this Act is amended or  
3             repealed as set out in the applicable items in the Schedule  
4             concerned, and any other item in a Schedule to this Act has effect  
5             according to its terms.  
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## Schedule 1—Amendments

### *Patents Act 1990*

#### **1 Subsection 18(2)**

Repeal the subsection, substitute:

(2) The following are not patentable inventions:

- (a) human beings, and the biological processes for their generation;
- (b) genetic materials that exist in nature, or are the same as or not markedly different from those existing in nature, whether such materials are in situ, isolated or purified;
- (c) any method that involves the mere comparison of genetic materials or genetic sequences in the provision of a diagnosis for a human being.

(2A) A reference in subsection (2) to genetic materials includes, but is not limited to, DNA or RNA whether in whole or in part or in fragments, however made.

*Patents Amendment (Genetic Materials) Bill 2012*

**Explanatory memorandum**

Introduction

The Australian economy is dedicated to the principle of competition. A notable exception to this principle is the patent system, which creates monopolies sanctioned by law as a way of encouraging inventive contributions. In general, an inventor of a new method of manufacture will be entitled to exclusively exploit their invention for 20 years in return for disclosing their invention to the world.

It is a bedrock principle of patent law that there must be an invention. In the health field, true inventions such as medicines, vaccines and new methods for diagnosis are patentable subject matter. However, discoveries of nature are not inventions and have never been patentable subject matter, irrespective of how difficult or useful that discovery may be.<sup>1</sup>

Knowledge about human genes belong to everyone. This is why, when the human genome was decoded 12 years ago, US President Clinton and British Prime Minister Blair issued a joint statement which said that 'To realise the full promise of this research, raw fundamental data on the human genome, including the human DNA sequence and its variations, should be made freely available to scientists everywhere. Unencumbered access to this information will promote discoveries that will reduce the burden of disease, improve health around the world, and enhance the quality of life for all humankind.'<sup>2</sup>

Notwithstanding the principles above, the practice of IP Australia over the past more than two decades has been to grant patents over human genes where such genes have been 'isolated' from the human body and to grant patents over diagnostic tests that do not involve any invention but consist only of mere comparisons of genetic sequences.

The objective of this amendment is twofold:

1. To address the issue of patent monopolies being granted over genetic material (including 'isolated' genetic material) where there has been no invention. S18(2) excludes from patentability:
  - (b) genetic materials that exist in nature, or are the same as or not markedly different from those existing in nature, whether such materials are in situ, isolated or purified;
2. To address the issue of patent monopolies being granted for tests which are only mental abstractions involving mere comparisons of genetic sequences without any invention. S18(2) excludes from patentability:
  - (c) any method that involves the mere comparison of genetic materials or genetic sequences in the provision of a diagnosis for a human being.

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<sup>1</sup> United States amicus curiae submission in the US Federal Court of Appeals case concerning the validity of Myriad Genetic's patents over breast and ovarian cancer genes, p35

<sup>2</sup> <http://clinton4.nara.gov/WH/EOP/OSTP/html/00314.html>

Excluding genetic material from patentability

S18(2)(b): This amendment seeks to advance medical and scientific research and the diagnosis, treatment and cure of human illness and disease by enabling medical and scientific researchers, doctors and clinicians to gain free and unfettered access to genetic materials that exist in nature or that are the same as or not markedly different from those materials, without any legal impediment created by the grant of a patent monopoly.

The Bill excludes from patentability genetic materials that have been 'isolated', since as the United States has noted in a recent US federal court case:

"The chemical structure of native human genes is a product of nature, and it is no less a product of nature when that structure is isolated from its natural environment than are cotton fibres that have been separated from cotton seeds or coal that has been extracted from the earth..."<sup>3</sup>

As Professor Ian Frazer has publicly noted:

"There is no more invention in isolating and characterising biological material that exists in our bodies...than in collecting and arranging a set of postage stamps."<sup>4</sup>

Practical example of why reform is needed: During the recent Senate Community Affairs References Committee inquiry into Gene Patents, the Peter McCallum Cancer Centre gave evidence that its research into breast and ovarian cancer had been delayed by 2 years and ended up costing 3 times as much because gene patent holders Myriad and Genetic Technologies refused to grant it permission to use the genes in its research.

As Professor Bowtell from the Peter MacCallum Cancer Centre said during the inquiry:

"We are coming into an era where lots of genes are actually being identified that work in concert to actually cause an outcome, like the risk of developing breast cancer, diabetes, stroke ... If the patents for each of those genes are held by different companies then it is going to be extremely difficult to assemble a practical test to test for a particular condition."

Excluding tests that are mere mental abstractions from patentability

S18(2)(c): The second objective of the Bill is to ensure that clinicians, doctors or those appropriately skilled in the medical sciences are able to use their medical training and knowledge to compare genetic materials in the provision of a diagnosis for a human being without any legal impediment created by the grant of a patent monopoly. The following cases highlight the need for reform in this area.

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<sup>3</sup> United States amicus curiae submission in the US Federal Court of Appeals case concerning the validity of Myriad Genetic's patents over breast and ovarian cancer genes, p10-11

<sup>4</sup> The Australian, 8/8/2009

In July 2008 an Australian company Genetic Technologies, which had acquired the exclusive patent rights to a number of Australian patents granted by IP Australia to Myriad Genetics over breast and ovarian cancer (BRCA) genes<sup>5</sup>, wrote to all of Australia's publicly funded clinical laboratories demanding that they immediately cease providing Australian women with BRCA genetic testing or they would be sued for patent infringement.

In September 2010 the ABC Four Corners program "Body Corporate" highlighted the fact that doctors at Westmead Hospital are sending children's DNA samples to Scotland for epilepsy testing rather than pay the fees and royalties demanded by Genetic Technologies which holds the patent rights for the epilepsy gene and genetic test.<sup>6</sup>

The US Federal Court of Appeal recently ruled (this aspect of the ruling is not the subject of an appeal) that Myriad's patent claims on the process of analysing whether a patient's genes had mutations that raised the risk of cancer was not patentable because it involved only "patent-ineligible abstract mental steps."

During that case, the Association for Molecular Pathology noted:

"That pathologists can be excluded from 'looking at' or 'reading' a patient's DNA sequence to characterise or assess the risk for disease is akin to prohibiting a physician from taking a patient's pulse to see if his or her heart is beating... the fact that patients can be prevented from accessing the information contained in their DNA would offend most people's conceptions of individual rights and personal liberty."

#### Economic incentives for research

In response to the argument that private companies will not engage in genetic research unless they have the economic incentives created by the patent system, Nobel Prize winners for economics and medicine Professors Joseph Stiglitz and John Sulston argue that:

"A deeper understanding of the economics and science of innovation leads to exactly the opposite conclusion. [Gene] patents ... not only prevent the use of knowledge in ways that would most benefit society, they may even impede scientific progress. Every scientific advance is built on those that came before it. There is still a great deal to learn about our genes, particularly how they contribute to disease. Gene patents inhibit access to the most basic information.

As we move into an era where the sequencing of all of an individual's genes is common and necessary for personalized medicine, free sharing of information about genes will be vital to understanding the role of these variations in human disease and other traits. In order to translate this information into medical advancements, the basic data must be freely available to everyone to interpret and develop. Our genetic makeup is

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<sup>5</sup> BRCA 1 and BRCA 2 genetic mutations linked to breast and ovarian cancers

<sup>6</sup> <http://www.abc.net.au/4corners/content/2010/s3004027.htm>

far too complicated for a single entity to hold the keys to any given gene and to be able to choose when, if ever, to share.”<sup>7</sup>

Furthermore, this Bill does not prevent the patenting of new medicines, vaccines, diagnostic processes etc that include the use of genetic materials. It simply prohibits the patenting of the basic genetic materials themselves. The freeing up of the underlying genetic information will foster more innovation and research, not less.

#### Cost to the PBS

The cost of the PBS has been unnecessarily and seriously impacted by gene patents. For example, a patent granted over the human gene, erythropoietin, gave the patent owner the exclusive right over that gene between 1984 and 2006 - 22 years. The patent owner was able to list a synthetic erythropoietin on the ATGR (Australian Therapeutic Goods Register) as therapeutic medicine from 1991, thereby earning tens of millions of dollars in sales from the PBS. However, the patent over the actual gene and protein made it impossible for any other drug company to make a competing version of the same synthetic protein - a protein which is naturally occurring and which the patent owner did not invent. The lack of competition not only gave the patent owner the ability to extract a higher than normal price from the PBS from 1991 onwards but even today, some 6 years after the patent expired, there is no competing synthetic erythropoietin product approved for sale in Australia because the control which the original patent gave over the actual human gene and protein has suppressed the development of a generic version of a synthetic erythropoietin. As a result the patent owner enjoys a virtual, if not legal, extension of its patent position and the PBS continues to pay a higher than normal price.

#### International agreements

Both TRIPS (Art. 27.1) and AUSFTA (Art. 17.9.1) provide that patents be only granted for “inventions” and only if they are “new”, “involve an inventive step” and are “capable of industrial application.” This means that products of nature, such as genetic materials, are not capable of being the subject of a patent.

Furthermore, both TRIPS (Art. 27.3(b)) and AUSFTA (17.9.2(b)) provide that “diagnostic ... methods for the treatment of humans and animals” may be excluded from patentability.

#### Health Community Support

The Cancer Council of Australia, the National Breast Cancer Foundation, Royal College of Pathologists of Australasia, Royal Australasian College of Surgeons, the Clinical Oncological Society and the Human Genetics Society support the amendments contained in the Bill.

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<sup>7</sup> Wall Street Journal, 17 April 2010

The Hon Melissa Parke MP  
Federal Member for Fremantle  
PO Box 6022  
Parliament House  
CANBERRA ACT 2600

Dear Ms Parke

Thank you for your letters of 13 March 2012 to Parliamentary Secretary Dreyfus and I, seeking Government support for your private members Bill, *the Patents Amendment (Genetic Materials) Bill 2012*. I am responding on behalf of us both.

Over recent years a number of inquiries and reports into issues around the patenting of genes have been undertaken. These include the Senate Community Affairs Committee's *Gene Patents* report released in November 2010, the Australian Law Reform Commission's 2004 report on *Genes and Ingenuity: Gene Patenting and Human Health*, and the Advisory Council on Intellectual Property's 2011 report on patentable subject matter.

In November 2011 the Government released a response to all these reports, and accepted the majority of recommendations, including that there be no ban on gene patents at this time. This response was approved by Cabinet in November 2011 and is consistent with the legal position in our major trading partners.

I am unable to provide support for your proposed Bill as this would be contrary to the decision by Cabinet to implement the recommendations of the Government response.

In addition, the Senate's Legal and Constitutional Affairs Legislation Committee's response to the private member's Bill *Patent Amendment (Human Genes and Biological Materials) Bill 2010* recommended the Bill should not be passed. The Committee agreed that removing an area of patentable subject matter, as proposed by the Bill, was not an appropriate solution to the complex set of issues. I note that an identical private member's Bill was introduced into the House of Representatives on 21 February 2011.

Your proposed Bill differs from the previous private member's Bills in that genetic materials rather than all biological materials would be excluded patentable subject matter, but it is generally similar in nature. I also note you have proposed to exclude methods involving mere comparison of genetic materials or sequences in the provision of a diagnosis for a human being.

I understand your concerns around the patenting of human genes and diagnostic tests. The Australian Government shares community concern over any potential for patents to prevent vital medical research or deny access to medical care. However, the *Patents Act 1990* already contains powerful provisions that can be used to deal with impacts associated with access to patented technology should problems arise, such as compulsory licensing

and Crown use provisions. The Government has committed to review existing compulsory licence provisions to ensure that they do operate effectively as a safeguard.

The *Raising the Bar Bill* will also address many of the concerns you are seeking to address through your private member's Bill. It will introduce a statutory research exemption applying to all technologies which will make it clear that researchers will not infringe a patent when carrying out research on the patented invention. The threshold for granting a patent is also being raised through changes to the 'inventive step' sections of the *Patents Act 1990*. This will make it harder to obtain patents in Australia across all technologies.

I acknowledge the importance of affordable public access to medical treatments and diagnostics. However, I also recognise the value of the patent system to stimulate innovation and provide an incentive supporting the development of new medical tests. I believe that through the implementation of the Government's response to the gene patents reports an appropriate balance between public interest and private rights has been found. After implementation, these reforms will be evaluated to assess their effectiveness.

Thank you for bringing your concerns to my attention.

Yours sincerely

GREG COMBET

Cc The Hon Nicola Roxon MP, Attorney-General  
The Hon Tanya Plibersek MP, Minister for Health

2010-2011-2012

The Parliament of the  
Commonwealth of Australia

HOUSE OF REPRESENTATIVES

*Presented and read a first time*

**Patents Amendment (Genetic Materials)  
Bill 2012**

**No.     , 2012**

*(Ms Parke)*

**A Bill for an Act to amend the *Patents Act 1990* to  
prevent the patenting of genetic materials existing  
in nature, and for related purposes**

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<b>Schedule 1—Amendments</b>		<b>3</b>
	<i>Patents Act 1990</i>	3

1 **A Bill for an Act to amend the *Patents Act 1990* to**  
2 **prevent the patenting of genetic materials existing**  
3 **in nature, and for related purposes**

4 The Parliament of Australia enacts:

5 **1 Short title**

6 This Act may be cited as the *Patents Amendment (Genetic*  
7 *Materials) Act 2012*.

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9 This Act commences on the day after this Act receives the Royal  
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1 **3 Schedule(s)**

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## Schedule 1—Amendments

### *Patents Act 1990*

#### **1 Subsection 18(2)**

Repeal the subsection, substitute:

(2) The following are not patentable inventions:

- (a) human beings, and the biological processes for their generation;
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(2A) A reference in subsection (2) to genetic materials includes, but is not limited to, DNA or RNA whether in whole or in part or in fragments, however made.

**Patents Amendment (Genetic Materials) Bill 2012**

**Explanatory memorandum**

**Introduction**

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It is a bedrock principle of patent law that there must be an invention. In the health field, true inventions such as medicines, vaccines and new methods for diagnosis are patentable subject matter. However, discoveries of nature are not inventions and have never been patentable subject matter, irrespective of how difficult or useful that discovery may be.<sup>1</sup>

Knowledge about human genes belong to everyone. This is why, when the human genome was decoded 12 years ago, US President Clinton and British Prime Minister Blair issued a joint statement which said that 'To realise the full promise of this research, raw fundamental data on the human genome, including the human DNA sequence and its variations, should be made freely available to scientists everywhere. Unencumbered access to this information will promote discoveries that will reduce the burden of disease, improve health around the world, and enhance the quality of life for all humankind.'<sup>2</sup>

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**The objective of this amendment is twofold:**

1. To address the issue of patent monopolies being granted over genetic material (including 'isolated' genetic material) where there has been no invention. S18(2) excludes from patentability:
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<sup>5</sup> BRCA 1 and BRCA 2 genetic mutations linked to breast and ovarian cancers

<sup>6</sup> <http://www.abc.net.au/4corners/content/2010/s3004027.htm>

far too complicated for a single entity to hold the keys to any given gene and to be able to choose when, if ever, to share.”<sup>7</sup>

Furthermore, this Bill does not prevent the patenting of new medicines, vaccines, diagnostic processes etc that include the use of genetic materials. It simply prohibits the patenting of the basic genetic materials themselves. The freeing up of the underlying genetic information will foster more innovation and research, not less.

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Furthermore, both TRIPS (Art. 27.3(b)) and AUSFTA (17.9.2(b)) provide that “diagnostic ... methods for the treatment of humans and animals” may be excluded from patentability.

#### Health Community Support

The Cancer Council of Australia, the National Breast Cancer Foundation, Royal College of Pathologists of Australasia, Royal Australasian College of Surgeons, the Clinical Oncological Society and the Human Genetics Society support the amendments contained in the Bill.

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<sup>7</sup> Wall Street Journal, 17 April 2010

2010

The Parliament of the  
Commonwealth of Australia

THE SENATE

*Presented and read a first time*

**Patent Amendment (Human Genes and  
Biological Materials) Bill 2010**

**No.     , 2010**

*(Senators Coonan, Heffernan, Siewert and Xenophon)*

**A Bill for an Act to amend the *Patents Act 1990* to  
prevent the patenting of human genes and  
biological materials existing in nature, and for  
related purposes**

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1     **A Bill for an Act to amend the *Patents Act 1990* to**  
2     **prevent the patenting of human genes and**  
3     **biological materials existing in nature, and for**  
4     **related purposes**

5     The Parliament of Australia enacts:

6     **1 Short title**

7                     This Act may be cited as the *Patent Amendment (Human Genes*  
8                     *and Biological Materials) Act 2010*.

9     **2 Commencement**

10                    This Act commences on the day after it receives the Royal Assent.

1 **3 Schedule(s)**

2 Each Act that is specified in a Schedule to this Act is amended or  
3 repealed as set out in the applicable items in the Schedule  
4 concerned, and any other item in a Schedule to this Act has effect  
5 according to its terms.

1 **Schedule 1—Amendment of the Patents Act**  
2 **1990**

3 **1 Paragraph 18(1)(a)**

4 Repeal the paragraph, substitute:

- 5 (a) is a manner of manufacture within the full meaning,  
6 including the proviso, of section 6 of the Statute of  
7 Monopolies; and

8 **2 Paragraph 18(1A)(a)**

9 Repeal the paragraph, substitute:

- 10 (a) is a manner of manufacture within the full meaning,  
11 including the proviso, of section 6 of the Statute of  
12 Monopolies; and

13 **3 Subsection 18(2)**

14 Repeal the subsection, substitute:

- 15 (2) The following are not patentable inventions:  
16 (a) human beings, and the biological processes for their  
17 generation; and  
18 (b) biological materials including their components and  
19 derivatives, whether isolated or purified or not and however  
20 made, which are identical or substantially identical to such  
21 materials as they exist in nature.

22 **4 After subsection 18(4)**

23 Insert:

- 24 (5) In this section:  
25 *biological materials*, in section 18, includes DNA, RNA, proteins,  
26 cells and fluids.

2010-2011

The Parliament of the  
Commonwealth of Australia

HOUSE OF REPRESENTATIVES

**Patent Amendment (Human Genes and  
Biological Materials) Bill 2010**

**No. , 2010**

*(Mr Dutton, Mr Oakeshott, Mr Forrest and Mr Turnbull)*

**A Bill for an Act to amend the *Patents Act 1990* to  
prevent the patenting of human genes and  
biological materials existing in nature, and for  
related purposes**

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## Schedule 1—Amendment of the Patents Act 1990

### 1 Paragraph 18(1)(a)

Repeal the paragraph, substitute:

- (a) is a manner of manufacture within the full meaning, including the proviso, of section 6 of the Statute of Monopolies; and

### 2 Paragraph 18(1A)(a)

Repeal the paragraph, substitute:

- (a) is a manner of manufacture within the full meaning, including the proviso, of section 6 of the Statute of Monopolies; and

### 3 Subsection 18(2)

Repeal the subsection, substitute:

- (2) The following are not patentable inventions:
  - (a) human beings, and the biological processes for their generation; and
  - (b) biological materials including their components and derivatives, whether isolated or purified or not and however made, which are identical or substantially identical to such materials as they exist in nature.

### 4 After subsection 18(4)

Insert:

- (5) In this section:

*biological materials* includes DNA, RNA, proteins, cells and fluids.

The Senate

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Legal and Constitutional Affairs  
Legislation Committee

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Patent Amendment (Human Genes and  
Biological Materials) Bill 2010

September 2011

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## MEMBERS OF THE COMMITTEE

### Members

Senator Patricia Crossin, **Chair**, ALP, NT

Senator Gary Humphries, **Deputy Chair**, LP, ACT (from 5 July 2011)

Senator Guy Barnett, **Deputy Chair**, LP, TAS (to 30 June 2011)

Senator Sue Boyce, LP, QLD (from 1 July 2011)

Senator Mark Furner, ALP, QLD

Senator Scott Ludlam, AG, WA (to 5 July 2011)

Senator Stephen Parry, LP, TAS (to 30 June 2011)

Senator Louise Pratt, ALP, WA

Senator Penny Wright, AG, SA (from 5 July 2011)

### Substitute Member

Senator Rachel Siewert, AG, WA, replaced Senator Scott Ludlam, AG, WA (to 5 July 2011) and Senator Penny Wright, AG, SA (from 5 July 2011) for the inquiry into the Patent Amendment (Human Genes and Biological Materials) Bill 2010

### Participating Members

Senator Sue Boyce, LP, QLD (to 30 June 2011)

Senator Helen Coonan, LP, NSW (to 22 August 2011)

Senator Bill Heffernan, LP, NSW

Senator Gary Humphries, LP, ACT (to 5 July 2011)

Senator Russell Trood, LP, QLD (to 30 June 2011)

Senator Nick Xenophon, IND, SA

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## ABBREVIATIONS

ACIP	Advisory Council on Intellectual Property
ACIP Report	Advisory Council on Intellectual Property, <i>Patentable Subject Matter</i> , Final Report, December 2010
ALRC	Australian Law Reform Commission
ALRC Report	Australian Law Reform Commission, <i>Genes and Ingenuity: Gene Patenting and Human Health</i> , Report 99, June 2004
AUSFTA	Australia-United States Free Trade Agreement
CCA/COSA	Cancer Council Australia/Clinical Oncological Society
DIISR	Department of Innovation, Industry, Science and Research
EM	Explanatory Memorandum
GM	genetically modified
GMIA	Generic Medicines Industry Association
IPTA	Institute of Patent and Trade Mark Attorneys
NHMRC	National Health and Medical Research Council
NRDC case	<i>National Research Development Corporation v Commissioner of Patents (1959) 102 CLR 252</i>
Patents Act	<i>Patents Act 1990</i>
Raising the Bar Bill	Intellectual Property Laws Amendment (Raising the Bar) Bill 2011
TRIPS Agreement	Agreement on Trade-Related Aspects of Intellectual Property Rights
USPTO	United States Patent and Trademark Office
WEHI	Walter and Eliza Hall Institute of Medical Research

## **RECOMMENDATIONS**

### **Recommendation 1**

**5.27 The committee recommends that the Senate should not pass the Bill.**

# CHAPTER 1

## INTRODUCTION

### Background

1.1 On 26 November 2010, the Senate referred the Patent Amendment (Human Genes and Biological Materials) Bill 2010 (Bill) to the Senate Legal and Constitutional Affairs Legislation Committee (committee) for inquiry and report by 16 June 2011. On 15 June 2011, the Senate granted an extension of time for reporting until 25 August 2011. On 23 August 2011, the granted another extension of time for reporting to 21 September 2011. The Bill was introduced into the Senate on 24 November 2010 by Senators Coonan, Heffernan, Siewert and Xenophon.<sup>1</sup> The purpose of the Bill is to amend the *Patents Act 1990* (Patents Act) to prevent the patenting of human genes and biological materials existing in nature.

1.2 The introduction of the Bill into the Senate followed a lengthy inquiry into the impact of gene patents by the Senate Community Affairs References Committee, which tabled its report, *Gene Patents*, on 26 November 2010. That report included a recommendation that the Senate refer the Bill 'to the relevant Senate committee for inquiry and report'.<sup>2</sup>

### Conduct of the inquiry

1.3 The committee advertised the inquiry in *The Australian* newspaper, and details of the inquiry, the Bill and associated documents were placed on the committee's website. The committee also wrote to a number of organisations and individuals, inviting submissions by 25 February 2011.

1.4 The committee received 122 submissions, which are listed at Appendix 1. Public submissions were published on the committee's website.

1.5 The committee held two public hearings for the inquiry, which took place on 28 and 29 April 2011 at Parliament House in Canberra. A list of witnesses who appeared at the hearing is at Appendix 2, and copies of the *Hansard* transcript are available online at <http://www.aph.gov.au/hansard>.

---

1 A private members' Bill with the same title and similar provisions as the Bill before the committee was introduced into the House of Representatives on 21 February 2011, sponsored by the Hon Peter Dutton MP, the Hon Malcolm Turnbull MP, Mr John Forrest MP and Mr Rob Oakeshott MP.

2 Senate Community Affairs References Committee, *Gene Patents*, November 2010, Recommendation 3.

## **Acknowledgement**

1.6 The committee thanks those organisations and individuals who made submissions and gave evidence at the public hearings.

## **Scope of the report**

1.7 The structure of this report is as follows:

- Chapter 2 provides a brief background to the introduction of the Bill;
- Chapter 3 outlines the key provisions of the Bill;
- Chapter 4 discusses the key issues raised in submissions and evidence; and
- Chapter 5 provides the committee's conclusions and recommendations.

## **Note on references**

1.8 References in this report are to individual submissions as received by the committee, not to a bound volume. References to the committee *Hansard* are to the proof *Hansard*. Page numbers may vary between the proof and the official *Hansard* transcript.

## **Terminology**

1.9 The committee notes that patent law, genetic science and health research are areas which rely on specific and technical vocabularies. The committee's report seeks to avoid unnecessary use of technical terms wherever possible.

## CHAPTER 2

### BACKGROUND

#### Australia's patent system

2.1 In Australia, the patent system is governed by the Patents Act. Patents are granted by a statutory officer, the Commissioner of Patents, and IP Australia is the government agency with responsibility for administering the patent system. A patent is a private property right granted by the Crown to the inventor of a product, method or process in a field of technology. A patent grants exclusive rights to the patent holder, allowing them to prevent others from exploiting the invention without a licence and to maximise the commercial potential of the invention.

2.2 Most granted patents are standard patents which offer a period of patent protection to inventions for 20 years. Innovation patents, which were introduced in 2001, offer protection to inventions which do not meet the inventive threshold required for standard patents and, correspondingly, have a more limited period of protection (eight years).

2.3 The patent system seeks to encourage the availability of new and useful technologies to society through the incentive of a monopoly to commercially exploit an invention for a given period. The patent system also promotes innovation through encouraging the diffusion of knowledge, as it is a condition of the grant of a patent that the inventor publicly discloses details of their invention.<sup>1</sup>

2.4 The Patents Act contains a number of requirements for the patentability of an invention. In particular, an invention will be patentable if:

- it is a 'manner of manufacture';
- it is novel and involves an inventive step (as judged against previous knowledge and practice, also known as the 'prior art');
- it is useful;
- the details of the invention are sufficiently well disclosed or described; and
- it is not the subject of one of the specific exclusions.<sup>2</sup>

2.5 The 'manner of manufacture' requirement and the specific exclusions are of particular relevance to the Bill.

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1 Senate Community Affairs References Committee, *Gene Patents*, November 2010, pp 8-19.

2 *Patents Act 1990*, sections 18 and 40. The requirements outlined here are not exhaustive and focus on aspects of patent law most relevant to the Bill.

---

### ***Manner of manufacture and specific exclusions***

2.6 The Patents Act requires a patentable invention to be a 'manner of manufacture within the meaning of section 6 of the Statute of Monopolies'.<sup>3</sup> The English Statute of Monopolies of 1623 is the historical predecessor of Australian patent law, including the current Patents Act. The original purpose of the Statute was to abolish monopolies which had been granted by the Crown on trades and industries. However, section 6 of the Statute made an exception for new inventions. Section 6 provided for a term of exclusive exploitation rights 'to the true and first inventor' who introduced 'any manner of new manufacture' to the jurisdiction, provided it met certain conditions.<sup>4</sup> As the Explanatory Memorandum (EM) to the current Bill notes:

Section 6 of the Statute of Monopolies, being one of the express exceptions, provided that 'manners of new manufacture' could be the subject of 'Letters Patent and Grants of Privilege' provided they were 'not contrary to the Law, nor mischievous to the State, by raising Prices of Commodities at home, or Hurt of Trade, or generally inconvenient'.<sup>5</sup>

2.7 The basis of the current legal conception of the term 'manner of manufacture' was established by the High Court of Australia in the case of *National Research Development Corporation v The Commissioner of Patents* (NRDC case).<sup>6</sup> In that case, the court endorsed a more expansive definition of 'manner of manufacture', whereby patentability is determined by reference to the policy intent of the Patents Act rather than by application of a strict definition. The Court stated:

The right question is: "Is this a proper subject of letters patent according to the principles which have been developed for the application of s. 6 of the Statute of Monopolies?"<sup>7</sup>

2.8 An invention will meet this requirement if it is an 'artificially created state of affairs' which belongs to the 'useful arts' rather than 'fine arts', and it must provide a material advantage in a field of economic endeavour. Judicial interpretation has also recognised a number of categories of subject matter that fail to satisfy the requirement. These include mere discoveries, ideas, scientific theories and laws of nature.<sup>8</sup>

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3 *Patents Act 1990*, paragraph 18(1)(a).

4 William van Caenegem, *Intellectual and Industrial Property in Australia*, 2009, p. 155.

5 EM, p. 2.

6 (1959) 102 CLR 252.

7 *National Research Development Corporation v Commissioner of Patents* (1959) 102 CLR 252 at 269.

8 Australian Law Reform Commission, *Genes and Ingenuity: Gene Patenting and Human Health*, Report 99, June 2004, p. 118.

2.9 The Patents Act also provides that 'human beings, and the biological processes for their generation, are not patentable inventions'.<sup>9</sup> For the purposes of an innovation patent, another exception to patentability exists for plants and animals, and the biological processes for the generation of plants and animals (but this does not apply if the invention is a microbiological process or a product of such a process).<sup>10</sup>

2.10 Judicial and academic commentary indicates that the absence of further express statutory exclusions in the Patents Act has been influential in the willingness of courts to accept a broad range of subject matter as a 'manner of manufacture'.<sup>11</sup> The mainstream view has been that the NRDC case, and the lack of other express exclusions on patentability in the Patents Act, have had an expansive effect on the limits of patentable subject-matter in Australia:

The lack of express statutory exceptions combined with the breadth of the NRDC judgment has enabled courts to remove the fetters that may otherwise prevent new developments from being patentable. The result has been a piecemeal erosion of formerly perceived classes of excluded subject matter. NRDC itself rejected the former exclusion of patents for horticultural and agricultural methods. Subsequent decisions declared patents valid for computer programs and methods of medical treatment for humans with the result that a number of formerly excluded classes of subject matter are now regarded as patentable. Patents are granted for computer programs, computer implemented systems used in business, living plants, animals, genetic materials and recombinant DNA techniques.<sup>12</sup>

### ***Generally inconvenient***

2.11 The Statute of Monopolies provides that a patent may not be granted on the grounds that a new manner of manufacture is 'contrary to law' or otherwise 'generally inconvenient'. However, under Australian law it is currently unclear whether inventions can be excluded from patenting on public policy grounds, such as for being 'generally inconvenient'.<sup>13</sup>

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9 This exclusion was an amendment moved by Senator Brian Harradine when the Patents Act was passed. Senator Brian Harradine, *Senate Hansard*, 20 September 1990, p. 2654.

10 *Patents Act 1990*, subsections 18(2), (3) and (4).

11 Senate Community Affairs References Committee, *Gene Patents*, November 2010, pp 12-13.

12 Mark Davison, Anne Monotti and Leanne Wiseman, *Australian Intellectual Property Law*, 2008, p. 410.

13 Senate Community Affairs References Committee, *Gene Patents*, November 2010, p. 14; Advisory Council on Intellectual Property, *Patentable Subject Matter*, Final Report, December 2010, p.11.

***Limitations on granted patents***

2.12 Under the Patents Act, the grant of a patent by the Commissioner of Patents does not guarantee or necessarily imply that the patent is legally valid. There are four opportunities for the validity of a patent to be tested under the Patents Act:

- each application is examined by IP Australia before it may be accepted or refused (examination);
- each accepted application may be opposed before grant by any party, including the Minister (opposition);
- applications may be re-examined before grant at the discretion of the Commissioner of Patents, and a patent must be re-examined after grant on request from any person in an approved form, including the Minister (re-examination); and
- post-grant, the validity of a granted patent can be challenged in the courts by any party, including the Minister (revocation).<sup>14</sup>

2.13 In practice, the grant of a patent does not give an absolute right to exploit an invention in any way the inventor chooses. A patent holder may still need to satisfy regulatory or legal requirements in order to exploit a patented product or process.

2.14 The Patents Act also contains certain safeguards which allow patent rights to be altered in some circumstances. For example, the Crown Use provisions of the Patent Act (sections 163-170) permit certain government entities to use, and to authorise others to use, patented inventions without the permission of the patent owner in certain circumstances. Such use is only permissible where the use is for the proper provision of services of the Commonwealth, or of a state, or a territory. The relevant government must give the patent owner remuneration for the use of their patent.<sup>15</sup>

2.15 The compulsory licensing provisions of the Patents Act (sections 133-140) provide that a compulsory licence can be sought where the patent holder fails to meet the reasonable requirements of the public. These provisions set out the circumstances where, for the purposes of granting a compulsory licence, the reasonable requirements of the public with respect to a patented invention are taken not to have been satisfied.<sup>16</sup>

2.16 These circumstances include where an existing trade or industry in Australia, or the establishment of a new trade or industry, is unfairly prejudiced, or the demand in Australia for the patented product, or for a product resulting from the patented process, is not reasonably met because of the patentee's failure to:

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14 Senate Community Affairs References Committee, *Gene Patents*, November 2010, p. 15.

15 Senate Community Affairs References Committee, *Gene Patents*, November 2010, p. 120.

16 Senate Community Affairs References Committee, *Gene Patents*, November 2010, p. 122.

- manufacture the patented product to an adequate extent and supply it on reasonable terms; or
- grant licences on reasonable terms.<sup>17</sup>

### *International treaties*

2.17 Australia is party to a number of multilateral and bilateral treaties which relate to the patent system, reflecting efforts to harmonise international intellectual property rules. Further details of two of these treaties, the Agreement on Trade-Related Aspects of Intellectual Property Rights and the Australia-United States Free Trade Agreement, are outlined below.

#### *Agreement on Trade-Related Aspects of Intellectual Property Rights 1994*

2.18 The Agreement on Trade-Related Aspects of Intellectual Property Rights 1994 (TRIPS Agreement) established, among other things, the minimum standard of patent protection that each member of the World Trade Organisation (WTO) must provide under its national laws. In particular, Article 27(1) of the TRIPS Agreement requires member countries, such as Australia, to make patents available to all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application.

2.19 Article 27(2) provides exceptions for the patentability of inventions 'the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment'. Article 27(3) provides that members may also exclude from patentability 'diagnostic, therapeutic and surgical methods for the treatment of humans and animals', as well as 'plants and animals other than micro-organisms'.

#### *Australia-United States Free Trade Agreement*

2.20 The Australia-United States Free Trade Agreement (AUSFTA) entered into force on 18 May 2004 and contains a number of provisions relating to the patent system. According to Article 17.9 of the AUSFTA:

1. Each Party shall make patents available for any invention, whether product or process, in all fields of technology, provided that the invention is new, involves an inventive step, and is capable of industrial application. The Parties confirm that patents shall be available for any uses or methods of using a known product.
2. Each Party may only exclude from patentability:
  - (a) inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal, or plant life or health or to avoid

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17 *Patents Act 1990*, section 135.

serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by law; and

(b) diagnostic, therapeutic, and surgical methods for the treatment of humans and animals.

## **BRCA gene patents**

2.21 The Senate Community Affairs References Committee gene patents inquiry was initiated in response to concerns arising from attempts in 2002-03 and 2008 by Genetic Technologies Ltd (Genetic Technologies), a genetic testing company, to enforce its patent rights over the BRCA1 and BRCA2 genes (BRCA gene patents) in Australia. The BRCA gene patents relate to methods and materials used to isolate and detect mutations in two genes which may indicate a predisposition to certain cancers, particularly ovarian and breast cancer. Myriad Genetics Ltd (Myriad), a company based in the United States, granted Genetic Technologies exclusive rights to BRCA gene testing in Australia.

2.22 In 2002-03 and 2008, Genetic Technologies sent 'cease and desist' letters to public laboratories, research bodies and other entities seeking to prevent these organisations from engaging in any further testing for the BRCA genes. However, in both cases, Genetic Technologies ultimately dropped legal demands in relation to testing for the BRCA genes. In a report to shareholders on 9 July 2003, Genetics Technologies stated that it was not seeking to enforce its rights over the genes and stated that the BRCA genes 'are our gift to the Australian people'.<sup>18</sup> Similarly, following its attempt to enforce its patent rights in 2008, Genetic Technologies announced that it had reviewed its decision and 'resolved to immediately revert to its original decision to allow other laboratories in Australia to freely perform BRCA testing'.<sup>19</sup>

2.23 The Senate Community Affairs References Committee indicated that its understanding was that, in relation to the 2008 demands, state health departments had negotiated with Genetic Technologies following the issuing of the 'cease and desist' letters.<sup>20</sup> A number of reasons were suggested for Genetic Technologies' change of position in relation to the BRCA patents. These included: public and professional criticism of the decision to enforce the patents; the previous purported 'gift' of the BRCA genes to the Australian people would have created difficulties for enforcement; negotiations with state health departments may have indicated that the demands or the patents could be legally contested; and the Australian Competition and Consumer Commission was considering, or had instituted an investigation into, whether enforcement of the BRCA gene patents raised issues of anti-competitive behaviour.<sup>21</sup>

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18 Genetic Technologies Ltd, 'A report to shareholders', 9 July 2003, p. 1.

19 Genetic Technologies Ltd, 'New position re BRCA testing', 2 December 2008, p. 1.

20 Senate Community Affairs References Committee, *Gene Patents*, November 2010, pp 6-7.

21 Senate Community Affairs References Committee, *Gene Patents*, November 2010, pp 6-7.

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## Public reviews

2.24 The introduction of the Bill follows a number of public inquiries and reviews of the law relating to gene patents and their potential impacts.

### *Australian Law Reform Commission – Genes and Ingenuity (ALRC Report)*

2.25 On 29 June 2004, the ALRC presented its extensive report on gene patenting and human health, which included 50 recommendations. While outlining a number of its concerns relating to gene patents, the ALRC concluded that inventions involving genetic materials and technologies should be assessed according to the same legislative criteria as other inventions:

In the ALRC's view, concerns about the patenting of inventions involving genetic materials and technologies should not be addressed by the introduction of legislative requirements that would relate only to the patentability of this type of invention. Such an approach may set an undesirable precedent for the way in which the patent system should accommodate new technologies in the future. The current requirements for patentability are technology-neutral and are able to adapt to new technologies as they arise. Introducing specific rules for inventions involving genetic materials and technologies may suggest that special requirements for patentability should be implemented for future technologies that raise a different set of issues. Such an approach would unnecessarily fragment and complicate Australian patent law.<sup>22</sup>

### *Senate Community Affairs References Committee – Gene Patents*

2.26 The Senate Community Affairs References Committee's report made 16 recommendations regarding gene patents, genetic testing and the patent system. Several of these recommendations supported or restated the recommendations in the ALRC Report. However, the Senate Community Affairs References Committee determined that 'it would not recommend at this stage the *Patents Act 1990* be amended to include an express prohibition on human genes and genetic products'. It concluded that 'there would need to be a very clear case and significant social and political consensus on the need for such a change' as the 'evidence to the inquiry shows there are legitimate and sometimes finely balanced arguments on both sides of the debate'.<sup>23</sup> The committee's decision not to recommend an express prohibition on gene patents was based on recent international and national legal developments relating to the patentability of genes, and the announcement of the current Bill 'which contains an express prohibition in specific terms'.<sup>24</sup>

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22 ALRC, *Genes and Ingenuity: Gene Patenting and Human Health*, Report 99, June 2004, p. 119.

23 Senate Community Affairs References Committee, *Gene Patents*, November 2010, pp 99-100.

24 Senate Community Affairs References Committee, *Gene Patents*, November 2010, p. 100.

2.27 The Senate Community Affairs References Committee stated:

While the Committee would support an amendment to the Act to ensure that isolated genetic materials are not classed as an invention and therefore patentable, the Committee acknowledges that there are many issues which require further investigation in relation to the Bill, such as the likely impacts, effectiveness and scope of an express prohibition relating to 'biological materials' as is proposed...The Committee believes that the introduction of the Bill to the Senate will provide a further, and much-needed, opportunity for the arguments and questions around the impacts and effectiveness of an express prohibition on gene patents to be considered.<sup>25</sup>

2.28 In its comments, the Senate Community Affairs References Committee also noted 'the strong consensus among opponents of an express prohibition on gene patents that the concerns which formed the basis of the Committee's inquiry can be more effectively addressed through a range of responses directed not at gene patents per se but at improving the operation of the patent system more generally'.<sup>26</sup>

***Advisory Council of Intellectual Property – Review of Patentable Subject Matter (ACIP Report)***

2.29 The Advisory Council on Intellectual Property (ACIP) is an independent body appointed by the Australian Government. ACIP advises the Minister for Innovation, Industry, Science and Research on intellectual property matters and the strategic administration of IP Australia. Adopting one of the recommendations made in the ALRC Report, the Minister, Senator the Hon Kim Carr, requested that ACIP conduct a review of patentable subject matter. The review included the appropriateness and adequacy of the 'manner of manufacture' test as the threshold requirement for patentable subject matter under Australian law, and the historical requirement that an invention must not be 'generally inconvenient'. Following wide consultation, ACIP provided its final report on the review of patentable subject matter (ACIP Report) to the Minister in December 2010 and the final report was publicly released on 6 February 2011.<sup>27</sup>

2.30 The ACIP Report made 11 recommendations, including several recommendations for amendments to the Patents Act, namely:

- a recommendation to define patentable subject matter 'using clear and contemporary language' that embodies the principles of inherent patentability as developed in the case law of Australian courts;

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25 Senate Community Affairs References Committee, *Gene Patents*, November 2010, pp 100-101.

26 Senate Community Affairs References Committee, *Gene Patents*, November 2010, p. 100.

27 ACIP, *Patentable Subject Matter – Options Paper*, September 2009; ACIP, *Patentable Subject Matter*, Final Report, December 2010.

- a recommendation that the specific exclusions which currently exist in the Patents Act should be maintained, but other specific exclusions, including 'to prevent the patenting of human genes and genetic products' should not be introduced; and
- a recommendation that a general exclusion on ethical grounds should be added to the Patents Act, as permitted under Australia's international obligations, 'to exclude from patentability an invention the commercial exploitation of which would be wholly offensive to the ordinary reasonable and fully informed member of the Australian public'.<sup>28</sup>

### ***IP Australia – public consultation and proposed legislation***

2.31 In 2009, IP Australia released several consultation papers, and sought submissions from interested parties, as part of a proposed broad package of intellectual property reforms.<sup>29</sup> On 3 March 2011, IP Australia released a public exposure draft of the Intellectual Property Laws Amendment (Raising the Bar) Bill 2011 (Raising the Bar Bill), and an associated explanatory memorandum, and sought submissions from interested stakeholders. On 22 June 2011, the Raising the Bar Bill was introduced into the Senate.<sup>30</sup>

2.32 As currently drafted, the Raising the Bar Bill will amend a number of pieces of intellectual property legislation including the Patents Act. The amendments to the Patents Act incorporate changes intended to raise the quality of granted patents, and allow free access to patented inventions for research and regulatory activities. In particular, the Raising the Bar Bill will:

- amend the Patents Act to remove restrictions on the information and background knowledge taken into account when assessing whether an application is sufficiently inventive to justify a patent;
- strengthen the requirements that a patented invention be useful: that is, that the invention works in the way that the patent says it does and that the specification explains how the invention works;
- raise the standards set for disclosure of an invention, to ensure that granted patents are no broader than the invention which has been disclosed;
- increase certainty in the validity of granted patents by expanding the grounds which the Commissioner of Patents can consider; and applying a consistent

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28 ACIP, *Patentable Subject Matter*, Final Report, December 2010, pp 2-20.

29 For example, see IP Australia, *Getting the Balance Right*, Consultation Paper, March 2009; IP Australia, *Exemptions to Patent Infringement*, Consultation Paper, March 2009; IP Australia, *Towards a Stronger and More Efficient IP Rights System*, Consultation Paper, November 2009.

30 *Journals of the Senate*, 22 June 2011, p. 1068.

standard of proof across all grounds, so that the Commissioner is not obliged to grant patents which would not pass scrutiny in a court challenge.<sup>31</sup>

2.33 In relation to access to patented inventions for research and regulatory activities, the Raising the Bar Bill will amend the Patents Act 'to draw a line between research and commercial activities, leaving researchers free to conduct their experiments without worrying about the patent system'. The amendments clarify that research and experimental activities relating to patented inventions are exempt from infringement, whereas commercial activities are not. The Raising the Bar Bill will also introduce an exemption for 'activities undertaken solely for the purpose of gaining regulatory approval to market or manufacture a patented technology'.<sup>32</sup>

### **Legal cases**

2.34 Legal cases in the United States and Australia regarding the patentability of genes and genetic material are also relevant in providing background and context to the current Bill.

#### ***United States***

2.35 On 29 March 2010, a legal challenge to the validity of the BRCA gene patents was decided in the US District Court for the Southern District of New York: *The Association of Molecular Pathology and Others v The United States Trademark Office and Myriad Genetics, Inc and Others* (Myriad case). Judge Robert Sweet found in favour of the parties challenging the US Patent and Trademark Office's (USPTO) approach to granting patents over genetic material. The court ruled that Myriad's patents claiming (a) isolated BRCA gene sequences, and (b) methods for comparing or analysing BRCA gene sequences to diagnose a predisposition for breast cancer, were invalid.<sup>33</sup>

2.36 As part of its inquiry, the Senate Community Affairs References Committee received advice from the USPTO that the decision in the Myriad case was not at that stage binding on the USPTO, and that its examination policy has not changed in response to the decision. Accordingly, the USPTO 'continues to issue patents directed to isolated genes, proteins and their derivatives that meet patentability requirements under the United States patents laws'. The USPTO advised in the event that a final decision is delivered on the case in a higher court, such as the US Court of Appeals for

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31 *Intellectual Property Law Amendment (Raising the Bar) Bill 2011, Explanatory Memorandum*, pp 8-9.

32 *Intellectual Property Law Amendment (Raising the Bar) Bill 2011, Explanatory Memorandum*, pp 9-10.

33 *The Association of Molecular Pathology and Others v The United States Trademark Office and Myriad Genetics, Inc and Others*, 09 Civ. 4515, S.D.N.Y, 29 March 2010, 4, available at <http://www.genomicslawreport.com/wp-content/uploads/2010/03/Myriad-SJ-Opinion.pdf>, accessed 2 August 2011.

the Federal Circuit or the US Supreme Court, it would 'conform its policy to that decision'.<sup>34</sup>

2.37 Following the decision, Myriad Genetics appealed to the Court of Appeals of the Federal Circuit. On 29 October 2010, the United States Department of Justice filed an *amicus curiae* brief<sup>35</sup> with the court which outlined disagreement with some of the positions taken in Judge Sweet's decision, and agreement with others. In particular, the brief agreed that genomic DNA that is simply isolated should not be patentable:

The boundary between eligible and non-eligible subject matter is defined, in significant part, by the settled principle that the patent laws do not embrace laws of nature, physical phenomena, or abstract ideas...In attempting to apply that principle here, the district court erroneously cast doubt on the patent-eligibility of a broad range of manmade compositions of matter whose value derives from the information encoding capacity of DNA. Such compositions - e.g., cDNAs [complementary DNA], vectors, recombinant plasmids, and chimeric proteins, as well as countless industrial products, such as vaccines and genetically modified crops created with the aid of such molecules — are in every meaningful sense the fruits of human ingenuity and thus qualify as "human-made inventions" eligible for patent protection...The district court correctly held, however, that genomic DNA that has merely been isolated from the human body, without further alteration or manipulation, is not patent-eligible.<sup>36</sup>

2.38 On 29 July 2011, the Court of Appeals for the Federal Circuit overturned much of Judge Sweet's original decision. In particular, it reversed by 2-1 Judge Sweet's finding 'that Myriad's composition claims to "isolated" DNA molecules cover patent-ineligible products of nature under [US patent law] since the molecules as claimed do not exist in nature'.<sup>37</sup> The plaintiffs have indicated they will consider requesting the entire appellate court rehear the gene patenting aspects of the case or appealing the decision to the United States Supreme Court.<sup>38</sup>

### ***Australia***

2.39 On 8 June 2010, Maurice Blackburn Lawyers, representing Cancer Voices Australia and Ms Yvonne D'Arcy, commenced proceedings in the Federal Court of

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34 Senate Community Affairs References Committee, *Gene Patents*, November 2010, p. 74.

35 An *amicus curiae*, or 'friend of the court', is a person not a party to a case who volunteers information to assist a court in deciding a matter before it.

36 United States Department of Justice, *Brief for the United States as amicus curiae in support of neither party*, 29 October 2010, pp 9-11.

37 *The Association of Molecular Pathology and Others v The United States Trademark Office and Myriad Genetics, Inc and Others*, 2010-1406, 29 July 2011, 8, available at <http://www.ca9.uscourts.gov/images/stories/opinions-orders/10-1406.pdf>, accessed 2 August 2011.

38 Andrew Pollack, 'Ruling Upholds Gene Patent in Cancer Test', *New York Times*, 30 July 2011, p. B1.

Australia, seeking to invalidate the BRCA patents in Australia. Court dates for hearings are provisionally set for 20 February 2012 onwards.<sup>39</sup>

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39 *Cancer Voices Australia & Anor v Myriad Genetics Inc & Ors*, Federal Court of Australia, NSD643/2010, available at <http://www.comcourts.gov.au/file/Federal/P/NSD643/2010/actions>, accessed 8 June 2011.

## CHAPTER 3

### OVERVIEW OF THE BILL

#### Key provisions of the Bill

3.1 The key provisions of the Bill amend the Patents Act.<sup>1</sup> In particular, the Bill amends section 18 which sets out the substantive requirements of a valid patentable invention for the purposes of a standard patent and innovation patent. Items 1 and 2 amend the 'manner of manufacture' test of patentability. Item 3 adds a new specific exclusion to patentability for 'biological materials', and Item 4 adds a new definition related to that exclusion.

3.2 The EM states that the Bill '(a) reinforces the applicability of the proviso in section 6 of the Statute of Monopolies within the meaning of section 18(1)(a) and section 18(1A)(a), (b) reinforces the applicability of the distinction between discovery and invention and (c) applies that distinction by expressly excluding from patentability, biological materials which are identical or substantially identical to such materials as they exist in nature, however made'.<sup>2</sup>

3.3 Item 1 of Schedule 1 of the Bill repeals existing paragraph 18(1)(a) of the Patents Act and substitutes '(a) is a manner of manufacture within the full meaning, including the proviso, of section 6 of the Statute of Monopolies; and'. In effect, this inserts the phrase 'within the full meaning, including the proviso' into the requirements of a patentable invention for the purposes of a standard patent.

3.4 Item 2 of Schedule 1 repeats this amendment of the requirements of a patentable invention for the purposes of an innovation patent. It repeals existing paragraph 18(1A)(a) and again substitutes 'a manner of manufacture within the full meaning, including the proviso, of section 6 of the Statute of Monopolies; and'.

3.5 Item 3 of Schedule 1 repeals subsection 18(2) and substitutes:

(2) The following are not patentable inventions:

(a) human beings, and the biological processes for their generation; and

(b) biological materials including their components and derivatives, whether isolated or purified or not and however made, which are identical or substantially identical to such materials as they exist in nature.

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1 Possible amendments to the Bill were also proposed during the inquiry. These are addressed in chapter 4.

2 EM, p. 2.

3.6 In effect, this adds new paragraph (b) to existing subsection 18(2) which currently provides that human beings, and the biological processes for their generation, are not patentable inventions.

3.7 Finally Item 4 of Schedule 1 inserts new subsection 18(5). It provides '**biological materials**, in section 18, includes DNA, RNA, proteins, cells and fluids' [bold in original]. The abbreviation DNA presumably refers to deoxyribonucleic acid and is currently used elsewhere in the Patents Act without further definition. The abbreviation RNA presumably refers to ribonucleic acid and is not currently used or defined in the Patents Act.

### *Amended section 18*

3.8 For convenience, the following extract indicates the proposed additions and deletions of the Bill's amendments to section 18 of the Patents Act. Underlined words are those added by the amendments in the Bill, while those words crossed out would be deleted.

### **Section 18 Patentable inventions**

#### *Patentable inventions for the purposes of a standard patent*

(1) Subject to subsection (2), an invention is a patentable invention for the purposes of a standard patent if the invention, so far as claimed in any claim:

(a) is a manner of manufacture within the full meaning, including the proviso, of section 6 of the Statute of Monopolies; and

(b) when compared with the prior art base as it existed before the priority date of that claim:

(i) is novel; and

(ii) involves an inventive step; and

(c) is useful; and

(d) was not secretly used in the patent area before the priority date of that claim by, or on behalf of, or with the authority of, the patentee or nominated person or the patentee's or nominated person's predecessor in title to the invention.

#### *Patentable inventions for the purposes of an innovation patent*

(1A) Subject to subsections (2) and (3), an invention is a patentable invention for the purposes of an innovation patent if the invention, so far as claimed in any claim:

(a) is a manner of manufacture within the full meaning, including the proviso, of section 6 of the Statute of Monopolies; and

(b) when compared with the prior art base as it existed before the priority date of that claim:

(i) is novel; and

(ii) involves an innovative step; and

(c) is useful; and

(d) was not secretly used in the patent area before the priority date of that claim by, or on behalf of, or with the authority of, the patentee or nominated person or the patentee's or nominated person's predecessor in title to the invention.

(2) The following are not patentable inventions:

(a) ~~H~~human beings, and the biological processes for their generation; and, are not patentable inventions.

(b) biological materials including their components and derivatives, whether isolated or purified or not and however made, which are identical or substantially identical to such materials as they exist in nature.

*Certain inventions not patentable inventions for the purposes of an innovation patent*

(3) For the purposes of an innovation patent, plants and animals, and the biological processes for the generation of plants and animals, are not patentable inventions.

(4) Subsection (3) does not apply if the invention is a microbiological process or a product of such a process.

(5) In this section:

biological materials, in section 18, includes DNA, RNA, proteins, cells and fluids.

# CHAPTER 4

## KEY ISSUES RAISED IN EVIDENCE

### Introduction

4.1 Key issues were raised in evidence in relation to a number of topics. These included:

- the drafting of the Bill;
- the efficacy of the Bill;
- the need for the Bill;
- the nature of discovery and invention;
- the impact of the Bill on healthcare;
- the impact of the Bill on investment;
- the impact of the Bill on research and development;
- the impact of the Bill on access to products;
- the impact of the Bill on access to knowledge;
- ethical issues related to the Bill;
- Australia's international obligations;
- support for the Raising the Bar Bill; and
- support for other policy approaches.

### Drafting of the Bill

4.2 A number of concerns were raised regarding the terminology used in the Bill. These concerns related to both the proposed amendments to current paragraphs 18(1)(a) and 18(1A)(a) as well as the proposed exclusion of 'biological materials' from patentability. In particular, several individuals and organisations noted that unclear or ambiguous provisions would result in uncertainty for patent applicants and investors in research, and could result in unnecessary and costly litigation.<sup>1</sup>

### *Title of the Bill*

4.3 Some submissions and witnesses considered that the title of the Bill does not accurately reflect the content of its provisions. For example Professor Dianne Nicol

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1 For example, Group of Eight, *Submission 28*, p. 2; AusBiotech, *Submission 97*, p. 5; Professor Douglas Hilton, Walter and Eliza Hall Institute of Medical Research, *Committee Hansard*, 28 April 2011, p. 4; Dr Brendan Shaw, Medicines Australia, *Committee Hansard*, 28 April 2011, p. 45.

was concerned that there is confusion about the Bill in the biotechnology sector, with some companies assuming it only applies to 'human genes'.<sup>2</sup> FB Rice & Co described the title of the Bill as 'misleading' as it implies that the Bill relates to 'human' biological material, while the proposed amendments in the Bill encompass biological material from any source.<sup>3</sup> Similarly, Griffith Hack and Griffith Hack Lawyers highlighted that '[d]espite the title of the Bill purporting to be for 'human genes and biological materials', nowhere within the Bill is there any limitation on the exclusion of patentability to biological materials derived from humans'.<sup>4</sup>

### ***Manner of manufacture***

4.4 Dr Luigi Palombi, the 'principal drafter of the Bill and Explanatory Memorandum',<sup>5</sup> outlined that the amendments to paragraph 18(1)(a) are intended to overturn 'two longstanding but, problematic' Full Federal Court of Australia decisions: *Anaesthetic Supplies Pty Ltd v Rescare Ltd* and *Bristol-Myers Squibb Co v F H Faulding & Co Ltd*.<sup>6</sup> Dr Palombi argued:

In so doing the Bill restores the original intent of the *Patents Act, 1990*, and one that goes to the heart of Australian patent law, by preventing the grant of patents over subject matter which would be "contrary to the Law, nor mischievous to the State, by raising Prices of Commodities at home, or Hurt of Trade, or generally inconvenient". This aspect of the Bill is designed to re-impose on the courts an obligation to inquire into the suitability, for the grant of a patent monopoly, subject matter that may be illegal, immoral, disreputable or otherwise injurious to Australian society or the economy and reinstate their power to strike these down *ab initio*, as if they had never existed.<sup>7</sup>

4.5 However, other submissions did not agree that this effect is clear in the proposed amendment. ResMed considered the amendment which inserts the phrase 'including the proviso' may reflect 'a concern that the "generally inconvenient" proviso is not currently law'. However in its opinion, while there may be doubt over how the 'generally inconvenient' proviso may operate, it is clear that it does in fact operate.<sup>8</sup>

4.6 Professor Natalie Stoianoff, Dr Ann Kurts and Dr Mark Lutherborrow considered the amendment to modify reference to the Statute of Monopolies in

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2 *Committee Hansard*, 28 April 2011, p. 57.

3 *Submission 77*, p. 1.

4 *Submission 47*, p. 1 [underlining in original].

5 *Submission 103*, p. 1.

6 *Anaesthetic Supplies Pty Ltd v Rescare Ltd* [1994] FCA 1065 and *Bristol-Myers Squibb Co v F H Faulding & Co Ltd* (2000) FCR 524. These decisions relate to the patentability of human medical treatments.

7 *Submission 103*, p. 1.

8 *Submission 80*, p. 12.

section 18 of the Patents Act to be 'superfluous'.<sup>9</sup> Similarly, Professor Dianne Nicol, Mr Johnathon Liddicoat, Dr Jane Nielsen and Mr Ben Mee considered that the change would 'add nothing to the development or state of the law relating to 'manner of manufacture' and would not achieve any paradigm shift in the relevance of social and ethical dimensions to determinations of patentability'. In their view, it is clear from the case law that the proviso to section 6, including the question of whether the invention would be 'generally inconvenient', is already incorporated into the 'manner of manufacture' test.<sup>10</sup> Professor Nicol added 'if we want to have some sort of public policy or morality provision then it would be better to state that explicitly rather than reaffirming an old provision from way back in 1623'.<sup>11</sup>

4.7 La Trobe University questioned the clarity of the amendments to paragraphs 18(1)(a) and 18(1A)(a):

The introduction of the proviso of the Statute of Monopolies provides no clarity or certainty that the resultant interpretation will in fact be to exclude discoveries from patentability. Moreover, the Bill does not link the introduction of the proviso with the restriction of biological materials. The applicability of the proviso to the other branches of science and engineering is therefore uncertain and should be clarified. Discoveries and inventions are not restricted to the field of biology.

Unclear legislation should be avoided at all costs. In its current form, the Bill would result in uncertainty for patent applicants and investors in scientific research and ultimately cause unnecessary litigation.<sup>12</sup>

4.8 Davies Collison Cave could not perceive a difference between the current term 'within the meaning' and the Bill's proposed amendment 'within the full meaning'. It cautioned that the effect of the change 'will be to simply introduce an unnecessary ambiguity into the legislation'. Similarly to ResMed, Davies Collison Cave considered that it is not apparent what is meant by the proposed term 'including the proviso', arguing that the addition of the term 'including the proviso' to the current wording of section 18 of the Patents Act would also introduce unnecessary ambiguity.<sup>13</sup>

4.9 Dr Charles Lawson observed that it is '[p]erhaps surprising, [that] a law directed to high technology in 2011 reaches back nearly 400 years to 1623 to a concept of "manner of manufacture" as a way of drawing a distinction between what is, and what is not, patentable'. While he considered that the Patents Act should be subject to a thorough review (particularly in relation to competition policy), his view

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9 *Submission 18*, p. 4.

10 *Submission 39*, pp 32-33.

11 *Committee Hansard*, 28 April 2011, p. 61.

12 *Submission 41*, p. 3.

13 *Submission 17*, pp 6-7.

was that 'the formulation in section 6 of the Statute of Monopolies...is probably not appropriate to the modern Australian economy'.<sup>14</sup>

4.10 In their joint submission, the Department of Innovation, Industry, Science and Research (DIISR) and IP Australia highlighted that the recent Advisory Council on Intellectual Property (ACIP) report on the 'manner of manufacture' had recommended amending the Patents Act to codify the legal principles established by the NRDC case. DIISR and IP Australia considered that 'any recommendations for change to subject matter eligibility should follow from consideration of the ACIP recommendations'.<sup>15</sup>

4.11 The ACIP Report noted:

Over time, the focus of the 'generally inconvenient' proviso has changed. The courts have imbued it with different functions – sometimes ethical, sometimes economic. The Australian High Court has referred to 'general inconvenience' a number of times as a possible ground of invalidity, but has neither applied that proviso to revoke a patent nor extinguished the concept.<sup>16</sup>

4.12 The ACIP Report supported the removal of the 'general inconvenience' proviso in favour of a general exclusion 'so as to exclude from patentability an invention the commercial exploitation of which would be wholly offensive to the ordinary reasonable and fully informed member of the Australian public'.<sup>17</sup>

### ***Exclusion of biological materials***

4.13 A number of submitters and witnesses expressed their concerns regarding the undefined use of the terms 'derivatives', 'components' and 'substantially identical' in the proposed exclusion of biological materials. For example, Professor Dianne Nicol, Mr Johnathon Liddicoat, Dr Jane Nielsen and Mr Ben Mee stated:

There are terms in the Bill that are not defined. Depending on the way they are interpreted, they could have far-reaching or limited effect. It is not at all clear what is intended by the use of these terms, nor whether they will be interpreted in a way that corresponds with the original intention.<sup>18</sup>

4.14 Davies Collison Cave also argued that the proposed prohibition from patentability for 'biological materials' and the associated definition of 'biological materials' 'would introduce substantial and wide ranging uncertainty in the Patents Act 1990 arising principally from the scope and potential impact of these

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14 *Submission 1*, pp 1-2.

15 *Submission 94*, p. 17.

16 ACIP, *Patentable Subject Matter*, Final Report, December 2010, p. 11.

17 ACIP, *Patentable Subject Matter*, Final Report, December 2010, p. 18.

18 *Submission 39*, p. 7.

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proposed amendments, particularly in relation to the ambiguity, or lack of clarity which exists in relation to most of the terminology to be introduced'.<sup>19</sup>

4.15 The use of the term 'substantially identical' was viewed by some submitters and witnesses as particularly problematic.<sup>20</sup> Professor Natalie Stoianoff, Dr Ann Kurts and Dr Mark Lutherborrow argued:

...the term "substantially identical" is ambiguous. It is unclear as to what quantum or character a lack of identity with a naturally occurring substance would be required before a synthetic molecule would be considered patentable. The use of this language introduces further ambiguity rather than clarifying the definition of patentable subject matter.<sup>21</sup>

4.16 Professor Andrew Christie argued that the focus on identity 'runs the risk of precluding the potential for reward of a patent where it should be granted'. He noted that submitters to the inquiry had provided examples of biological materials 'which are changed but changed as little as possible to achieve the effect'. In these examples, inventions which meet the other requirements of patentability (novelty, inventiveness and utility) could be 'wrongly taken out of consideration for patentability' because they are substantially identical to material existing in nature.<sup>22</sup>

4.17 The National Health and Medical Research Council (NHMRC) was concerned about the proposed open definition for 'biological materials'. In particular, the NHMRC highlighted the lack of definition of 'substantially identical' which 'has the potential to obstruct and suppress innovation and translation of the outcomes of biomedical research into products and/or treatments to improve the health and wellbeing of Australians and people around the world'. As an example, the NHMRC noted a product of synthetic biology, while not a biological material, is modelled on biological material and would appear to be excluded under the Bill.<sup>23</sup> Similarly, the ALRC noted that it would be difficult to effectively define an exclusion relating to genetic materials. In relation to the formulation used in the Bill 'it is unclear...whether cDNA [complementary DNA] is "substantially identical" to genomic DNA'.<sup>24</sup>

4.18 However, Dr Luigi Palombi argued that the term 'substantially identical' is not new to intellectual property law, noting its extensive use in trade mark law. He stated that 'it is open for an Australian court to interpret the term "substantially identical" in the context of section 18(2)(b) by drawing a distinction between a naturally occurring

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19 *Submission 17*, pp 7-9.

20 For example, Institute of Patent and Trade Mark Attorneys, *Submission 49*, p. 7; Professor Ian Frazer, *Submission 92*, p.1; Professor Douglas Hilton, Walter and Eliza Hall Institute of Medical Research, *Committee Hansard*, 28 April 2011, p. 10.

21 *Submission 18*, p. 10.

22 *Committee Hansard*, 29 April 2011, pp 27-28.

23 *Submission 46*, p. 1.

24 *Submission 30*, p. 4.

biological material and one that has been modified so that it can no longer be said to be a product of nature but, instead, be a product of humankind'.<sup>25</sup> Further:

While it may be argued that absent a statutory definition of 'substantially identical' there is some uncertainty in how the Australian courts will interpret and apply section 18(2)(b), the counter to that argument is that there already exists a body of law, albeit foreign, which provides guidance on point...<sup>26</sup>

4.19 Dr Palombi also considered that the term 'substantially identical' is necessary as an 'anti-avoidance provision' in order to 'avoid the wordplay that patent attorneys constantly apply to these sorts of claims'.<sup>27</sup>

#### *Increased possibility of litigation*

4.20 Unclear provisions in the Bill were seen to potentially create uncertainty, which would discourage investment in research and encourage unnecessary litigation. For example, AusBiotech predicted 'a frenzy of legal activity' would be necessary to interpret the language of the Bill.<sup>28</sup> The Institute of Patent and Trade Mark Attorneys (IPTA) highlighted the risks that the unclear language in the Bill would have, meaning that the community would be reliant on the courts to define the Bill's boundaries. This could result in long and costly litigation:

It should also be remembered that when a biotechnology case is litigated, the clarification which it provides is limited to the scope of the issue which has been brought before the court...The community would be, therefore, reliant on the handing down of multiple decisions to bring clarity across the scope of the Bill. Whether or not this would occur is entirely dependent on the willingness of parties to both initiate and then follow through (i.e. not settle) their litigation. Realistically, this process is beyond anyone's control and would likely take decades to resolve, at enormous cost.<sup>29</sup>

4.21 Similarly, Professor Dianne Nicol, Mr Johnathon Liddicoat, Dr Jane Nielsen and Mr Ben Mee noted that these uncertainties in terminology could result in patents claiming innovations with respect to biological materials in Australia being subject to 'protracted and expensive litigation'.<sup>30</sup> Griffith Hack and Griffith Hack Lawyers suggested that if the Bill were implemented 'there will be many millions of dollars wasted on patent attorney and lawyers' fees debating the interpretation of the exclusion, money that would be better spent on research and commercialisation'.<sup>31</sup>

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25 *Submission 103*, p. 2.

26 *Submission 103*, p. 3.

27 *Committee Hansard*, 29 April 2011, p. 17.

28 *Submission 97*, p. 5.

29 *Submission 49*, p. 9 [underline in original].

30 *Submission 39*, p. 13.

31 *Submission 47*, p. 4.

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*Possible amendments to clarify meaning*

4.22 Possible amendments to the exclusion for biological materials were also suggested (and subsequently supported by Dr Luigi Palombi).<sup>32</sup> For example, the Cancer Council Australia and the Clinical Oncological Society of Australia (CCA/COSA) proposed that the exclusion on patentability in the Bill (Item 3) should be replaced with:

(b) biological materials whether isolated or purified or not and however made which are identical to such materials as they exist in nature.<sup>33</sup>

4.23 CCA/COSA considered that this would clarify the distinction between invention and discovery. The amendment would replace several terms considered problematic in other submissions, including 'substantially', 'components' and 'derivatives'.

4.24 Further, CCA/COSA recommended that the provision of the Bill which defines 'biological materials' (Item 4) should also be replaced to read:

(5) In this section:

**biological materials**, in section 18, includes DNA, RNA, proteins, cells and fluids including their components

**identical**, in section 18, means a biological material which is structurally and functionally identical and where any structural change or difference is immaterial to its function.

4.25 CCA/COSA considered that these suggested amendments to the Bill would add clarity, would ensure biological materials which have been structurally and functionally altered continue to be patentable, and 'should assure competitive researchers and investors that the patentability of biological materials adapted inventively for industrial use remains a commercial incentive'.<sup>34</sup>

4.26 At the public hearing on 28 April 2011, Senator Heffernan tabled a document with the committee which outlined similar proposed amendments to the Bill. Senator Heffernan's proposed amendments differ from the CCA/COSA amendments by proposing a more concise definition of 'identical':

**identical**, in section 18, means a biological material which is structurally and functionally identical.<sup>35</sup>

4.27 Some witnesses considered that the proposed amendments would address their concerns in relation to the scope of the Bill.<sup>36</sup> However, others did not consider

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32 *Submission 103, Supplementary Submission*, pp 5-6.

33 *Submission 72*, p. 2.

34 *Submission 72*, pp 2-3.

35 Amendment to the Bill tabled by Senator the Hon Bill Heffernan on 28 April 2011.

these amendments to the Bill would address their concerns.<sup>37</sup> For example, Professor Dianne Nicol and Mr Johnathon Liddicoat asserted that the amendment would not resolve the questions they raised regarding the Bill's lack of clarity, broad scope and potential for unintended consequences.<sup>38</sup>

### *Support for the Bill's approach*

4.28 However, Professor Peter Drahos did not consider the language of the Bill to be too broad. In relation to the term 'biological materials', he noted that other jurisdictions had also used general language in this area and '[t]o refer to some subset of biological materials...sets up a dangerous inference that other naturally occurring materials that have been isolated are patentable'. In relation to the term 'substantially identical', he noted that this concept is used in other areas of intellectual property law and the concept is important to prevent applicants introducing minor variations to defeat the purpose of the Bill.<sup>39</sup> In a similar vein, Ms Anna George considered the approach taken in the Bill to be 'simple, clear and unambiguous'.<sup>40</sup>

4.29 In contrast to many of those who expressed apprehensions about the breadth of biological materials covered by the language in the Bill, the National Coalition of Public Pathology was concerned that the inclusion of specific examples in the definition of 'biological materials' would limit the range of biological materials covered. Further, it considered that the list was not complete and may change over time in light of new knowledge and discoveries.<sup>41</sup>

### **Efficacy of the Bill**

4.30 Many submissions and witnesses expressed their concern that the drafting of the provisions of the Bill would not achieve the Bill's intent, as outlined in the EM. The EM states:

The purpose of this Bill is to advance medical and scientific research and the diagnosis, treatment and cure of human illness and disease by enabling doctors, clinicians and medical and scientific researchers to gain free and unfettered access to biological materials, however made, that are identical or substantially identical to such materials as they exist in nature.<sup>42</sup>

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36 For example, Dr Martin Cross, Generic Medicines Industry Association, *Committee Hansard*, 28 April 2011, p. 53.

37 For example, Dr Trevor Davies, Institute of Patent and Trade Mark Attorneys, *Committee Hansard*, 28 April 2011, p. 31; Mr Matthew Cossey, Croplife Australia, *Committee Hansard*, 29 April 2011, p. 12.

38 Answer to question on notice, provided 12 May 2011.

39 *Submission 25*, p. 2.

40 *Submission 55*, p. 6.

41 *Submission 33*, p. 2.

42 EM, p. 2.

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**Method claims**

4.31 Some submitters and witnesses noted that the Bill's exclusion on biological materials would not exclude from patentability therapeutic or diagnostic methods, even if these methods involve the use of biological material.<sup>43</sup> Professor Natalie Stoianoff, Dr Ann Kurts and Dr Mark Lutherborrow commented that both therapeutic and diagnostic methods are patentable under current Australian law. An exclusion from patenting the substance used would not prevent these methods or formulations from being patented.<sup>44</sup> Similarly, the Law Council of Australia considered the Bill 'misconceived' as 'the Bill would not affect the patentability of the diagnostic method which originally sparked the current debate: the Myriad BRAC1 and BRAC2 tests'.<sup>45</sup>

4.32 Dr Tania Obranovich from the Institute of Patent and Trade Mark Attorneys believed that, as diagnostic methods would remain patentable under the Bill, it 'would do very little to alleviate the very real concerns of the community' and could 'unintentionally create a range of new problems'.<sup>46</sup> Unintended consequences were also predicted by FB Rice & Co, should the Bill cause a shift from product claims to method claims in patent applications. It noted that the 'well known principle of the patent system is that product claims are easier to enforce than method claims'. If product claims for patented inventions are excluded by the Bill, 'patentees may have to spend more time and money to prove that their rights are being infringed'.<sup>47</sup>

4.33 Professor Dianne Nicol, Mr Johnathon Liddicoat, Dr Jane Nielsen and Mr Ben Mee also argued that the Bill was too narrow in this respect:

While the Bill seeks to exclude biological materials it does not exclude methods of using those materials. Hence, some of the most controversial aspects of patenting in the field of biotechnology are not fully addressed by this Bill, particularly methods of diagnostic testing and non-commercial research methods. The Bill also does not address problems created by broad downstream patent claims. Moreover, experience in Europe suggest[s] that specific exclusions of this nature tend to be worked around by creative drafting.<sup>48</sup>

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43 For example, see Institute of Patent and Trade Mark Attorneys, *Submission 49*, p. 8; CSIRO, *Submission 78*, pp 6-7.

44 *Submission 18*, p. 10.

45 *Submission 48*, p.2.

46 *Committee Hansard*, 28 April 2011, p. 30.

47 *Submission 77*, p. 5.

48 *Submission 39*, p. 3.

### ***Timing of legislative intervention***

4.34 During the inquiry, an argument was made that that the Bill may be too late to address the problems it seeks to solve.<sup>49</sup> This argument reflects the conclusion in the ALRC Report in 2004 that 'if there had been a time to recommend that gene patents should not be patentable, that time has long since passed'.<sup>50</sup> For example, La Trobe University suggested that, because of the completion of the Human Genome Sequencing Project in 2003, '[i]t is likely that the effect of the Bill would be to shut the gate after the horse has bolted, since the genes discovered by the project are already either patented or in the public domain and therefore not able to be patented'.<sup>51</sup> Similarly, the Law Council of Australia submitted:

...the argument now being mounted in respect of patents claiming genes and gene sequences is many years after the priority date of the particular patent at which point the criteria for patentability were considered. In the area of gene technology, what was patentable 20 years ago is likely not to be patentable today...given the rapid development of the technology area in the meantime...[T]he conclusion of the human genome project has had a significant effect on what is and what is not now patentable.<sup>52</sup>

4.35 The Association of Australian Medical Research Institutes noted that most patents only have a 20-year duration and many of the early gene sequence patents with overly broad claims were issued in the late 1980s and early 1990s. It concluded that many of these patents have now either expired or are nearing expiration; and with each new field of technology, as patent examiners have become more expert in understanding the nature of a new field, the scope of patent claims has over time become more appropriate.<sup>53</sup>

4.36 However, IVD Australia suggested that the Bill could affect existing patents, noting there are no transitional provisions included that would limit its application only to patents applied for after the Bill passes.<sup>54</sup> The Department of Health and Ageing also noted that the Bill does not include transitional provisions and does not provide clarity over the effect on patent applications currently being examined by IP Australia.<sup>55</sup> DIISR and IP Australia commented that effects on existing patents

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49 See, for example, ALRC, *Submission 30*, p. 2; Professor Dianne Nicol, Mr Johnathan Liddicoat, Dr Jane Neilsen and Mr Ben Mee, *Submission 39*, p. 41; AusBiotech, *Submission 97*, p. 2.

50 ALRC, *Genes and Ingenuity*, Report 99, June 2004, p. 13.

51 *Submission 41*, p. 3.

52 *Submission 48*, p. 3.

53 *Submission 63*, p. 3.

54 *Submission 57*, pp 7-9; see also CSIRO, *Submission 78*, p. 2.

55 *Submission 68*, p. 2.

could raise constitutional issues regarding the compensation of acquisition of property by the Commonwealth.<sup>56</sup>

### *Support for passage of the Bill*

4.37 Others supported the passage of the Bill. The Australian Reproductive Health Alliance argued that the Bill would clarify and reinforce the existing provisions of the Patents Act 'to give the clear message that "scientific discoveries" should not be the subject of patents'.<sup>57</sup> Similarly, Ms Stephanie Gleeson argued:

As biotechnology has potentially many economic, social, environmental and health consequences, the best course of action would be for the Parliament to pass this current amendment as a safeguard against ad hoc developments by the courts. Passing this amendment will provide clarity for the law and encourage cooperation between researchers to reward scientific endeavour whilst ensuring public access to publically owned biological materials.<sup>58</sup>

4.38 Dr Luigi Palombi acknowledged that the Bill is only one of several measures which need to be taken in order to improve patient access to genetic tests. However, '[w]hile other policy and legislative changes are required this Bill is an integral part of the solution'.<sup>59</sup> He described the Bill as follows:

It is a nuanced, controlled and expertly crafted response to a specific problem in Australia's patent system. It is like a surgeon's scalpel removing a festering boil. That it prevents the patenting of biological materials which exist in nature is an achievement in itself. It puts to an end, once and for all, any suggestion that the mere isolation of a biological material from its natural environment transforms that material from a product of nature into a product of invention. But it does more. It also prevents the patenting of modified biological materials when those modifications are so minor, insignificant or immaterial that they cannot be said to transform the biological material into being an 'invention'.<sup>60</sup>

### *Scope of the Bill*

4.39 The Second Reading Speech characterises the Bill as 'very narrow' and only seeking 'to clarify and apply existing patent law'.<sup>61</sup> Dr Luigi Palombi considered a narrow scope of exclusion was contemplated by the Bill. He noted the following matters would fall outside of the proposed prohibition:

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56 *Submission 94*, p. 23.

57 *Submission 27*, p. 1.

58 *Submission 37*, p. 5.

59 *Submission 103*, p. 6.

60 *Submission 103*, p. 8.

61 *Senate Hansard*, 24 November 2010, p. 2100.

(a) products, process or methods that make use of, or include as a component or components, naturally occurring biological materials, even if identical or substantially identical to any that exist in nature, in such things as diagnostics, pharmaceuticals, therapeutic products or methods, treatments and cures; and

(b) biological materials derived from naturally occurring biological materials provided such derivatives are not (a) identical or (b) substantially identical to any that exist in nature; and

(c) naturally occurring biological materials which have been modified, genetically or otherwise, so that in their modified form the way they function is so changed when compared to their premodification state that they can no longer be considered to be identical or substantially identical to any that exist in nature.<sup>62</sup>

### *Concerns regarding the Bill's scope*

4.40 However, a large number of submitters and witnesses raised concerns regarding the broad range of areas which could be affected by the exclusion on patentability of 'biological materials' in the Bill.<sup>63</sup> AusBiotech found the scope of the Bill 'broad and seemingly without limits'. It believed the Bill would encompass:

[G]enes, DNA, RNA, cDNAs, oligonucleotide primers, proteins, peptides and amino acids, lipids, carbohydrates, vaccines, bacteria, viruses, antibiotics, enzymes, hormones, immunoglobulins and other blood products, stem cells, anti-toxins, antivenoms, skin and other tissues, allergenics, probiotics, antibodies, epitopes, monoclonal Abs, recombinant therapeutics and other personalised medicines.<sup>64</sup>

4.41 If the Bill were to pass, AusBiotech foreshadowed profound negative impacts across diverse sectors of the Australian economy and community, including those focused on: agriculture; animal production; diagnostics; vaccines; and biopharmaceuticals to treat major diseases such as arthritis, cancer and multiple sclerosis.<sup>65</sup>

4.42 Several submissions which opposed the Bill noted that the origin of the public debate was in relation to patents on human gene sequences. They argued that the broad exclusion in the Bill for 'biological materials' was therefore unjustified. For example, Professor Ian Frazer commented that the 'Bill is intended to prevent the

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62 *Submission 103*, p. 2.

63 For example, see CSIRO, *Submission 78*, p. 6; Australian Academy of Science, *Submission 100*, p. 2; Biotechnology Industry Organisation, *Submission 86*, p. 4; Prima BioMed, *Submission 73*, pp 2-3.

64 *Submission 97*, p. 5.

65 *Submission 97*, p. 5.

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patenting of human genes and biological materials...[T]his intent is much broader than would be necessary to obviate my concerns with the Myriad genetics patents'.<sup>66</sup>

4.43 FB Rice & Co argued:

There are many Australian companies whose existence relies upon the patenting of biological materials such as antibodies and stem cells. In our opinion, these companies can rightly feel aggrieved by their technology seemingly being encompassed by the Bill because until now the public debate has essentially been limited to human genes and genetic testing.<sup>67</sup>

4.44 Others emphasised the importance of the patents over biological material which may be affected by the amendments proposed in the Bill. DIISR and IP Australia stated that '[p]atents over biological material are fundamental to innovation and investment in the development of new and beneficial medical, industrial, environmental technologies and food'.<sup>68</sup>

4.45 Eli Lilly Australia used the example of therapeutic antibodies to illustrate the potential impact of the Bill, noting that such antibodies are being developed as treatments for a wide range of diseases, including various infectious diseases, cancers, autoimmune diseases, Alzheimer's disease, diabetes, cardiovascular disease and various musculoskeletal diseases:

[M]any of these antibodies are fully human in structure, meaning they are derived from human antibody genes...[B]ecause they are derived from human genes, therapeutic human antibodies or the DNA that encodes them could be viewed as substantially identical to materials as they exist in nature'.<sup>69</sup>

4.46 The Walter and Eliza Hall Institute of Medical Research (WEHI) asserted that the Bill 'goes far beyond human gene patents, therapeutics and diagnostics...[I]t relates to all biological material and would impact negatively on many other areas such as the veterinary, agriculture, aquaculture, biofuel, brewing and biomaterials sectors'. Without evidence-based analysis, WEHI suggested that the risks of unintended negative economic and social consequences could be considerable.<sup>70</sup> The Peter MacCallum Cancer Centre held a similar position:

The amendments, if accepted, may have profound implications not only in the field of medicine (antibiotics, antibodies, synthetic hormones), but also veterinary science, agriculture, industry and the rapidly expanding field of green and renewable energy...There has been insufficient discussion or

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66 *Submission 92*, p. 1.

67 *Submission 77*, p. 2.

68 *Submission 94*, p. 4.

69 *Submission 52*, p. 2.

70 *Submission 59*, pp 16 & 20.

evidence available to make any changes to patent law that are so profound in their potential impact at this stage.<sup>71</sup>

4.47 Evidence to the committee highlighted that, because the previous public discussion had focused on patents on human gene sequences, the impact on the biotechnology sector of an exclusion on patenting biological materials has not been adequately considered. For example, Professor Natalie Stoianoff, Dr Ann Kurts and Dr Mark Lutherborrow noted that the previous Senate inquiry had been directed to the impact of gene patenting on human health and '[t]o date there has been no [i]nquiry or any other basis for asserting that biological materials in general should be excluded from patent protection'.<sup>72</sup>

4.48 CropLife Australia argued that there were potential impacts for the agriculture sector in Australia which had not been considered, and had not been dealt with during the previous inquiries into gene patents. In particular, it noted the lengthy regulatory hurdles for new genetically modified (GM) crops, the need for patent protection to prevent 'free-riders', and the importance of GM crops for Australian farmers to remain viable in an international marketplace:

This Bill would effectively stop the commercialisation of future GM crops in Australia because companies would refuse to risk their intellectual property by releasing it here. This would undermine hundreds of millions of dollars in private and public investment in this research and would have major implications for how Australian science is viewed globally. In addition to these effects, the competitiveness of Australian agriculture would be greatly reduced.<sup>73</sup>

4.49 Additionally, CropLife Australia highlighted the importance of agricultural chemicals, such as pesticides, and outlined a number of pesticides isolated from naturally occurring compounds:

Overall, the proposed Bill would lead to a reduction in newer softer chemicals being used in agriculture and an increased reliance on older, more synthetic chemicals, many of which are currently subject to regulatory review.<sup>74</sup>

4.50 Agrifood Awareness Australia agreed that, while the initial focus of the Bill was on medical applications, the Bill would 'impact all areas of biotechnology research and development, including Australian agriculture'. This would 'have negative consequences for the agriculture sector, leading to a decline in the global

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71 *Submission 24*, p. 4.

72 *Submission 18*, p. 11.

73 *Submission 65*, p. 7.

74 *Submission 65*, p. 9.

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competitiveness of our agriculture sectors with flow-on impacts to rural and regional communities'.<sup>75</sup>

4.51 The Institute of Patent and Trade Mark Attorneys (IPTA) was concerned that the Bill 'arguably encompasses virtually all biological materials even where they are structurally different from their native counterparts'. It noted that the 'active agents of many of the pharmaceutical products we take for granted are in fact biological materials isolated from natural sources or their derivatives'.<sup>76</sup> Dr Tanya Obranovich from the IPTA elaborated on this point in evidence:

The bill proposes to exclude from patentability all biological materials which are identical or substantially identical to materials as they exist in nature. Since the ban extends to all organisms, the bill would adversely impact not only health care but also sectors as diverse as agriculture, animal husbandry and food technology. The breadth of biological materials which the exclusion would encompass is enormous. Therefore, the potential impact of the functioning of all of these sectors would be significantly impacted.<sup>77</sup>

4.52 However, the Cancer Council Australia and the Clinical Oncological Society (CCA/COSA) supported a broader approach:

...genes are not the only natural biological materials fundamental to medical research and healthcare services that can be locked up by commercial monopolisation. There is a valid view that excluding only genetic products from patentability would not protect from monopoly other biological materials integral to competitive medical research, such as proteins and peptides.<sup>78</sup>

4.53 While he maintained reservations regarding the provisions of the Bill, Dr Graeme Suthers from the Royal College of Pathologists also noted that there are advantages in phrasing an exclusion in general terms, such as 'biological materials', because 'there are lots of diagnostic chemicals that we want to analyse and that we need to analyse in the delivery of health care...[T]hey are not just genetic ones'.<sup>79</sup> Similarly, Professor Peter Drahos stated:

[T]he phrase 'biological materials' is used for the purposes of exclusion because what you are trying to do is to ensure that the law excludes those things that are naturally occurring. To confine it to some subset sets up the dangerous inference that other naturally occurring biological materials are patentable.<sup>80</sup>

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75 *Submission 51*, p. 1.

76 *Submission 49*, pp 6-7.

77 *Committee Hansard*, 28 April 2011, pp 29-30.

78 *Submission 72*, p. 6.

79 *Committee Hansard*, 28 April 2011, p. 16.

80 *Committee Hansard*, 28 April 2011, p. 23.

## Need for the Bill

4.54 Conflicting evidence was received regarding the need for the Bill.

### *No necessity for the Bill*

4.55 Many of the submitters and witnesses opposed to the passage of the Bill highlighted that its proposed amendments are not supported by the findings of the three most recent public inquiries examining this area: the ALRC Report; the Senate Community Affairs References Committee report; and the ACIP Report.<sup>81</sup> For example, IVD Australia argued that there is 'little evidence to support claims that gene patents restrict research or that Australian scientists lack free access to biological materials because of issues with pre-existing patents'. It noted that the finding in the Senate Community Affairs References Committee report that 'the evidence does not show that gene patents are systematically leading to adverse impacts [in the areas of healthcare and medical research]' is 'at odds with the policy behind the Bill'.<sup>82</sup> Similarly, in the view of DIISR and IP Australia, there was no evidence that access to diagnostic testing or medicines is restricted or that present patentability of biological material is impacting adversely on research activities in Australia.<sup>83</sup>

4.56 Others emphasised their own experiences in relation to patents. The Walter and Eliza Hall Institute of Medical Research (WEHI) asserted that in its experience, 'patents have minimal or no negative impact on research and the effects predicted by proponents of the "anti-commons issue" are not borne out in the available data, and fears of [patents] blocking the use of upstream discoveries are largely unfounded'. Using the example of the BRCA1 patent, WEHI highlighted that the grant of that patent had not impeded subsequent research or patent applications.<sup>84</sup> This point was also emphasised by AusBiotech, which noted that the grant of the BRCA1 patent had not prevented 'over 5,500 BRCA1 primary sequence publications...[w]ith no fewer than 49 Australian research organisations having contributed to this total'.<sup>85</sup>

4.57 This position was endorsed by GlaxoSmithKline:

There is no coherent body of evidence establishing that patents have had a negative impact on access to healthcare or have impeded research to any significant degree in Australia or elsewhere.<sup>86</sup>

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81 For example, Walter and Eliza Hall Institute for Medical Research, *Submission 59*, p. 3; Pfizer Australia, *Submission 60*, p. 2; CropLife Australia, *Submission 65*, p. 4.

82 *Submission 57*, p. 8.

83 *Submission 94*, p. 5.

84 *Submission 59*, pp 9-13.

85 *Submission 97*, p. 6.

86 *Submission 69*, p. 2.

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***Necessity for the Bill***

4.58 However, other evidence to the committee emphasised the problems with the current patent system which the Bill aims to solve or alleviate. In particular, the Generic Medicines Industry Association (GMIA) had the view that innovation, research, and market competition have been unnecessarily stymied in the Australian pharmaceutical and biopharmaceutical industries because of the increasing reach of patent rights:

Patent monopolies regarding critical pharmaceuticals and biopharmaceuticals which have been invalidated elsewhere have either remained unchallenged in Australia (due to the relatively small size of the Australian market) or have been held to be valid in Australia (due to significant differences in Australian law). Australian industry and the Australian public have been disadvantaged and will continue to be disadvantaged if these issues are not rectified.<sup>87</sup>

4.59 GMIA argued that case law in Australia has drifted away from global trends in relation to standards of patentability, resulting in patents being easier to obtain and harder to revoke than in the rest of the world. It claimed the threshold for 'inventive step' is easier to meet in Australia and patent examinations are less robust:

Patents that were not granted or have been invalidated in other jurisdictions continue to deliver royalties and profits to the owners and licensees of equivalent patents in Australia, resulting in higher prices to the Australian public.<sup>88</sup>

4.60 GMIA perceived that policy positions are changing in Europe and the United States in relation to patenting biological materials. For these reasons, GMIA supported legislative intervention in Australia:

GMIA acknowledges that Australia will be "ahead of the curve" if the Gene Patenting Bill is implemented without amendment, but supports Australia aligning its position with global trends, and taking the global lead in this important area.<sup>89</sup>

4.61 GMIA also highlighted the difficulties in challenging inappropriate patents and obtaining access to some patented substances:

When we go to challenge a patent, we normally expect—especially when we go through the appeals—that we are going to be delayed anywhere between 2½ to three years to get through all the appeals and the legal system, and it will normally cost somewhere in the region of \$2 million to

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87 *Submission 71*, p. 1.

88 Answer to question on notice, provided 12 May 2011, p. 3.

89 *Submission 71*, pp 3-6.

\$3 million. That is what you are up against when you have to challenge a patent even if the patent is non-valid.<sup>90</sup>

4.62 Mylan, a large generic pharmaceutical company, echoed several of GMIA's concerns:

The patenting of naturally occurring biological materials is stifling medical and scientific research as well as the diagnosis, treatment and cure of human illness and disease. Such patenting prevents doctors, clinicians and medical and scientific researchers from gaining free and unfettered access to these materials...[T]hese monopolies go well beyond the traditional scope of patent protection and are unfairly hampering free competition in the development of biogeneric medicines.<sup>91</sup>

4.63 The increasing importance of genetic testing and biological materials was also highlighted by those supporting legislative change. For example, Dr Graeme Suthers from the Royal College of Pathologists noted that greater understanding of human genetics is leading to 'more and more genetic testing' and the type of therapeutics being developed are shifting 'more and more [to] biological [treatments] rather than straight chemicals'.<sup>92</sup> However, others considered the increasing importance of genetic and biological materials in healthcare was an argument against the excluding these materials from the patent system. Dr Anna Lavelle from AusBiotech stated:

In the modern world, the new age of medicines will be based on biologics and that is what makes this bill so potentially dangerous in terms of thwarting new medicines, therapies and technologies that are coming through, and that is based on the last 30-odd years of genetic and biological research.<sup>93</sup>

4.64 The Cancer Council Australia and the Clinical Oncological Society of Australia (CCA/COSA) had the view that problems with the gene patent legal framework are 'well-documented'. They noted that attempts to monopolise genetic tests for breast and ovarian cancer risk through the enforcement of a patent licence have been withdrawn, following a sustained public outcry. However, 'there was nothing in the law that could have protected Australian women's access to testing in public laboratories'.<sup>94</sup>

4.65 Professor Peter Drahos argued that the significant pressures on national patent offices, including in Australia, are negatively affecting the quality of patent examination being undertaken. He suggested that creating 'exemption[s] in certain

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90 Dr Martin Cross, Generic Medicines Industry Association, *Committee Hansard*, 28 April 2011, p. 51.

91 *Submission 70*, p. 3.

92 *Committee Hansard*, 28 April 2011, p. 16.

93 *Committee Hansard*, 29 April 2011, p. 5.

94 *Submission 72*, p. 6.

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areas' is one of a series of 'regulatory adjustments' which could be taken to address this issue.<sup>95</sup>

## Discovery and invention

4.66 A number of submitters and witnesses focused on the distinction between discovery and invention in the granting of patents over biological materials. This evidence highlighted both the complexity of the subject and the variety of views held regarding it.

4.67 The EM states that the Bill 'reinforces the applicability of the distinction between discovery and invention' in the Patents Act. Further:

It has long been accepted that natural phenomena are not patentable inventions. This is because the elucidation of a natural phenomenon such as the discovery of a naturally occurring thing, while adding to the storehouse of human knowledge, does not transform it into a product of humankind...This distinction between invention and discovery has thus been an accepted part of English patent law for hundreds of years and was received law by the Australian colonies. After Federation the Australian parliament maintained that distinction in the Patents Act, 1903. Likewise, successive Australian parliaments followed suit in the Patents Act, 1952 and the Patents Act, 1990.<sup>96</sup>

4.68 However, Dr Chris Dent provided the committee with his research, which focuses on the complex historical underpinnings of the Statute of Monopolies. He argued that there 'is no evidence that there was a clear distinction between invention and discovery in the early 17<sup>th</sup> century' and it is therefore not correct for the EM to claim that such a distinction 'is in keeping with the original intent of the English Parliament'. He concluded that 'to import the whole of s.6 of the Statute of Monopolies would only make the issue of interpretation more challenging'.<sup>97</sup>

4.69 Submitters and witnesses in support of the Bill emphasised the distinction between discoveries and inventions. For example, Mylan stated:

Biological materials that are identical or substantially identical to any that exist in nature should not be patentable because they are a product of nature and have not been transformed into a product of humankind, historically regarded as a prerequisite for patentability. Simply put, they are not 'inventions'. Just as a cotton ball removed from a cotton plant is not an invention, neither is a human gene mutation linked to, say, breast or ovarian cancer.<sup>98</sup>

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95 *Committee Hansard*, 28 April 2011, pp 25-26.

96 EM, p. 1.

97 *Submission 40*, p. 8.

98 *Submission 70*, p. 3.

4.70 However, the Group of Eight universities considered the Bill to be 'unnecessary' as, in their view, the distinction is clear in the current wording of the Patents Act:

While the requirement to be a manner of manufacture...can be open to a wide interpretation, the requirement for an inventive step should be sufficient to ensure that discoveries cannot be the subject of granted patents.<sup>99</sup>

4.71 Professor Andrew Christie argued that the Bill uses the wrong criterion for drawing the distinction between discovery and invention:

The distinction between a non-patentable discovery and a patentable invention is not determined by whether or not the material is identical or substantially identical to that which exists in nature. Rather, the distinction is determined by whether or not the material is an artificially created state of affairs...The 'artificially created state of affairs' criterion has been recognised as the appropriate test for distinguishing between a discovery and an invention since at least the 1959 decision of the Australian High Court in [the NRDC case]. In adopting this form of words, the High Court sought to make it clear that the key determinant of whether subject matter is an invention is the extent to which the alleged inventor has 'created' (as distinct from 'discovered') the material.<sup>100</sup>

4.72 Similarly, Dr Tania Obranovich from the Institute of Patent and Trade Mark Attorneys noted that 'across the entire developed world isolated biological materials are regarded as patentable, on the basis that they represent an artificially created state of affairs'. However, she pointed out that the fact that isolated biological materials can form patentable subject matter does not mean they will be patented, as new inventions must also meet the other requirements of patentability.<sup>101</sup>

4.73 Conversely, Dr Luigi Palombi argued that the intent of the Bill is supported by judicial decisions going back more than 150 years:

[P]atent law and the judicial interpretation of patent law in the United States, the United Kingdom and Australia is that you cannot patent a composition of matter or substance if that substance is a natural phenomenon. It matters not how the substance is made; it matters not what the substance does. If the substance is identical to a natural phenomenon then, regardless of how much time, sweat, blood and money it has taken to make it or develop a process of making it, the substance itself cannot be the subject of a valid patent monopoly.<sup>102</sup>

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99 *Submission 28*, p. 1.

100 *Submission 19*, p. 3.

101 *Committee Hansard*, 28 April 2011, p. 30.

102 *Committee Hansard*, 29 April 2011, p. 14.

4.74 In considering the Raising the Bar Bill, the Royal College of Pathologists of Australasia put its view that the distinction between a discovery and an invention with utility lies at the heart of the test for patentable subject matter, and should not be incorporated into flexible concepts of manner of manufacture. It considered that there should be an explicit, proscriptive, plain language test for patentable subject-matters 'which precludes discoveries from consideration, irrespective of the utility of those discoveries'.<sup>103</sup>

4.75 Others supported the intention of the Bill to provide clarity regarding the distinction between discoveries and inventions for biological materials, but did not support the specific provisions of the Bill itself.<sup>104</sup> For example, while it maintained concerns about the Bill's breadth and effectiveness, the Department of Health and Ageing supported the Bill's intention to clarify the distinction between a discovery and an invention:

It is the Department's view that isolated gene sequences that are homologous to those that occur naturally are discoveries, and we have concerns about these being considered patentable subject matter eligible for the grant of a patent monopoly. Despite the energy and ingenuity expended to identify the natural function of a particular gene, its mere isolation from the larger human genome and extraneous cellular material does not give rise to an invention where the isolated gene sequence remains identical to the sequence of its native homologue.<sup>105</sup>

4.76 However, Ms Fatima Beattie from IP Australia noted that new inventions can be created 'by deconstructing' existing material:

[Y]ou can take a large molecule and you can create a new invention out of that large molecule by deconstructing it, by creating a smaller molecule which has a different functionality, a different structure and a different application from that large molecule...Isolated genetic sequences are, in fact, molecules that have been created by deconstructing a larger molecule. An isolated gene sequence is created by breaking covalent bonds from a molecule and finding a practical use for that molecule. That is what makes them eligible for consideration of a patent grant.<sup>106</sup>

4.77 James & Wells Intellectual Property also highlighted the aspect of 'isolation' which was viewed as the key criterion in considering the patentability of biological materials. It argued that 'it is not the ability to isolate the gene that makes it inventive and patentable...it is most often the intensive research which results in the identification of advantages and commercial uses of the isolated gene which is inventive'. In that context, it noted that the purpose of the Bill is to give doctors and

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103 Answer to question on notice, provided 3 May 2011.

104 For example, see Department of Health and Ageing, *Submission 68*, p. 2; Tasmanian Government, *Submission 96*, p. 1.

105 *Submission 68, Supplementary submission*, pp 1-2.

106 *Committee Hansard*, 29 April 2011, p. 36.

researchers unfettered access to biological materials 'as they exist in nature' but that isolated forms of biological material do not exist in nature.<sup>107</sup> Similarly GlaxoSmithKline stressed that isolated genes on their own, with no known utility, are not sufficient for a patent to be granted under the current system.<sup>108</sup>

4.78 Referring to the NRDC case, Mr Matthew Cossey from Croplife Australia noted that there is a need for 'clear parameters, principles and a guiding framework' capable of allowing patent law to 'evolve as technology evolves'. In this regard, he stated that 'for more than half a century...there have been recognition that it is very hard in statute to define to the point of differentiations on a specific level between innovation and discovery'.<sup>109</sup>

### **Impact on healthcare**

4.79 Concerns which were previously expressed during the Senate Community Affairs References Committee's inquiry regarding the potential impact of gene patents on healthcare, medical research and the training and accreditation of healthcare professionals, were repeated in several submissions to the current inquiry.<sup>110</sup> For example, Clinical Associate Professor Judy Kirk, Director of the Familial Cancer Service at Westmead Hospital, emphasised the importance of genetic testing for the treatment of cancer. She was concerned that patenting could cause limitations on the use of the human DNA sequence which may hamper clinical services and stifle ongoing research in this rapidly changing field:

[C]ommerical monopolisation of genes and other biological material has the potential to impact negatively on health outcomes in Australia, by reducing access to diagnostic and therapeutic procedures, stifling research and development and reducing the effectiveness of professional training and development.<sup>111</sup>

4.80 While the Royal College of Pathologists did not support the specific amendments proposed in the Bill, it nonetheless argued:

[Gene patent] [m]onopolies have serious consequences for the training, delivery, quality and reliability for medical testing. They also have the potential to compromise research into better genetic tests...[G]ene patents can and do compromise the equitable delivery of health care. We do not accept that the care of some patients...should be compromised at the whim

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107 *Submission 53*, pp 1 & 3.

108 *Submission 69*, p. 5.

109 *Committee Hansard*, 29 April 2011, p. 4.

110 For example, see Human Genetics Society of Australasia, *Submission 5*, pp 1-4; South Australian Government, *Submission 15*, pp 2-4.

111 *Submission 2*, pp 1-2.

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of a patent holder who may legally restrict a doctor's freedom to make a diagnosis.<sup>112</sup>

4.81 Cancer Voices NSW strongly supported the Bill, based on the likelihood that gene patents will increase healthcare costs and discourage medical research. It noted the important role of genes in the treatment of cancer, and submitted that it did not wish to see 'patent monopolies over human genes, badly limiting needed opportunities in diagnosis, prognosis and treatment of cancer'.<sup>113</sup> Similarly Dr Jennifer Leary, Laboratory Director at the Familial Cancer Service of Westmead Hospital asserted:

A goal of any society must be to strive for equitable access to the healthcare benefits that arise from the unhindered access to genetic and biological information as it is discovered. A patent that restricts access to this information potentially prevents this equity. Use of the discovery in an invented procedure, product, process etc might then be rewarded by patent protection. Any changes to the Patent Act must be in keeping with the advancement of healthcare and medical research for the benefit of all Australians.<sup>114</sup>

4.82 Dr Luigi Palombi argued that the Bill would improve patient access to genetic tests by preventing 'the monopolisation for 20 years (a very significant period of time) of the fundamental raw ingredients of these genetic tests'. Further:

This frees up other scientists and doctors to use these biological materials to make new and inventive medical and scientific products, processes and methods using these materials in laboratories and for clinical use...[T]he Bill enhances access to genetic testing by ensuring that genetic information is not controlled by any one individual, company or organisation.<sup>115</sup>

4.83 Alphapharm, part of generic pharmaceutical company Mylan, argued:

The patenting of biological materials – as found in nature or if modified in ways that produce no material change in function – must not be allowed to continue. The practice threatens to severely inhibit medical and scientific research because the patent monopoly that these kinds of patents provide means that the biological materials are quarantined to the exclusive benefit of the patent holder. Such broad and unjustified patent monopolies reduce innovative competition in the development of new and inventive medicines. More importantly, they will interfere with the right of every Australian citizen to have future access to cost-effective, lifesaving medicines.<sup>116</sup>

4.84 However, the Consumer Health Forum of Australia considered that 'calls to ban the patenting of genes will not improve consumer access to services such as

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112 *Submission 4*, p. 2.

113 *Submission 8*, p. 2.

114 *Submission 61*, p. 2.

115 *Submission 103*, p. 6.

116 *Submission 75*, p. 2.

diagnostic tests', and noted that the Bill would not 'prevent patenting of therapeutic methods and non-biological products such as chemotherapy'.<sup>117</sup>

4.85 Others argued that, without patent protection to encourage investment and innovation, new medicines and diagnostic methods may never be developed or made available in Australia. Thus the Bill could have a detrimental effect on healthcare in Australia.<sup>118</sup> For example, DIISR and IP Australia suggested that, if patent protection is not available in Australia for some products developed overseas, 'it is possible the Australian public could not access many important medicines'.<sup>119</sup>

4.86 Similarly, Medicines Australia listed a large number of medicines and vaccines with active ingredients which could be defined as 'biological materials' (extracted overleaf) and noted that 'some half a million Australians were treated using these medicines and vaccines'. Medicines Australia argued:

Had a ban on patents on biological materials been in place ten years ago, Australian patients today would likely not have access to many of the medicines and vaccines listed...These medicines and vaccines would have been ineligible for patent protection, and the companies which developed them would, in many cases, not have sought to market them in Australia.

Passage of this Bill, or a variant of it, would lead to enormous uncertainty around the patent status of many current and future life-saving medicines. This would have serious effects on patient access to medicines in Australia.<sup>120</sup>

4.87 Dr Brendan Shaw for Medicines Australia continued:

Right now, there are over 400 biological medicines in development globally, targeting diseases such as diabetes, cancer, AIDS, arthritis and Alzheimer's. It is uncertain whether these medicines would be eligible for patents in Australia if this bill becomes law. If even part of this global development cycle were threatened as a result of our decisions here, it would be Australian patients who, along with Australian industry, would pay the price. That is, if companies are forced to cease research and development into new products, or even if some of them choose not to bring patented products to Australia for fear of exposing their intellectual property to free riders, Australian patients would have to settle for older, less effective medicines.<sup>121</sup>

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117 *Submission 16*, pp 1-2.

118 For example, see Dr Malcolm Lyons, *Submission 20*, p. 1; Dr Brendan Shaw, Medicines Australia, *Committee Hansard*, 28 April 2011, p. 36.

119 *Submission 94*, p. 23.

120 Medicines Australia, *Submission 89*, pp 5-6.

121 *Committee Hansard*, 28 April 2011, p. 36.

Table 1. Extract from Medicines Australia submission.<sup>122</sup>

Major Indications <sup>12</sup>	Generic Name	Brand Name
rheumatoid arthritis	Anakinra	Kineret®
rheumatoid arthritis	Adalimumab	Humira®
Diabetes mellitus	Insulin aspart	NovoRapid®
multiple sclerosis	Natalizumab	Tysabri®
rheumatoid arthritis	Abatacept	Orencia®
Anticoagulant	Bivalirudin	Angiomax®
fertility treatment	Choriogonadotropin α	Ovidrel®
Anaemia	Darbepoetin alfa	Aranesp®
severe sepsis	Drotrecogin alfa	Xigris®
osteoporosis	Teriparatide	Forteo®
anaemia	Epoetin beta	NeoRecormon®
cardiac ischemia	Eptifibatide	Integrilin®
rheumatoid arthritis	Etanercept	Enbrel®
prostate cancer	Triptorelin embonate	Diphereline®
multiple sclerosis	Glatiramer acetate	Copaxone®
Crohn's Disease	Infliximab	Remicade®
anaemia	Epoetin alfa	Epex 2000®
colorectal cancer	Cetuximab	Erbitux®
fertility treatment	Follitropin alfa	Gonal-F 75®
macular degeneration	Ranibizumab	Lucentis®
neutropenia	Pegfilgrastim	Neulasta®
hepatitis C	Peginterferon alfa-2b	PEG-Intron®
HIV	Enfuvirtide	Fuzeon®
heart attack	Retepase	Rapilysin 10 U®
leukaemia	Rituximab	Mabthera®
myocardial infraction	Tenecteplase	Metalyse®
thyroid cancer	Thyrotropin alfa	Thyrogen®
breast cancer	Trastuzumab	Herceptin®

4.88 A similar point was made by Industry and Investment NSW which argued that the inability to patent certain inventions based on biological materials, such as vaccines and biological therapeutics could be 'a disincentive to companies to provide their new products to the Australian market' and 'may have an impact on the cost and availability of new medicines'. The loss of these newly developed products could also lead to 'a reduction of healthcare standards' and 'reduce economic productivity and capacity associated with advances in human health'.<sup>123</sup>

4.89 Pfizer Australia also commented:

We fear a ban on the patenting of all genetic material and derivatives in Australia would halt commercial development and supply and access to a wide range of innovative medicines and health technologies in Australia...The Bill will reduce research and development in Australia; it will reduce the chances of further medical discoveries particularly in the promising fields of biologics and vaccines; it will reduce Australians' access to new medicines available elsewhere in the world.<sup>124</sup>

122 Medicines Australia, *Submission 89*, p. 5.

123 *Submission 105*, p. 2.

124 *Submission 60*, p. 3.

4.90 While AusBiotech considered that improved patient access to novel tests and therapies was essential, it did not agree that the Bill would have that effect:

The claimed purpose of the Bill, to deliver free and unfettered access to biological materials, is not sufficient on its own to deliver new medicines and tests to Australians. Arguably the opposite is a more likely outcome with fewer innovative products and technologies reaching the community since the absence of patents for biological materials will be a serious disincentive for foreign and domestic private investors and others interested in commercialising innovation in Australia.<sup>125</sup>

4.91 Roche, the world's largest biotechnology company, stated that, if the Bill were passed, pharmaceutical and biotechnology companies 'would be extremely unlikely to undertake clinical trials in Australia if their medications in development could not be patented here'. Roche noted that, annually, over 18,000 Australians participate in clinical trials which provide them with access to medicines in development.<sup>126</sup>

### **Impact on investment**

4.92 A large number of submissions, mainly from pharmaceutical and biotechnology companies and research institutes, highlighted the potential risks to investment in research and development, and the possible negative impacts on their operations, if the Bill were to be passed.<sup>127</sup> For example, Chemskill described the commercial impact of the Bill on the biotechnology industry as 'devastating':

The removal of the current patent law will undeniably discourage a vast number of businesses to invest at the research point. This will [translate] into job losses for research scientists and a reduction in the number of graduate placements in the scientific sector which our universities so heavily rely on...[W]e will be absolutely and negatively affected by the passing of this Bill in its current form.<sup>128</sup>

4.93 Many submitters and witnesses noted that the development of new products in these areas involve a high level of investment and a high degree of risk.<sup>129</sup> For example, Sanofi Aventis submitted that '[t]he research and development of new medicines, particularly biologic medicines, is a complex, expensive and protracted endeavour, taking over a decade and costing over \$1 billion for each successful new medicine'.<sup>130</sup>

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125 *Submission 97*, pp 6-7.

126 *Submission 42*, p. 8.

127 For example, Chemskill, *Submission 31*, p. 1; Metabolic Pharmaceuticals, *Submission 38*, p. 2; Grasslanz Technology, *Submission 45*, pp 5-6; Hexima, *Submission 58*, p. 1; Pfizer Australia, *Submission 60*, p. 1; Prima BioMed, *Submission 73*, p. 3.

128 *Submission 31*, p. 1.

129 For example, Australian Institute of Innovation, *Submission 34*, p. 1.

130 *Submission 32*, p. 1.

4.94 DIISR and IP Australia highlighted that patenting is particularly important for the biotechnology industry:

Biotechnology inventions are expensive to produce, with a high risk of failure and a long time to market, but are comparatively inexpensive to reproduce, or reverse engineer. Current estimates of the full cost of bringing a new pharmaceutical (chemical or biological) entity to market are around US\$1.2 to \$1.3 billion. Given the high cost of conducting research and development (R&D) before commercialisation, it is crucial for businesses, particularly small start-ups, to attract private investment.<sup>131</sup>

4.95 The intellectual property protection of the patent system was seen as critical to mitigating the risks of developing new products and allowing researchers to attract investment. Medicines Australia explained the important role of patent protection in researching new medicines:

By guaranteeing a clearly defined period of market exclusivity, patents (and other forms of intellectual property rights such as data exclusivity) act to mitigate the extraordinary risk of bringing new medicines to market, making it significantly more likely for private enterprises to continue to invest in research and development.<sup>132</sup>

4.96 Any uncertainty regarding the ability or capacity to secure patents over inventions related to biological materials was perceived as discouraging investment. For example, Mr Johnathon Liddicoat told the committee that Australian medical biotechnology companies have indicated that 'they need strong, unfettered, clear patent protection to raise tens of millions of dollars from investors to take products through rigorous clinical trials'.<sup>133</sup> Professor Dianne Nicol expanded on this point:

[P]atents are often used as a tool to get venture capital and to negotiate with downstream pharmaceutical companies and partners, and they are all looking for robust intellectual property protection. So if there is any uncertainty about the scope of protection then it could well deter investment, deter downstream partnering opportunities.<sup>134</sup>

4.97 The Bill was also perceived as potentially discouraging foreign investment in Australia. CropLife Australia argued that a ban on biological patents would increase the level of disparity between intellectual property law in Australia and in other jurisdictions, and this would 'further stifle foreign investment in Australian biotechnology and reduce, or significantly delay, technology transfer from overseas'.<sup>135</sup> It noted the ALRC Report into gene patents had commented:

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131 *Submission 94*, p. 5.

132 *Submission 89*, p. 4.

133 *Committee Hansard*, 28 April 2011, p. 57.

134 *Committee Hansard*, 28 April 2011, p. 60.

135 *Submission 65*, p. 16.

Australia's adoption of a position that diverges from the general international consensus would likely have adverse implications for Australia's participation in the global biotechnology market and might adversely affect the extent to which foreign entities participate in, and provide capital investment for, research and commercialisation of genetic materials and technologies in Australia.<sup>136</sup>

4.98 In contrast, comparisons were also made to approaches taken in other countries to patenting human genes and biological material, and the influence of patents on investment. For example, Dr Luigi Palombi noted recent large investments by international companies, such as Amgen and GlaxoSmithKline, in Brazil despite local restrictions on patenting biological materials.<sup>137</sup> Similarly, Professor Drahos stated:

Countries which have moved down the path of regulating gene patents – for example, Brazil – have suffered no adverse impact on investment; to the contrary, investment continues to rise in those countries in the biotech sector.<sup>138</sup>

4.99 However, it was also suggested that there could be other reasons for investments into developing countries, such as Brazil, including the pursuit of market growth in countries which previously may not have been perceived as territories with the highest level of patent protection.<sup>139</sup>

### **Impact on research and development**

4.100 As outlined above, the effect of the Bill on investment was identified as a key impact on research and development in Australia. However a number of other research and development issues were also raised, particularly in relation research and development moving offshore, the impact on specific research and development organisations and the effect on publicly funded research.

4.101 There was significant concern expressed that the Bill may cause investment in research, research companies and researchers to move to jurisdictions with clearer or more stable patent protection. In particular a number of submissions took the view that the amendments in the Bill would inhibit research and investment in pharmaceuticals

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136 Australian Law Reform Commission, *Genes and Ingenuity: Gene Patenting and Human Health*, Report 99, June 2004, p. 173.

137 *Committee Hansard*, 29 April 2011, p. 23.

138 *Committee Hansard*, 28 April 2011, p. 22.

139 Dr Julian Clarke, Walter and Eliza Hall Institute of Medical Research, *Committee Hansard*, 28 April 2011, p. 6; Ms Deborah Monk, Medicines Australia, *Committee Hansard*, 28 April 2011, p. 39.

and biotechnology in Australia, and could potentially cause it to move offshore.<sup>140</sup> The Institute of Patent and Trade Mark Attorneys commented:

Australia risks becoming a pariah (and a backwater) within the international biotechnology community of the developed world... Since research is often conveniently centred where development and investment occur, Australia runs the risk that Australian scientists and their research programs will move overseas to where the patenting and commercialisation becomes centred. We also open ourselves to cherry picking of promising Australian research programs by overseas research institutes, companies and investors.<sup>141</sup>

4.102 Professor Dianne Nicol, Mr Johnathon Liddicoat, Dr Jane Nielsen and Mr Ben Mee noted that the exclusion in the Bill would not prevent patenting of these materials in other jurisdictions. This created a risk that 'Australian innovations in biotechnology will be developed offshore'.<sup>142</sup>

4.103 A number of research and development companies and institutes in Australia highlighted the potential adverse consequences of the Bill for them. These organisations emphasised that patents were considered key assets and the passage of the Bill in its current form 'may have serious consequences for their operations'.<sup>143</sup> For example, the Perth Bone & Tissue Bank noted the significant expenditure on developmental research work that it has undertaken, and stated that, if the Bill prevented several of their pending patent applications, it would mean that clinical studies for their research products would not be financially possible.<sup>144</sup>

4.104 The potential impact of the Bill on publicly funded research was also outlined. A joint submission on behalf of six universities in the Sydney Basin emphasised the link between research funding and patents. The submission noted that university research is increasing reliant on external funding through partnerships with corporate and venture capital entities. The cornerstone of the ability of universities to attract commercial partnerships to increase research funding is through providing tangible value through patents and other intellectual property. In their view, universities benefit from the intellectual property system because patents:

- inform and advance research programs through associated [re]searches;
- provide a vital platform for collaboration with industry;

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140 For example, see Group of Eight, *Submission 28*, p. 2; Roche, *Submission 42*, p. 8; Dr Teresa Schafer, Mr Tim Clark and Mr George Raitt (partners in Piper Alderman), *Submission 50*, p. 5.

141 *Submission 49*, pp 10-11.

142 *Submission 39*, p.13.

143 For example, see Amgen Australia, *Submission 12*, p. 1; Garvan Institute of Medical Research, *Submission 64*, p. 1; Baxter Healthcare, *Submission 91*, p. 1.

144 *Submission 13*, p. 1.

- enable secure investment and income streams from technology licensing deals, which provide growth in research and rewards for inventors;
- define rights and ownership over materials and inventions, enabling the attraction of funds and world class staff and students;
- support academic career progression; and
- underpin the translation of research innovation.<sup>145</sup>

4.105 Sydnovate, the Technology Transfer Office of the University of Sydney, considered that a broad interpretation of the Bill could negatively affect the patentability of many inventions generated from researchers in their science and medicine faculties. It estimated 25 per cent of the University of Sydney's 221 active patent families could be adversely affected by the proposed change in legislation.<sup>146</sup>

4.106 Others emphasised the large contribution of public funding to research and development activities in Australia and overseas. For example Dr Graeme Suthers from the Royal College of Pathologists noted that a large amount of the funding for research regarding biological materials 'both national and internationally, is coming from the public purse for the benefit of the public'.<sup>147</sup> In this context, Dr Hazel Moir highlighted the lack of reliable data regarding the impact of patents on research and investment:

Despite the overwhelming evidence that patent systems, including that in Australia, largely benefit a fairly small number of foreign firms, there are frequent loud voices from patent owners, and others earning income from patent monopolies, arguing that if any changes are made all industrial innovation and scientific research will cease. There is no substantive evidence for this position – only the subjective views of those benefiting financially from the current system.<sup>148</sup>

## **Access to products**

4.107 Many companies highlighted that the Bill could inhibit the development of new products in Australia. For example, AusBiotech emphasised the important role of private sector investment and partnerships to 'translate' or develop new research and products from 'bench to bedside':

Australia must rely on companies and financiers to take the risks and invest in the commercialisation of novel medicines and diagnostic technologies. This Bill is a tragedy in the making for a 'smart country' like Australia;

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145 University of Western Sydney, University of Sydney, University of New South Wales, Macquarie University, University of Wollongong and Newcastle University, *Submission 54*, p. 2.

146 *Submission 66*, p. 2.

147 *Committee Hansard*, 28 April 2011, p. 19.

148 *Submission 29*, p. 3.

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Australian innovations will be lost as they follow the funding to the US, Europe and Asia. Global pharmaceutical companies may not include Australia in their market launch plans and ultimately Australians will have delayed access to new medicines and tests.<sup>149</sup>

4.108 Similarly, Croplife Australia outlined that it typically took 8-10 years and \$80-\$100 million to develop a biotech crop trait from the discovery phase to the point where it has received all the regulatory approvals for commercialisation.<sup>150</sup> It emphasised the importance of patent protection (in conjunction with plant breeder rights) to allow developers to recoup the investment made to bring the trait into the marketplace. It stated:

If the Bill were to ban patents on these gene sequences, then there would be nothing stopping a competitor from cross breeding the GM trait into a different variety and claiming plant breeder rights. This process would take one growing season and would completely undermine the original technology provider's investment. With such a significant "free rider" effect, no company would invest in developing the technology in the first place.<sup>151</sup>

4.109 Grasslanz Technology, an agricultural research and development company, highlighted its considerable investment 'in research and development of endophyte innovations suited to temperate pasture grasses'. It stated that should the Bill pass 'then investments in Australia by Grasslanz Technology in related technologies (endophytes, GMOs, etc) will cease' and new technologies will not be developed and commercialised for Australian industries to use.<sup>152</sup>

4.110 FB Rice & Co referred to research which estimated that the development of a single molecular diagnostic test could cost US\$40 million. It commented that if 'genetic diagnostics are not afforded patent protection it is difficult to see who is going to bother developing them'.<sup>153</sup> The Australian Institute of Innovation also argued that restricting the scope of patents is also likely to lead to higher costs for new products:

If constraints are imposed on the investment opportunity set, a response will occur, either in the form of a withdrawal of investment capital generally or a requirement for higher returns on the remaining opportunity set.<sup>154</sup>

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149 *Submission 97*, p. 7.

150 *Submission 65*, p. 5.

151 *Submission 65*, p. 6.

152 *Submission 45*, pp 5-8.

153 *Submission 77*, p. 6.

154 *Submission 34*, p. 2.

**Access to knowledge**

4.111 Others highlighted that the patent system encourages researchers and companies undertaking research to publish their results in order to claim patent protection.<sup>155</sup> For example, the Garvan Institute of Medical Research had a positive view of the influence of patents on research:

At the Garvan, the existence of patents [has] not at all impeded our research activities. In fact, at times, patents are often considered in a similar light to journal publications in providing access to new information and technology that promotes progress in the research community. It often prevents researchers from "reinventing the wheel" and facilitates most effective use of scarce resources.<sup>156</sup>

4.112 If patent protection for new inventions did not exist, new research could remain undisclosed. For example, SciVentures commented that '[i]f the types of subject matter that can be patented is reduced, then logically one way for a company to protect their investment is to keep the scientific advances [they have made] a secret as long as possible'.<sup>157</sup> The Peter MacCallum Cancer Centre agreed that there is a risk that, without the possibility of patent protection, 'biotechnology and pharmaceutical companies may shift to a model of trade secrets, for which there are no time limits and no statutory limitations'.<sup>158</sup>

**Ethical issues**

4.113 Ethical issues were often raised by those who supported the Bill, and also by those who were sympathetic to the intent of Bill, but did not support its specific provisions. For example, Ms Elizabeth Gleeson considered the granting of patents for human genes and biological materials to be 'ethically reprehensible', and stated that '[h]uman genes belong to each of us as individuals and have not been invented or manufactured by anyone'. While noting its serious concerns with the provisions of the Bill, the National Health and Medical Research Centre submitted that 'widespread community concern regarding the patenting of naturally occurring gene sequences indicates a need for clarity'.<sup>159</sup>

4.114 Ethical objections to the patenting of human genes and biological materials were expressed in a number of ways. In relation to patenting biological materials, Mr Craig Patterson stated that 'an imperialist attitude where discovery means

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155 For example, Prima BioMed, *Submission 73*, p. 1; Dr Anna Lavelle, AusBiotech, *Committee Hansard*, 29 April 2011, p. 4.

156 *Submission 64*, p. 2; see also Sydnovate, *Submission 66*, p. 1.

157 *Submission 23*, p. 3.

158 *Submission 24*, p. 4.

159 *Submission 46*, p. 2.

ownership...is a philosophy now repudiated in our society'.<sup>160</sup> Similarly, Greenpeace Australia Pacific considered that '[I]iving organisms should not be placed on the same level as human technical inventions'.<sup>161</sup> Dr Luigi Palombi argued that the Bill would prevent 'privatisation of genetic sequence information – information which belongs to humanity and is not the product of human ingenuity but is the product of human evolutionary and natural processes'.<sup>162</sup>

4.115 The Breast Cancer Action Group NSW commented:

As an ethical and philosophical principle, we do not believe that genes as natural parts of the human body should be patentable. We strongly recommend that Australian patent law be amended so that no part of a living thing can be patented.<sup>163</sup>

4.116 However, the Law Council of Australia considered that the ethical issues raised appear to be 'based largely on misconceptions as to the nature of patent protection' and noted that 'the assertion that a patent gives the patentee "ownership" of a gene is incorrect as a matter of law: there is a fundamental distinction between a patent which protects an invention as a form of intellectual property and the physical property in genetic material'.<sup>164</sup>

4.117 The ACIP inquiry into patentable subject-matter also considered the issue of patents on genetic material. It acknowledged the concerns of people regarding patents over 'undesirable, unethical or offensive inventions'. Consequently, ACIP proposed a general exclusion to preclude the patenting of inventions the commercial exploitation of which would be wholly offensive to the ordinary reasonable and fully informed member of the Australian public.<sup>165</sup>

### **Australia's international obligations and other jurisdictions**

4.118 Many submitters held the view that an amendment of the Patents Act to expressly exclude patent protection for biological materials would conflict with Australia's international obligations, particularly the TRIPS Agreement and the AUSFTA. However, others considered that the exclusions in those treaties, or their interpretation, would allow the exclusion for 'biological materials' proposed in the Bill.

4.119 Several submitters and witnesses noted the requirement in Article 27 of the TRIPS Agreement that patent protection should be available 'for any inventions,

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160 *Submission 79*, p. 1.

161 *Submission 122*, p. 1.

162 *Submission 103*, p. 6.

163 *Submission 84*, p. 1.

164 *Submission 48*, p. 4.

165 ACIP, *Patentable Subject Matter*, Final Report, December 2010, p. 1.

whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application'. Additionally, they argued that the Bill would be in conflict with the requirement that 'patents shall be available and patent rights enjoyable without discrimination as to...the field of technology'.<sup>166</sup>

4.120 A number of submitters also argued that the exclusion for 'biological materials' in the Bill would not be permitted under the allowed exclusions from patentability in the TRIPS Agreement and the AUSFTA. For example, the International Federation of Intellectual Property Attorneys highlighted that the exclusion for biological materials in the Bill does not fall within the permitted exclusion in the AUSFTA 'to protect *ordre public* or morality' or 'diagnostic, therapeutic, and surgical methods for the treatment of humans and animals'. Therefore, the exclusion in the Bill would be in violation of the AUSFTA.<sup>167</sup>

4.121 Dr Teresa Schafer, Mr Tim Clark and Mr George Raitt (partners in Piper Alderman) argued:

The introduction of legislation which specifically seeks to restrict the patentability of biotechnological inventions would appear, in the absence of reasons why commercial exploitation is necessary to be prevented to protect *ordre public* or morality, to be contrary to the TRIPS Agreement and AUSFTA, both of which provide that patents should be available "in all fields of technology".<sup>168</sup>

4.122 However, Professor Peter Drahos considered that the Bill would not breach Australia's treaty obligations. He noted that neither the TRIPS Agreement, or the AUSFTA, define 'invention':

The international framework allows states to exclude subject matter from the meaning of invention. All states take advantage of the open meaning of invention in this framework.<sup>169</sup>

4.123 Professor Drahos also argued that the Bill would not mean Australia was 'out of step with other countries' and listed examples of other jurisdictions which have taken a different approach to the patenting of biological materials.<sup>170</sup> Professor Dianne Nicol, Mr Johnathon Liddicoat, Dr Jane Nielsen and Mr Ben Mee also noted that jurisdictions such as Brazil, Mexico, Argentina and the Andean Community have

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166 *Agreement on Trade-Related Aspects of Intellectual Property Rights*, Article 27 (1); for example see Davies Collison Cave, *Submission 17*, pp 9-10; Dr Ann Kurts, Dr Mark Lutherborrow and Professor Natalie Stoianoff, *Submission 18*, p. 13; International Federation of Intellectual Property Attorneys, *Submission 35*, pp 2-5.

167 *Submission 35*, p. 6.

168 *Submission 50*, p. 2.

169 *Submission 25*, p. 1.

170 *Submission 25*, p. 1.

provisions which prohibit patenting of biological materials, but suggested these exclusions may result from a response to 'the threat of biopiracy'. They suggested that an emerging norm of excluding biological materials from patentability in developing countries 'does not necessarily provide guidance to Australia'.<sup>171</sup> Similarly, the Institute of Patent and Trade Mark Attorneys commented that 'it is not desirable to effectively model the future of the Australian patent system on that of undeveloped or developing countries with entirely different economic and Governmental structures to Australia'.<sup>172</sup>

4.124 Others compared the approach of the Bill to the approaches taken in the United States, Europe, Japan, China and other major trading partners of Australia.<sup>173</sup> DIISR and IP Australia commented that Australia's current position is consistent with most other countries and that presently the United States, China and Japan 'all consider isolated biological material, including gene sequences, to be eligible for patent protection' where the other substantive requirements of patentability are met.<sup>174</sup> Ms Fatima Beattie from IP Australia noted that if the Bill were enacted, Australia would be out of step with patenting activities 'in all the developed and most of the developing countries'.<sup>175</sup>

4.125 Several submitters and witnesses referred to the European Biotechnology Directive which expressly states that biological material which is isolated from its natural environment, or produced by technical processes, may be the subject of a patentable invention even if it previously occurred in nature.<sup>176</sup> Article 5 of that directive clarifies the distinction between invention and discovery in relation to genes and material isolated from humans:

Article 5

1. The human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions.
2. An element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element.
3. The industrial application of a sequence or a partial sequence of a gene must be disclosed in the patent application.

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171 *Submission 39*, p. 40.

172 *Submission 49*, p. 16.

173 For example, Institute of Patent and Trade Mark Attorneys, *Submission 49*, pp 12-14; Professor Peter Drahos, *Committee Hansard*, 28 April 2011, pp 23-24.

174 *Submission 94*, p. 11.

175 *Committee Hansard*, 29 April 2011, p. 34.

176 *Directive on the legal protection of biotechnological inventions*, Directive 98/44/EC, Article 3(2).

4.126 Dr Tania Obranovich from the Institute of Patent and Trade Mark Attorneys argued that, as Europe expressly enshrines the patentability of biological materials, the enactment of the Bill would put Australian patent law 'directly at odds with Europe'.<sup>177</sup>

4.127 Mr Doug Calhoun also commented that the patentability of biological materials, internationally and in Australia, was recognised by the enactment of the Budapest Treaty.<sup>178</sup> The treaty provided for the establishment and maintenance of depositories of cultures of micro-organisations and other biological materials in support of patents. He argued that the consequential amendments to the Patents Act following Australia becoming a signatory to the Budapest Treaty, 'implicitly acknowledged that biological materials are patentable inventions'.<sup>179</sup>

4.128 Those opposed to the Bill often emphasised the importance of maintaining Australian intellectual property rules which are in harmony with international standards and with those of Australia's major trading partners.<sup>180</sup> Bayer CropScience believed that 'the current Bill, by concentrating on "biological materials" almost certainly infringes on Australia's international obligations under TRIPS...and AUSFTA treaties and would reverse decades of work aimed at harmonising Australian and international approaches to patents'.<sup>181</sup> In contrast, the Cancer Council Australia/Clinical Oncological Society of Australia (CCA/COSA) argued that 'Australia is not beholden to any international obligations in relation to domestic gene patent policy; the public interest, particularly public health and access to healthcare, should be the priority'.<sup>182</sup>

### Support for the Raising the Bar Bill

4.129 A number of submitters and witnesses recommended that the Bill should be rejected in favour of the Raising the Bar Bill.<sup>183</sup> For example, Medicines Australia

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177 *Committee Hansard*, 28 April 2011, p. 30; see also Ms Fatima Beattie, IP Australia, *Committee Hansard*, 29 April 2011, p. 34.

178 Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure, (Budapest 1977), [http://www.wipo.int/treaties/en/registration/budapest/trtdocs\\_wo002.html](http://www.wipo.int/treaties/en/registration/budapest/trtdocs_wo002.html), accessed 18 April 2011. Australia became a treaty country in 1987.

179 *Submission 21*, pp 7-8.

180 For example, Foursight Associates, *Submission 36*, pp 1-2; CSL, *Submission 56*, p. 2; Croplife Australia, *Submission 65*, p. 13; Ms Fatima Beattie, IP Australia, *Committee Hansard*, 29 April 2011, p. 34

181 *Submission 7*, p. 2.

182 *Submission 72*, p. 7.

183 For example, Institute of Patent and Trade Mark Attorneys, *Submission 49*, p. 20; CSL, *Submission 56*, p. 3; AusBiotech, *Submission 97*, p. 8; Industry and Investment NSW, *Submission 105*, p. 3; Dr Julian Clark, Walter and Eliza Hall Institute of Medical Research, *Committee Hansard*, 28 April 2011, p. 13; Mr Johnathon Liddicoat, *Committee Hansard*, 28 April 2011, p. 58.

stated that the government's proposed legislation is 'likely to clarify and strengthen the conditions required to be met in order for a technology to become patented...[T]his will help ensure the distinction between 'discovery' and 'invention' is clear'. According to Medicines Australia, the Raising the Bar Bill would 'in all likelihood raise the threshold for granting a patent without the adverse unintended consequences' anticipated from possible introduction of the Bill before the committee.<sup>184</sup> Amgen Australia also considered that any concerns regarding access to biological materials for research would be addressed by the amendments in the Raising the Bar Bill 'which contains a statutory provision clarifying researchers' freedom to conduct experiments without infringing patents'.<sup>185</sup>

### Support for other policies approaches

4.130 Other policy approaches to address the potential adverse impacts of patents on human genes and biological materials were also highlighted. In particular, many submitters and witnesses preferred policy approaches which were 'technology neutral'.<sup>186</sup> These include: better use of the existing provisions of the Patents Act, such as the 'compulsory licensing' and 'crown use' provisions; an express research exception; and other options canvassed in the ALRC Report, the Senate Community Affairs References Committee report and the ACIP Report.<sup>187</sup> For example, Griffith Hack and Griffith Hack Lawyers stated:

There are alternatives to the proposed Bill, using technology neutral language...[T]hese include the introduction of a provision to exempt patent infringement for experimental use of patented technology and clarification of the Crown Use and compulsory licensing provisions of the Patents Act.<sup>188</sup>

4.131 AusBiotech also argued that the interests and needs of the Australian public can be protected via the safeguard mechanisms that already exist in the law. In relation to the crown use and compulsory licensing provisions of the Patents Act, it commented that while these provisions had never been invoked in relation to healthcare in Australia 'it may be that the spectre of these provisions within the patent system offer a degree of protection to the Australian community from undesirable behaviour in relation to the exercise of patent rights'.<sup>189</sup> However CCA/COSA did not view the Crown use provisions of the Patents Act as an effective mechanism in this

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184 *Submission 89*, p. 8.

185 *Submission 12*, p. 7.

186 For example, CSL, *Submission 56*, p. 3; Dr Tania Obranovich, Institute of Patent and Trade Mark Attorneys, *Committee Hansard*, 28 April 2011, p. 30; Dr Anna Lavelle, AusBiotech, *Committee Hansard*, 29 April 2011, p. 9.

187 For example, Group of Eight, *Submission 28*, p. 2; IVD Australia, *Submission 57*, p. 10; Hexima, *Submission 58*, p. 2; CSIRO, *Submission 78*, p. 2.

188 *Submission 47*, p. 2. See also Prima BioMed, *Submission 73*, p. 1.

189 *Submission 97*, p. 8.

regard, as the 'inability or reluctance of jurisdictions to invoke the provisions underscored their limitations as a feasible legal instrument to protect the public interest from gene patent exploitation'.<sup>190</sup>

4.132 Alternative options to address the potential problems created by patents were also raised in evidence. La Trobe University noted that the 'Pharmaceutical Benefits Scheme provides Australia with a robust and flexible mechanism by which the public may gain affordable access to otherwise expensive patented pharmaceutical and biological medication while maintaining a viable pharmaceutical research and development industry'.<sup>191</sup> This reflects the ALRC Report into gene patents in 2004 which recommended that 'options for using government funding and purchasing power to control the cost of goods and services that are subject to gene patents and used in the provision of healthcare' should be examined.<sup>192</sup>

4.133 AusBiotech supported a tribunal-like model or the appointment of a 'Patents Ombudsman' with whom the public, clinicians, researchers and industry could raise grievances.<sup>193</sup> Professor Peter Drahos noted his proposal for patent transparency registers to assist the tracking of granted patents.<sup>194</sup> DIISR and IP Australia also advised that other approaches, such as patent pools, have been used successfully in industries such as software and consumer electronics:

Patent pools can be defined as an agreement between two or more patent owners to license one or more of their patents to one another and/or third parties. The key benefit of patent pools is in reducing transaction costs for users having to identify relevant patents and then seek cross licensing arrangements with multiple individual patent holders.<sup>195</sup>

4.134 Dr Graeme Suthers of the Royal College of Pathologists supported a proposal by the United States Secretary's Advisory Committee on Genetics, Health and Society to create 'a statutory exemption from liability for medical tests that have been developed under a patent'.<sup>196</sup>

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190 *Submission 72*, p. 5.

191 *Submission 41*, p. 4.

192 ALRC, *Genes and Ingenuity: Gene Patenting and Human Health*, Report 99, June 2004, p. 474.

193 *Submission 97*, p. 2. Dr Anna Lavelle, AusBiotech, *Committee Hansard*, 29 April 2011, pp 5-6.

194 *Committee Hansard*, 28 April 2011, p. 25.

195 *Submission 94*, p. 24.

196 *Committee Hansard*, 28 April 2011, p. 14; see also, Secretary's Advisory Committee on Genetics, Health and Society, *Gene Patents and Licensing Practices and Their Impact on Patient Access to Genetic Tests*, April 2010, p. 94, [http://oba.od.nih.gov/oba/sacghs/reports/SACGHS\\_patents\\_report\\_2010.pdf](http://oba.od.nih.gov/oba/sacghs/reports/SACGHS_patents_report_2010.pdf), accessed 6 June 2011.

4.135 Finally, a number of submissions, such as CCA/COSA, supported both an amendment to the Patents Act to exclude human genes and/or biological materials from patentability (in the case of CCA/COSA with some amendments), along with corresponding implementation of recommendations made in previous public reviews, such as the ALRC Report.<sup>197</sup>

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197 Cancer Council Australia and Clinical Oncological Society, *Submission 72*, p. 6; Human Genetics Society of Australasia, *Submission 5*, p. 4.

# **CHAPTER 5**

## **CONCLUSIONS AND RECOMMENDATIONS**

### **Introduction**

5.1 The committee notes that the Bill has been introduced in the context of a number of other reviews and other ongoing processes. IP Australia has recently finalised over two years of consultation in relation to the reforms which have been introduced as part of the Raising the Bar Bill. Legal cases related to the patentability of human genes are also currently being undertaken, both in Australia and overseas. Australian Government responses are also anticipated in relation to:

- the report of the ALRC inquiry on gene patenting and human health;
- the report of the Senate Community Affairs Committee inquiry on gene patents; and
- the report of the ACIP inquiry on patentable subject matter.

5.2 These events will be relevant to the broader issues identified in the EM as being affected by the Bill.

### **Key issues**

5.3 In the view of the committee, the key issues to be addressed regarding the provisions of the Bill and the issue of the patenting of human genes and biological materials are:

- the distinction between discoveries and inventions;
- the scope of the Bill's exclusion for biological materials;
- access to treatments, diagnostics and methods for healthcare;
- the freedom to conduct research;
- investment in research and development;
- access to new products and knowledge;
- ethical issues with respect to the patenting of human genes and biological materials;
- the crown use and compulsory licensing provisions of the Patents Act; and
- international considerations.

### ***Discovery and invention***

5.4 The Bill before the committee attempts to make amendments to the Patents Act in order to clarify the distinction between invention and discovery in the patents system. However, it is evident from the inquiry that there is not wide

agreement that the amendments proposed facilitate this clarification. In the view of the committee, the amendments proposed in the Bill will, at best, not assist to clarify the distinction between discovery and invention in the patent system and, at worst, make the distinction more obscure.

5.5 The inquiry touched on several of the difficult policy questions regarding the appropriate distinction between discovery and invention in relation to patents over human genes and biological materials. However, these difficult policy questions are not limited to these particular subject matters. Other controversial areas include the grants of patents over computer software and business methods. Further, there are likely to be new fields of technology in the future where the issue of the appropriate distinction between discovery and invention will need to be carefully considered. This indicates to the committee that a technology neutral approach to this issue is preferable to an approach which will focus on one category of inventions only.

5.6 ACIP has recently completed an extensive inquiry into patentable subject matter. ACIP concluded that:

The current test for patentable subject matter as applied by the courts in Australia is the best one available to us. It has the flexibility to cope with a variety of concepts and to adapt to new technologies.<sup>1</sup>

5.7 ACIP has proposed codifying the 'principles of inherent patentability (as developed by the High Court in the NRDC case and in subsequent Australian court decisions)'. In the view of the committee, this is an approach that is likely to add clarity to the Patents Act. In contrast, the amendments proposed in the Bill to alter the 'manner of manufacture' test in section 18 of the Patents Act are not likely to generate certainty within the patent system.

5.8 The proposed amendments contained in the Raising the Bar Bill also illustrate that other technology neutral changes to requirements in the Patents Act are viable. These amendments would tighten the requirements for the grant of patents in all fields of technology through proposals to raise the standards for inventive step, usefulness and disclosure of inventions. In the view of the committee, these proposals should contribute to improving the quality of inventions which are granted patents.

### ***Scope of the Bill***

5.9 While previous inquiries and public discussions have focused on the patenting of human genes, the Bill goes further and proposes a specific exclusion for biological materials which are identical or substantially identical to such materials 'as they exist in nature'. The evidence received during the inquiry indicates that this exclusion is likely to have significant implications for a broad range of sectors and industries in Australia, including healthcare, pharmaceuticals, agriculture, food manufacturing and biotechnology. Extensive inquiries by the ALRC, the Senate Community Affairs

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1 ACIP, *Patentable Subject Matter*, Final Report, December 2010, p. 42.

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Committee and ACIP have not revealed any persuasive evidence that would justify this type of broad exclusion from patentability for all biological materials.

5.10 The broad scope of the Bill, and the imprecise language of its provisions, was perceived by many as being potentially detrimental to Australia's patent system, the research sector and the many industries reliant on a stable patent system. The committee agrees that this ambiguity in the language of the Bill could discourage investment in research and development, and encourage litigation by those seeking to clarify patent rights.

5.11 The use of the term 'substantially identical' highlights many of these issues, particularly in view of the examples provided of current patented products, and those in development, which included inventive elements designed to mimic biological materials 'as they exist in nature'. The uncertain scope of the exclusion proposed for biological materials creates a risk that worthy inventions, which meet all the other requirements of patentability, will be unable to claim patent protection. Some amendments to the Bill were suggested during the inquiry to clarify the scope of the biological materials exclusion. However, in the view of the committee, these suggestions do not resolve the key deficiency of the Bill in seeking to carve out a broad category of subject matter from patentability.

#### *Access to healthcare*

5.12 The context for the debate over patents granted in relation to human genes and biological materials is the increasing scientific understanding of these materials and their increasing application to healthcare. As Dr Graeme Suthers from the Royal College of Pathologists noted, the relationship between genetic tests and clinical care 'is in a state of rapid flux at the moment'.<sup>2</sup>

5.13 Like the Senate Community Affairs Committee, the committee received commentary which was concerning in relation to the potential impacts of the patents system on equitable access to healthcare. However, there was no evidence received by the committee that patents on human genes or biological materials are systematically leading to adverse impacts in the provision of healthcare in Australia. Further, as a number of submissions and witnesses highlighted, the enactment of the Bill would not resolve the issue which focused public attention on the patenting of human genes in Australia in the first place: the claims of Genetic Technologies over BRCA1 and BRCA2 genetic testing.

5.14 The evidence the committee received suggests that the key measure proposed by the Bill, the exclusion from patentability of biological materials which exist in nature, would also have significant adverse consequences for healthcare in Australia. This could potentially include:

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2 *Committee Hansard*, 28 April 2011, p. 20.

- long delays for Australian patients to access new diagnostic tests, medicines and treatments;
- reduced access for Australian patients to clinical trials; and
- a reduction in investment for medical research and development in Australia.

### ***Freedom to research***

5.15 It is clear that legal uncertainty in relation to patents can cause anxiety for researchers and delays for research. In the BRCA example, legal claims by Genetic Technologies caused the research of the Peter MacCallum Cancer Centre to be delayed for a significant period. Currently, there is no provision in the Patents Act which clarifies the rights of researchers to freely conduct experiments. To ensure certainty exists for researchers, there was considerable support expressed during the inquiry for an explicit research exemption in the Patents Act. The amendments proposed in the Raising the Bar Bill clarify that research and experimental activities relating to patented inventions are exempt from infringement. In the view of the committee, a clear research exemption is the preferable approach to provide certainty for researchers. The Bill's proposed exclusion for biological materials would not provide this certainty for researchers.

### ***Investment in research and development***

5.16 The evidence the committee received indicates that patents over human genes and biological materials have not hindered research, particularly medical research, in Australia. In contrast, there was clear evidence from submitters and witnesses that these patents have encouraged and contributed to research and development activities. Patents allow researchers to attract investment to pursue the development of new inventions and allow companies to mitigate the risks associated with developing costly new products, such as medicines.

5.17 The committee agrees that the significant amendments proposed in the Bill risk creating uncertainty regarding the stability of Australia's patent system. A broad range of research organisations and companies highlighted their concerns that the ambiguous nature of the Bill's provisions could negatively affect investment in research and development in Australia. Uncertainty regarding the capacity to secure patent protection for new inventions, caused by the enactment of the Bill, is likely to discourage investment in research and development and potentially drive investment funding and research activities overseas.

### ***Access to new products and knowledge***

5.18 In the view of the committee there is a clear risk that, without certainty in relation patent protection for biological materials, companies will have less incentive to develop and commercialise new products for the Australian market. This could negatively impact these companies, and their employees and shareholders, but also Australian industries and consumers who would lose access to these new products. Additionally, there is a risk that without clear patent protection for inventions related

to biological materials, there will be less incentive for researchers to publicly disclose recently developed knowledge and inventions in this area. Other researchers would then be unable to utilise and build on this new knowledge in their own endeavours.

### ***Ethical considerations***

5.19 In addition to social, economic and policy considerations, there are clearly ethical dimensions to the issue of patenting human genes and biological materials. Particularly in the case of patents over human gene sequences, many in the community feel uncomfortable that the patent system may allow applicants to claim a degree of ownership over material which already exists, in another form, in nature.

5.20 The recent ACIP report on patentable subject matter (ACIP Report) included significant discussion in relation to these ethical concerns. It noted that it was important that the social contract of the patent system should be able to take into account both economic and ethical matters when regulating the subject matter eligible to be patented. The report proposed maintaining the current specific exclusions, including for 'human beings, and the biological processes for their generation' as well as amending the Patents Act to insert a general ethical exclusion. This general exclusion would exclude from patentability inventions 'the commercial exploitation of which would be wholly offensive to the ordinary reasonable and fully informed member of the Australian public'.<sup>3</sup>

5.21 The ACIP Report recognised the benefit in having a flexible approach to this issue through creating an arrangement which considers Australian values as they exist at the relevant time. In the view of the committee, the ACIP proposal for a general ethical exclusion has merit and is a preferable approach to prevent the grant of patents which would be perceived as unethical by the community.

### ***International considerations***

5.22 In the view of the committee, the enactment of the Bill could breach Australia's international obligations under the TRIPS Agreement and the AUSFTA to allow for the patenting of inventions in 'all fields of technology' without discrimination. While there is explicit scope in these international agreements for other relevant exceptions, such as to protect *ordre public* or morality and for human healthcare, the provisions of the Bill are not framed in these terms.

5.23 Examples of restrictions on the patenting of biological materials in some developing countries were raised during the inquiry. However, in the view of the committee, the factors driving these sorts of exclusions in developing countries do not necessarily translate to an advanced research jurisdiction such as Australia. The international legal position may, or may not, be in the process of evolution, but it is too early to be certain how these issues will be resolved. The committee's view is that, until a clear approach exists in comparable jurisdictions, significant advantages

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3 ACIP, *Patentable Subject Matter*, Final Report, December 2010, p. 17.

remain for Australia in maintaining the harmonisation of its intellectual property regime with international standards and those of its major trading partners.

### ***Crown use and compulsory licensing***

5.24 The committee does not agree with the characterisation, made during the inquiry, that the Crown Use and compulsory licensing provisions in the Patents Act are not effective because they are rarely, if ever, utilised. The existence of legislative mechanisms can effectively influence patent-holder behaviour. For example, it can be argued that these provisions were an important contributing factor in the decision of Genetic Technologies to abandon its legal claims in relation to BRCA1 and BRCA2 genetic testing. However, the committee was also concerned to hear that there may be some complexity with the operation of the crown use provisions, depending on whether they were exercised in the right of the Commonwealth or in the right of the states.<sup>4</sup> This subject may be an appropriate topic of future inquiry by ACIP.

### **Conclusion**

5.25 During the inquiry, the Bill was described as 'well-intentioned' and the committee agrees with this characterisation. However, the committee does not agree that the Bill represents an effective solution to the problems which may be caused by patents over human genes and biological materials. In particular, the committee is concerned that proposed amendments in the Bill, which are focused on addressing a specific issue, could have a large number of unintended consequences across the entire patent system with indeterminate impacts on a range of industries and sectors.

5.26 Like many of those who gave evidence, the committee prefers the solutions offered in the proposed amendments of the Raising the Bar Bill. However, the committee does not consider that the amendments in the Raising the Bar Bill will resolve all of the issues in the patent system. In the opinion of the committee, serious consideration should also be given to the proposals for legislative enactment of the patentable subject matter test and the general 'ethical' exclusion made in the ACIP report on patentable subject matter. Other reforms may also be necessary in the future, particularly in relation to ensuring equitable access to healthcare. In this context, the committee recognises that the Senate Community Affairs References Committee has indicated it will maintain a 'watching brief' in relation to the impact of gene patents in Australia.<sup>5</sup> Despite the need for further reform to the patent system, the committee agrees that removing an area of patentable subject matter, as proposed by the Bill, is not an appropriate solution to this complex set of issues.

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4 Mr Chris Reid, Department of Health and Ageing, *Committee Hansard*, 29 April 2011, p. 36.

5 Senate Community Affairs References Committee, *Gene Patents*, November 2010, p. 102.

**Recommendation 1**

**5.27 The committee recommends that the Senate should not pass the Bill.**

**Senator Trish Crossin  
Chair**

**DISSENTING REPORT BY  
SENATOR THE HON BILL HEFFERNAN,  
SENATOR RACHEL SIEWERT AND  
SENATOR NICK XENOPHON**

**EXECUTIVE SUMMARY**

The Australian patent system has been in operation since 1903.

In 1990 the current Patents Act came into operation. It was the result of an extensive process of consultation, commenced in 1979 by the then Minister Productivity, the Hon. Ian Macphie. In 1984 the Industrial Property Advisory Council handed its report to the then Minister for Science and Technology, the Hon. Barry Jones MP. The IPAC Report was then reviewed and examined by stakeholders. In 1989 the Patents Bill was introduced into Parliament.

However, during the ten years of consultation no economic study assessed whether and how the Australian patent system maximises the social benefits and minimises the social costs to Australians; yet this is the principal objective.

With Australia joining the World Trade Organization in 1995, amendments were made to comply with the Agreement on Trade Related Aspects of Intellectual Property (TRIPS). Again after the signing of the Australia and United States Free Trade Agreement (AUSFTA), the Act was further amended. And yet again, no economic study was conducted into how these changes to Australia's patent system would impact on Australians.

Amid claims that Australia's patent system is important to fostering Australian innovation, the available anecdotal and statistical evidence seriously undermines these claims. Not only does Australia grant around 90% of patents to foreigners, but the percentage of resident-inventors of granted patents places Australia between Brazil and Israel. More recently IP Australia has admitted that Australia's patentability standards are too low compared with its major trading partners. So they were in 1990 when Mr Jones promised the Australian Parliament that the new Patents Act would make Australia a more innovative country. But the evidence shows that since 1990 Australian innovation, at least as measured by the number of granted patents, has not improved. According to IP Australia the consequences of an imbalance in the system is a reduction in "access to follow-on innovation for Australian innovators and the advantages that flow to Australian consumers from access to information about new technology and competition in the Australia marketplace."

And the grant of patents over biological materials which are identical or substantially identical to those existing in nature only contributes further to the imbalance and makes the consequences which IP Australia refers to only more severe. The grant of a

patent according to TRIPS must be for an invention, yet many thousands of patents have been granted, mainly to foreigners, over things that no one invented. Human genes carrying identical genetic information to that contained in the human genome have been patented on the pretext of being isolated from the human body. Human proteins have likewise been patented. The result has been to impose burdens and restraints on those that are striving to find new diagnostics, medicines, treatments and cures for human illness and disease. Rather than contributing to Australia's capacity to innovate these patents have retarded that capacity.

This Bill provides the Australian Parliament with a unique opportunity to address a very serious issue by recalibrating Australia's patent system in one specific respect. And while the Bill does not address all of the issues that must be addressed if the Australian patent system is to continue to be relevant in the 21<sup>st</sup> century, the passage of this Bill will make a significant contribution to the betterment of the Australian people by ensuring through legislation that things which no one invented cannot be monopolised and commoditised.

As the U.S. Supreme Court has said time and again, natural phenomena are not patentable subject matter, not because their discovery is obvious or does not involve risk and ingenuity but because they "manifestations of ... nature, free to all men and reserved exclusively to none".

That IP Australia has, through an errant policy, permitted the patenting of natural phenomena in violation of this basic principle of patent law requires legislative intervention. This Bill sets out that legislative intervention.

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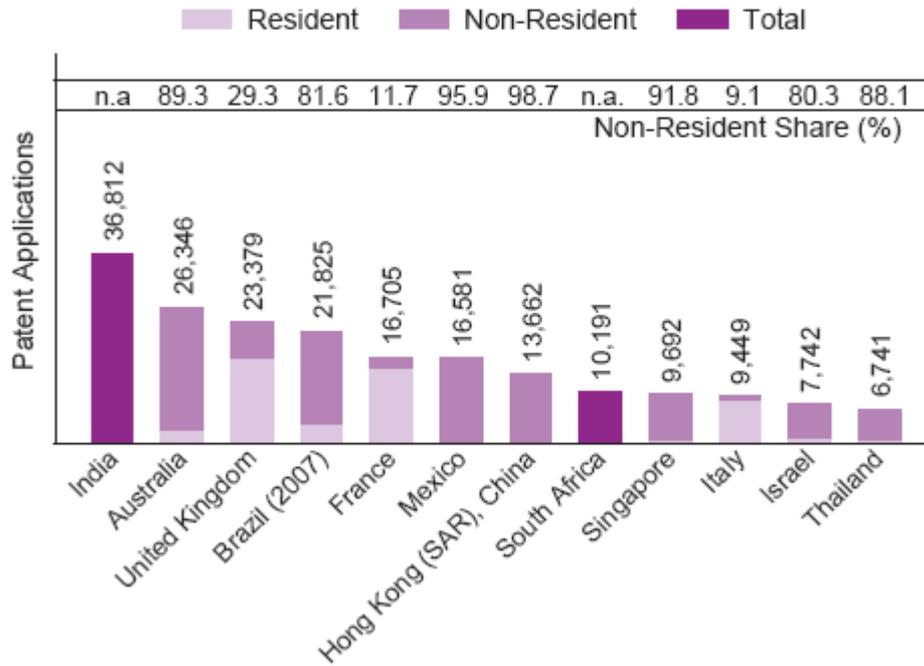
## INTRODUCTION

1.1 On 29 August 1984 the Industrial Property Advisory Committee (IPAC), the predecessor to the Advisory Committee on Intellectual Property (ACIP), provided its report to the then Minister for Science and Technology, the Hon. Barry Jones MP. The IPAC report was the end result of a five year review of Australia's patent system and the operating legislation, the *Patents Act, 1952*. The report was not unanimous. The dissenter, Prof. Donald Lamberton, an economist from the University of Queensland, wrote:

This Report does not live up to its claim to have adopted an economic perspective and to have applied economic criteria. It has not consistently applied economic criteria; it has not made full use of available empirical evidence; and the concept of social cost, so frequently mentioned, has never really been fully grasped. The underlying idea of the process of innovation is little more than faith that more patent protection will ensure more innovation. The sensible objective is rightly declared to be "to modify the Australian patent laws, adjusting the length, strength and breadth of patent rights" to maximize the net benefit. It is unfortunate that the Report soon strays from this path.

No amount of talk about individual patent successes nor about a future in which the Australian economy has magically become progressive, innovation-oriented, and competitive on the world scene, can hide the facts that Australia exports little in the way of manufactured goods and has few inventions for sale. Most patents are granted to overseas firms. To make the most of this situation, Australia needs to reduce social costs to the extent possible without inhibiting innovation and without provoking international retaliation. As a small nation, there is scope for such action. The constraints of the Convention are largely myth.

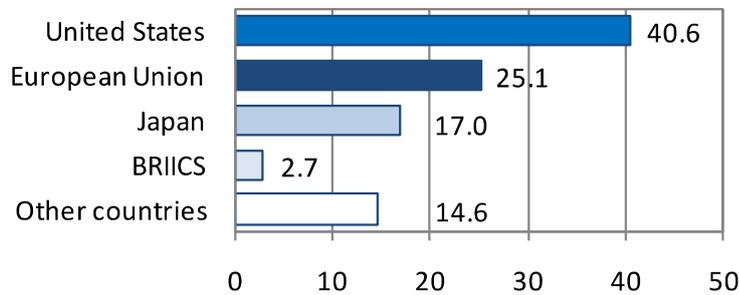
1.2 Other than the fact that today Australia manufactures less than it did in 1984, we understand on the basis of the evidence provided to this Committee that Prof Lamberton's comments are as relevant today as they were then. According to IP Australia's own statistics Australian innovation, as measured by the number of Australian patents applied by and granted to Australian residents, has not improved in 30 years. Patent statistics provided by the World Intellectual Property Office (WIPO) are corroborative. The percentage of Australian patents granted to non-Australian residents in 2008 was 89.3%. By way of contrast the same figure for Japan was 15.6%; Germany, 21.1%; Korean Republic, 25.5%; China, 32.9%, Russian Federation, 33.8% and the U.S., 49.2%. WIPO also confirms that today the only two countries that come anywhere near the U.S., the E.U. and Japan, the three dominant patent filing countries or regions in 1985, are China and the Korean Republic. What these statistics demonstrate is that if the number of foreign owned Australian patents are removed from the total number of patents granted by IP Australia, this country lags between Brazil and Israel. Only Thailand, Singapore, Mexico and Hong Kong have even lower resident-inventors.



Source: WIPO, World Intellectual Property Indicators, 2010.

1.3 To put Australia’s biotechnology industry into a global perspective it needs to be understood that the three dominant countries are the United States with 40.6% (of all biotech patents); E.U., 25.1% and Japan, 17%. These three countries alone produced 82.6% of all biotechnology patents in 2005. The remaining 17.4% is produced by 150 countries (WTO membership is 153 countries) and of that figure, 2.7% is attributable to Brazil, India and China. Australia is, therefore, a most insignificant player in this market.

**Share of countries in biotechnology patents 2005**



Source: OECD Compendium of Patent Statistics, 2008

1.4 According to the Productivity Commission’s 2007 report, *Public Support for Science and Innovation*, venture capital plays an important role in providing funding

to expansion phase businesses but not to start-up and early stage businesses in Australia. The Productivity Commission's Report stated:

Venture capital brings with it not only access to finance but management expertise and contacts as well. Firms can also benefit from being able to tap into the established network of relationships that venture capitalists have built up over time. In these ways, venture capitalists may significantly improve the probability that start-up and early stage firms succeed in commercialising their IP.

However, the enormous size of the venture capital markets in the U.S., the E.U. and Japan, when compared to that of Australia, even if Australia's venture capital market is expanding, helps only partially to explain why Australia lags significantly behind these countries in the biotechnology sector. The Productivity Commission was advised in submissions of other factors impeding funding of start-ups and early stage businesses, such as:

- (a) "Australian private equity market tend to be skewed towards later stage development" as opposed to start-ups (which disadvantages "commercial opportunities in academia" because venture capital consortia "necessarily take a very short term approach to liquidity and therefore identify only late stage projects") and early stage firms;
- (b) "... limited access to venture capital seriously constrains the ability of start-ups and early firms to commercialise knowledge and technology;
- (c) "seeking to license their knowledge and technology relatively early (which can mean that the value of the IP is heavily discounted)"; and
- (d) "adopting a cautious approach to patenting because of the difficulty of covering the cost of protecting their IP."

#### 1.5 The Productivity Commission summed up as follows:

A well functioning and self-sustaining venture capital market potentially provides a relatively efficient mechanism for identifying, screening and funding the most promising early stage commercialisation ventures. However, the general consensus appears to be that Australia still has some way to go in achieving this goal. The most significant impediments to the development of the venture capital sector in Australia are considered to be the scale of the existing venture capital industry, the relatively small pool of investment managers and the lack of a strong track record in delivering the kind of returns needed to attract major institutional investors to this high risk market.

1.6 The Productivity Commission's report, however, did not adequately explain how Biota, an Australian biopharma company that was spun-out of the C.S.I.R.O.'s development of the anti-flu vaccine (zanamivir) or Relenza as it is better known, failed to maximise the value of the product after licensing it to GlaxoSmithKline in 1990. According to Mr. Peter Cook, Biota's CEO and managing director, "the worry

for small biotech companies is that Big Pharma will acquire a product and then ‘park it.’” In 2004 Biota sued GlaxoSmithKline in the Victorian Supreme Court seeking \$700 million in damages for allegedly not adequately promoting the medicines. The law suit was settled in 2008 for \$20 million.

1.7 Despite Prof. Lamberton’s dissent, the then Minister relied on the IPAC report in drafting, what was to become, the *Patents Act, 1990*. Nonetheless, in light of Prof. Lamberton’s concerns an important question which needs to be answered, in our opinion, is: has Australia’s patent system produced a net economic and social benefit to Australia in the past 30 years? On the basis of statements like: “the patent system ... promotes innovation through encouraging the diffusion of knowledge” contained in the majority report, it would seem that the majority believe that it has. But we are not convinced. Where is the data to support this statement? Certainly, none was provided to this Committee by those that subscribed to it.

1.8 During the second reading of the *Patents Bill, 1989* on 1 June 1989, the then Minister told the Parliament that it was a “complete redraft of the Patents Act 1952, which it repeals and replaces.” He also explained that starting in 1979, when the then Minister for Productivity, the Hon. Ian Macphree announced the IPAC review of the Australian patent system, that Mr. Macphree had been “faced ... with criticisms of that complex legal and economic policy instrument which is the Patents Act.”

1.9 According to Mr. Jones, one of the major reforms ushered in by the *Patents Bill, 1989* was its “language and structure”, which he said was “down to earth, so that mere mortals without law degrees have some chance of understanding what it is all about, at least in general terms.”

1.10 Mr. Jones also acknowledged that the IPAC report did not “wholeheartedly embrace the patent system”. And while the Australian government eventually made the decision to retain the patent system, Mr. Jones said that it was not to be treated as “some kind of mysterious sacrament which has to be observed if we are to proceed along the path to economic heaven”, rather, it had to earn its way by “maximis[ing] the social benefits and minimis[ing] the social costs to Australians”, the very point made by Prof. Lamberton.

1.11 Next, Mr Jones told the Parliament that the patent system was “out of kilter” with those of its major trading partners.

1.12 Mr. Jones said that “by strengthening Australia's patent law and by incorporating more universal standards within that law”, the *Patents Bill, 1989* would place Australia “in a sounder position in relation to the negotiations in both GATT and WIPO”. He also said that “an adjustment of the standards of novelty and inventiveness” would require testing patent applications “against disclosures in documentary form anywhere in the world” and this was a desirable outcome in that it would “make it harder to get a ... standard patent” in Australia.

1.13 However, a mere 22 years later, in a report entitled, ‘Getting the Balance Right’, IP Australia has acknowledged that “Australia’s patentability standards are set

at a level that is lower than the standards set in countries who are our major trading partners” particularly in regards to the standards “for full description of inventions” and “inventive step”. The consequences, according to IP Australia are significant.

These differences potentially upset the balance between the patent system and competition. They allow the grant of broader patents in Australian than elsewhere, and they allow the grant of patents that may disclose less information about the inventions that they claim than is disclosed elsewhere. This reduces access to follow-on innovation for Australian innovators and the advantages that flow to Australian consumers from access to information about new technology and competition in the Australia marketplace.

1.14 So in much the same way as Mr Jones did in 1989 with the *Patents Bill*, the present Minister for Industry, Innovation, Science and Research, Senator the Hon Kim Carr, has done with the *Raising the Bar Bill, 2011*.

1.15 And while the *Raising the Bar Bill, 2011* has been referred to in the majority report, we question its relevance in the context of this inquiry particularly when the email that accompanied the Bill’s release to stakeholders stated that the Bill did “not deal with gene specific issues” but was seeking to “raise [specific] standards across all technologies”. The problem is, the word ‘technologies’ is something of etymological stretch.

1.16 The Oxford Dictionary defines ‘technology’ to mean “the application of scientific knowledge for practical purposes”. But genes and proteins are not technologies. They are natural phenomena. For example claim 1 of Australian Patent 686004 entitled, *In vivo mutations and polymorphisms in the 17q-linked breast and ovarian cancer susceptibility gene* is a claim to genetic mutations that are causative of breast cancer in humans. How is that a ‘technology’?

Claim 1: An isolated nucleic acid coding for a mutant or polymorphic BRCA 1 polypeptide, said nucleic acid containing in comparison to the BRCA 1 polypeptide encoding sequences set forth in SEQ.ID No: 1 one or more mutations or polymorphisms selected from the mutations set forth in Tables 12, 12A and 14 and the polymorphisms set forth in Tables 18 and 19.

1.17 A closer inspection of the Tables referred to in this claim demonstrate that the source of the “isolated nucleic acid” of claim 1 are people with breast cancer. Table 12, at page 89 of the patent specification, specifically refers to ‘patients’ and identifies them by way of a number that provides public anonymity while enabling the researchers to know the exact physical source of the genetic “mutations or polymorphisms” linked to breast cancer. That it does so is beyond argument given that another column is headed “Age of Onset”. The information contained in the table also specifies the nucleic and amino acid sequences linked to the same “mutations or polymorphisms”. Moreover, the claim itself makes no reference to, nor is it qualified by, any practical application to which the biological material may be put. It is a claim,

pure and simple, to the biological material, that is, that part of the human genome linked to breast cancer.

1.18 Our confidence in our view is fortified by the position adopted by the U.S. government, as argued by the U.S. Department of Justice in its amicus curiae brief filed with the U.S. Court of Appeals for the Federal Circuit (CAFC) in October 2010.

1.19 The brief said:

The mere fact that genes do not occur in “isolated” form in nature does not provide a principled basis for patent-eligibility. See *Intervet*, 617 F.3d at 1294-95 (Dyk, J., concurring in part). Many natural products — coal beneath the earth, cotton fibers mixed with cotton seeds, the stigmas of the saffron flower — must be physically separated, i.e., “isolated,” from their natural environments before becoming useful to mankind, but few would doubt that coal, cotton, and saffron are products of nature and not patent-eligible. Likewise, the unique nucleotide sequence that induces human cells to express the BRCA1 protein is no more an invention of appellants or NIH when captured in a test tube than in its natural context in the human body. The process of applying restriction enzymes to select and extract a naturally occurring segment of DNA in the human genome from its chromosomal environment (now well understood in the art) was undoubtedly patent-eligible when it was first conceived, and an improved process for doing so may be the subject of a patent in the future. But the isolated DNA segment itself remains, in structure and function, what it was in the human body.

1.20 Just as ‘coal’, ‘cotton fibres’ and the ‘stigmas of saffron flowers’ are not *technologies*, nether is a biological material that has been isolated, removed or extracted from the natural world *if it is identical or substantially identical to how it exists in nature*. Furthermore, if the biological material is also new or unknown, its elucidation is an act of discovery, not an act of invention. Therefore, the discovery of a hitherto unknown microbe, plant or animal or any component of each of these things, even if there is a new and practical application to which they can be put to, is not an act of invention in regard to the biological material *per se*. More is required. The U.S. Supreme Court in *Diamond v Chakrabarty* 100 S. Ct. 2204 (1980) established the requisite legal threshold for the purposes of U.S. patent law in 1980. The Supreme Court held that in genetically modifying a naturally occurring bacterium so that it would degrade crude oil, Dr. Chakrabarty had produced a new bacterium with *markedly different characteristics from any found in nature* and which had the potential for significant utility.

1.21 The fact that the process of discovery can also be expensive, risky and time consuming does not justify patenting the end result. Again, support comes from the U.S. Supreme Court. Justices Breyer, Souter and Stevens in *Laboratory Corporation of America Holdings v Metabolite Laboratories Inc* 126 S. Ct. 2921 (2006) held that a principle which “finds its roots in both English and American law” prevents patent protection extending to “laws of nature, natural phenomena and abstract ideas” not because “‘laws of nature’ are obvious, or that their discovery is easy, or that they are not useful [for] such matters [even though they] may be costly and time consuming;

monetary incentives may matter; and the fruits of those incentives and that research may prove of great benefit to the human race ... [but because] sometimes too much patent protection can impede rather than ‘promote the Progress of Science and useful Arts’”.

1.22 In other words, while an invention can be the subject of a patent monopoly, a discovery cannot be. The deep seated principle which Justices Breyer, Souter and Stevens refer to is so fundamental to the proper and legitimate function of the patent system that undermining it not only threatens the legitimacy of the patent system, but threatens our economic system, which is foremost based on free competition.

1.23 Sixteen years after IPAC’s report, the Intellectual Property and Competition Review Committee (IPCRC) examined the impact of intellectual property on Australia’s economic system. In its report, presented to both Senator the Hon. Nicholas Minchin, then Minister for Industry, Science and Resources and the Hon. Daryl Williams AM QC MP, then Attorney-General, in September 2000 IPCRC reinforced the importance of maintaining a clear division between discovery and invention. The IPCRC report stated:

The Committee considers that the goals underpinning the National Competition Policy are well served by a patent policy that rigorously distinguishes between *discoveries* that advance our understanding of the nature, structure and properties of matter, and *inventions* that apply this understanding to useful products and processes. **Within such a policy, only the latter should qualify for patent protection.** (bolding added, italics original)

1.24 While IPRCR’s report took into account the approach taken by the High Court of Australia in *The Commissioner of Patents v National Research Development Corporation (NRDC)* (1959) 102 CLR 252, it did not rely *solely* on the NRDC decision. Importantly, IPCRC went beyond NRDC because “other considerations reinforce the need to distinguish between discovery and invention”. This contrasts sharply with the more limited analysis applied by ACIP in its Patentable Subject Matter Report. The IPCRC’s report explained the serious economic consequences of blurring the line between discovery and invention:

It is important that patent rights are clearly defined in a way that the difficulty and costs for the public or a competitor to determine the scope of a patent right are kept within reasonable limits. This result would not hold were the patent right extended to discovery. In particular, although ‘discovery’ is a heterogeneous category, it seems reasonable to suppose that it can be far more difficult to define and enforce the scope of a patent claim relating to, say, a law of nature than to a particular useful application of scientific and technological principles. Moreover, with the passage of time, it becomes ever more difficult to identify the uses in which a particular principle is embodied. ***Property rights in discoveries would therefore be costly to define and implement and could give rise to unreasonable barriers to potential competitors or to those who wished to use the ‘discovery’ in other fields of endeavour. It may also add very significant burdens on scientific communication.*** (emphasis added)

1.25 As regards the ACIP Patentable Subject Matter Report, which itself sprang from one of the recommendation in the Australian Law Reform Commission's Inquiry into the patenting of human genes, ACIP's recommendation to abandon the 'manner of manufacture' test is, in view of both the IPAC and IPCRC reports, concerning.

1.26 Not only did the IPAC report specifically consider the 'manner of manufacture' test, but, having done so recommended its retention in the *Patents Act, 1990* in spite of the fact that one of the key objectives of the legislation was the use of plain, modern and, relatively, simple language. The fact that IPAC was determined, in view of this Ministerial mandate, to retain the reference to s.6 of the *Statute of Monopolies, 1623* suggests that the 'manner of manufacture' test cannot be as easily overlooked as ACIP has done. The IPAC report said this:

We consider that the existing concept operates quite satisfactorily. It has the advantage of being underpinned by an extensive body of decided case law which facilitates its application in particular circumstances. At the same time it has, in the past, exhibited a capacity to respond to new developments.

1.27 Furthermore, the IPCRC Report took the same approach 16 years later and after taking into account the operation of the *Patents Act, 1990*, over a 10 year period. IPCRC stated:

The Committee believes that Australia has on the whole benefited from the adaptiveness and flexibility that has characterised the 'manner of manufacture' test. As a result, we recommend that this test be retained.

1.28 Specifically, in the context of gene patenting, the IPCRC looked at the 'manner of manufacture' test and examined how an initiative taken by the U.S. Patent and Trade Mark Office (USPTO) could be applied in Australia to deal with the issues that gene patenting was then raising. The USPTO had proposed the implementation of 'utility' guideline for use by U.S. patent examiners in their assessment of patentability, in an attempt to reinforce the distinction between discovery and invention under U.S. patent law. That guideline has since been implemented in the U.S. The IPCRC report described the effect of this guideline as follows:

The implementation of these guidelines would preclude the patenting of discoveries for which a specific, substantial and credible use has not been defined [in the claim].

1.29 That said, in ACIP's Patentable Subject Matter Report, none of ACIP's 11 recommendations adopted the IPCRC recommendation. To the contrary, at page 13 of the ACIP report, ACIP recommended that the *Patents Act, 1990* be amended by simply repealing the 'manner of manufacture' test entirely and replacing it with a test based *solely* on the following words:

"an artificially created state of affairs in the field of economic endeavour".

1.30 What is relevant, in our opinion, is to contrast the approach of the IPCRC with that of ACIP. The IPCRC report made it clear that "a specific, substantial and credible use" of a naturally occurring biological material, such as a gene, was essential to be

part of the definition of the invention as defined in the patent claims. It was not, as ACIP recommend, a matter for the “specific, substantial and credible use” to be described in the patent specification only.

**1.31 The problem with ACIP’s recommendation is that absent a causal link between a naturally occurring biological material and “a specific, substantial and credible use” in the patent claims, the scope of patentable subject matter is broadened beyond the present ‘manner of manufacture’ test. Artificiality effectively becomes the only criterion to be satisfied in order to meet ACIP’s patentable subject matter threshold since the criterion of ‘economic endeavour’ can be assumed to apply even to an isolated DNA sequence.**

**1.32 In other words, should ACIP’s recommendation be adopted, literally anything artificial, including a human gene that has been isolated from the human genome, will be patentable subject matter if the patentee can attribute “a specific, substantial and credible use” in the patent specification as opposed to the patent claims. This means it will be possible to claim an isolated biological material as one invention and claim the specific, substantial and credible uses of those materials as other inventions. The net effect of ACIP’s recommendation is to legitimise IP Australia’s policy.**

1.33 We are of the opinion, however, that IPCRC’s approach is to be preferred over ACIP’s approach. The IPCRC report stated:

... mere discoveries - that is, the identification and specification of the nature, structure and properties of existing matter and its interaction - should continue to be excluded from the class of patentable subject matter. We consider that this principle should exclude from the scope of patent protection the mere identification of a gene sequence, much as it would preclude the granting of a patent over, say, Mendel’s law.

1.34 The point being that regardless of which test is applied, whether it be the current ‘manner of manufacture’ test or the one proposed by ACIP, the Bill which is the subject of this Inquiry seeks to impose a *per se* prohibition so that, consistent with the IPCRC’s position, the Australian patent system “should continue” to exclude from “the *class* of patentable subject matter” any subject matter that comes within the new amended s.18(2)(b) that was tabled by Senator Heffernan during the Committee hearings, namely:

biological materials whether isolated or purified or not and however made, *which are identical or substantially identical to such materials as they exist in nature.* (emphasis added)

The new amended s.18(5) which accompanied Senator Heffernan’s proposal provided new definitions:

***biological materials***, in section 18, includes DNA, RNA, proteins, cells and fluids and their components.

***identical***, in section 18, means a biological material which is structurally and functionally identical.

The reason being that these things are not the product of invention, but the product of discovery.

The new amendment in full is attached to this dissenting report as ‘Appendix A’

1.35 Artificiality should not be the sole criterion of patentable subject matter and it is incorrect, in our opinion, for ACIP to assert that the central principle of the *NRDC* decision is accurately reflected in its key recommendation particularly when this passage in *NRDC* is taken into consideration:

The statement was that fruit and other growing crops, although the assistance of man may be invoked for their planting and cultivation, do not result from a process which is a "manner of manufacture". This may be agreed. However advantageously man may alter the conditions of growth, the fruit is still not produced by his action.

1.36 The High Court in *NRDC* draws a distinction between processes that can be used in the production of naturally occurring things, such as fruit, and the naturally occurring things themselves. According to the High Court, a new process to grow fruit may be patentable subject matter, but the fruit itself is not. This is completely consistent with the Bill.

1.37 *NRDC* is often portrayed as the definitive case on patentable subject matter. However, it is important to appreciate three relevant facts about *NRDC*. First, it was decided in 1959. Next, the invention in that case had nothing to do with a naturally occurring biological material, rather it was about a horticultural process. Finally, legal controversy was whether the *effect* produced by the horticultural process, which involved the use of known herbicides to kill weeds without killing the crops over which the herbicide was sprayed, was itself capable of being patented. And while *NRDC* is an important decision with respect to the ‘manner of manufacture’ test, it must be applied in context taking into account, what IPRCR described as, “other considerations[which] reinforce the need to distinguish between discovery and invention”.

1.38 Thus, the Bill seeks to both clarify the existing patent law and overturn a policy which IP Australia adopted in 1988 and which we believe to be inconsistent with that law.

1.39 IP Australia’s policy, first developed by the USPTO in concert with the European Patent Office and the Japanese Patent Office in June 1988, has not been judicially reviewed in Australia. As a result, IP Australia has perused a policy based on an internally generated and untested interpretation of *NRDC*, an interpretation apparently shared by ACIP, which ignores the concerns expressed by IPCRC that *NRDC* was not definitive on its own and that “other considerations reinforce the need to distinguish between discovery and invention”.

1.40 Once again, our opinion is backed up by the U.S. Department of Justice which, representing the U.S. government, has criticised the very policy which the USPTO adopted in 1988. The U.S. Department of Justice states:

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Methods of identifying, isolating, and using such DNA molecules may be patented, as may any new and useful alteration of those molecules through human intervention. Genomic DNA itself, however, is a product of nature that is ineligible for patent protection, whether or not claimed in “isolated” form. *We acknowledge that this conclusion is contrary to the longstanding practice of the Patent and Trademark Office, as well as the practice of the National Institutes of Health and other government agencies that have in the past sought and obtained patents for isolated genomic DNA.* The district court’s judgment in this case, however, prompted the United States to reevaluate the relationship between such patents and the settled principle under Supreme Court precedent that the patent laws do not extend to products of nature. For the reasons below, the United States has concluded that isolated but otherwise unaltered genomic DNA is not patent-eligible subject matter under 35 U.S.C. § 101. (italics added)

1.41 And while the recent Myriad CAFC decision brought down on 29 July 2011 disagreed with the U.S. government, the 2:1 decision is now under appeal. We also take into account that judicial opinion in the U.S. is evenly divided on the issue once the original decision is taken into account. Consequently, a definitive ruling on the legality of the policy under U.S. patent law is not likely to occur any time soon.

1.42 The question for this Parliament is: should it wait for the controversy to be resolved in the U.S. or Australian courts or should it resolve the issue now by way of legislative amendment to the *Patents Act, 1990*?

1.43 A relevant consideration for the Parliament are the circumstances described in the attached media article whereby Myriad was under no compunction because of its patent rights to manufacture or provide or allow others to provide a genetic test that improved its reliability or accuracy. (see Appendix B)

## THE SUBMISSIONS

2.1 The Bill is the subject of much criticism. The criticism, however, has come mainly from sectorial interests associated with the biotechnology, pharmaceutical and agri-biotech industry. Along with Ausbiotech, the peak biotech industry association in Australia, the critics include patent attorneys, patent lawyers, research scientists, patent and legal professional associations, medical and scientific research institutes and their representative professional bodies and Australian universities who are either the holders of patents which contain claims to biological materials that are identical or substantially identical to those that exist in nature or who have acted for, procured, or benefited directly or indirectly from such patents and their procurement.

2.2 The Bill, however, is supported, as written or in principle, by a more representative section of the Australian community that includes Cancer Council Australia, Department of Health and Ageing, the South Australian government, the Human Genetics Society of Australasia, the Australian Medical Association, Meat and Livestock Ltd, Cancer Voices Australia, Cancer Voices New South Wales, the Royal College of Physicians, The Royal College of Pathologists of Australasia, the Tasmanian government, Breast Cancer Action Group NSW and the Generic Medicines Industry Association.

2.3 The Royal College of Pathologists of Australasia (RCPA), which declared in its submission that it does not “depend on revenue from gene patents” supports the intent of the Bill because:

- (a) it holds “grave reservations” over policy adopted by IP Australia.
- (b) “a person with a patent over a gene sequence can restrain another person from using that sequence to make a medical diagnosis.”
- (c) “The patent holder did not create the gene, the mutation, or the disease - but the patent holder can restrict a doctor’s freedom to make a diagnosis. This restriction is not based on the machine or process by which the doctor might make the diagnosis, but is focused on the biological basis of the disease itself.”
- (d) “The power of the patent holder in this situation compromises the very foundation of health care in this country. Such a restriction should have no place in our society.”
- (e) “biological materials which are ‘identical or substantially identical to such materials as they exist in nature’ should not be patentable. *We would go further, arguing that any substance which is identical to that found in nature should not be patentable. Such substances are discoveries, not inventions.*” (emphasis added)

2.4 On the other hand the Human Genetics Society of Australasia (HGSA) unequivocally supports the Bill because:

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- (a) “of serious concerns relating to the current operation of the patent system in relation to patenting of genes and the balance of commercial benefits of patent protection versus social, community and health impacts.”
  - (b) “identifying naturally occurring genetic material and its function is not an invention but a discovery.”
  - (c) “gene sequences are not of themselves a new ‘manner of manufacture’ and that they have more of a collaborative genesis than other inventions.”

2.5 The HGSA submission is adopted by The Royal College of Physicians in full.

2.6 The South Australian government unequivocally supports the Bill as proposed because:

- (a) “broad patent claims specifically related to human genes and biological materials, as they exist in nature, have been shown to have an adverse impact on the provision of health care, including medical research, the scope of the provision of training and accreditation of health care professionals and the cost of performing certain genetic tests within South Australia.”
- (b) it provides “greater clarity ... by ensuring that the discovery of naturally existing biological material is not patentable.”

2.7 The Department of Health and Ageing supports the “intention” of the Bill because:

- (a) “genes (or portions of genes) and biological materials that have a natural homologue (i.e. are identical to those that are ‘naturally-occurring’) are not inventions and hence should not be considered patentable subject matter.”
- (b) “The intrinsic nature and function of a gene is not altered when it is isolated, purified or cleaved to remove the regions that do not code for the formation of proteins.”
- (c) “Free access to genetic material, including the normal genome and its mutations (as well as information relating to the association of genes with disease), is essential to promote continued innovation in the prevention, diagnosis, prognosis and treatment of disease.”

2.8 Cancer Council Australia supports the intent of the Bill because it has “the potential to prevent monopolisation of genetic sequences and other biological substances that should be freely available for competitive research and to help ensure equitable access to healthcare.”

2.9 The Generic Medicines Industry Association supports the intent of the Bill because:

- (a) “the Australian pharmaceutical and biopharmaceutical industries, innovation, research, and market competition have been unnecessarily stymied because of the increasing reach of patent rights.”
- (b) “Patent monopolies regarding critical pharmaceuticals and biopharmaceuticals which have been invalidated elsewhere have either remained unchallenged in Australia (due to the relatively small size of the Australian market) or have been held to be valid in Australia (due to significant differences in Australian law). Australian industry and the Australian public have been disadvantaged and will continue to be disadvantaged if these issues are not rectified.”

2.10 Mylan, Inc a U.S. company and the world’s third largest producer of generic medicines that operates in Australia via its fully owned subsidiary, Alphapharm, supports the Bill because:

- (a) The Bill “aims to redress the imbalance in the patent framework in Australia by raising the bar for what is considered to be patentable material.
- (b) “The Bill merely seeks to clarify and apply the true intent of patent law and amend that part of the Patents Act that provides the patentability criteria for the grant of a valid patent monopoly.”
- (c) “Biological materials that are identical or substantially identical to any that exist in nature should not be patentable because they are a product of nature and have not been transformed into a product of humankind, historically regarded as a prerequisite for patentability.”
- (d) “The patenting of naturally occurring biological materials is stifling medical and scientific research as well as the diagnosis, treatment and cure of human illness and disease. Such patenting prevents doctors, clinicians and medical and scientific researchers from gaining free and unfettered access to these materials, however made, that are identical or substantially identical to such materials as they exist in nature.”

2.11 The Australian Medical Association supports the Bill because:

Allowing doctors, clinicians, and researchers free and unfettered access to such biological materials has the very real potential to facilitate greater, more competitive research into the development of genetic technologies. This would benefit patients, health care professionals, and the broader health care system by allowing more equitable access to a wider range of genetic tests and related technologies.

2.12 Meat and Livestock Limited, a producer-owned company investing \$47 million annually on meat and livestock research and development on behalf of 47,000 cattle, sheep and goat producers, supports the Bill because:

- (a) “MLA’s genetic and genomic improvement programs are encountering many of the same issues currently being debated in humans, as these same problems

also apply to gene discovery in animals and plants. More and more, we are seeing that general discoveries of nature have sought to be patented. This patenting is hampering the evolution of our research and our understanding of the underlying causes for genetic variation in animals and plants, and improvement in our national genetic improvement programs.”

- (b) “If the protection of genes and gene markers continues, it will be imperative for MLA and the research organisations involved to reassess their current strategy and investment in genetic and genomic research, development and implementation. At this point in time there are no obvious ways to avoid the loss of research effectiveness or the substantially higher transaction costs. This has the potential to stifle our ability to continually improve the productivity and sustainability of the Australian meat and livestock industry.”

## ANSWERING THE CRITICISMS

3.1 The Bill seeks to achieve two outcomes which we maintain are vitally important to the credibility of Australia's patent system. The first is to restore the full scope of the 'manner of manufacture' test as it was understood and applied in Australian patent law prior to 1994. It was this test which both the IPAC and IPCRC reports recommended be retained. The critics of this aspect of Bill have failed to address this point. The second, is to reinforce the distinction between discovery and invention in respect of one specific context. The IPCRC report made specific reference to the importance of the maintenance of this distinction only a decade ago and after TRIPS was in operation. The critics of the Bill have raised a plethora of excuses as to why this Bill should not be passed but none of them have addressed the plain simple fact that a gene and a protein which are identical to what exists in nature, regardless of its state or how it is made, is not something that anyone invented. And if there is no inventor, how can there be an invention?

### ***Overruling Anaesthetic Supplies Pty Ltd v Rescare Ltd (1994) FCA 1065 and Bristol-Myers Squibb Co v F H Faulding & Co Ltd (2000) FCR 524***

3.2 Before *Anaesthetic Supplies Pty Ltd v Rescare Ltd* (1992) 25 IPR 119 the scope of the 'manner of manufacture' test was broader in that the proviso in s.6 of the *Statute of Monopolies, 1623* was understood to empower the courts to invalidate, on the grounds of public policy, patents that failed to meet the social, economic, ethical or moral norms of Australian society. Specifically, the issue in that case was whether a method for the treatment of sleep apnoea in a human being was patentable subject matter. The *Statute* provides that a patent is invalid if the subject matter is "contrary to the Law, ... mischievous to the State, by raising Prices of Commodities at home, or Hurt of Trade, or generally inconvenient".

3.3 In *Rescare*, Justice Sheppard, in dissent, held that it was not. He held that even though the Parliament had not in the *Patents Act, 1990* expressly banned patents over medical methods, as it had done with regards to process for human cloning (s.18(2)), it did not mean that the courts were not empowered to rely on the proviso to do so. In his opinion, it was "not going too far" in circumstances where the exercise of a patent owner's exclusive patent rights over the use of an invention "might mean the death or unnecessary suffering of countless people", to rely on the proviso to invalidate the patent. In his view the technology in issue and the human disease itself, which he believed to be "life-threatening", meant that a patent that sought to monopolise this method of human treatment was not 'manner of manufacture'.

3.4 Justices Lockhart and Wilcox, however, disagreed. Wilcox J. explained "that, in the face of apparently deliberate decisions by Parliament not to build this particular exclusion into its legislation, courts should be hesitant to introduce the exclusion by reference to those very general principles."

3.5 Six years later in *Bristol-Myers Squibb Co v F H Faulding & Co Ltd* the Full Federal Court followed *Rescare*. In doing so, the Court overruled the decision of

Justice Heerey who, in attempting to apply the proviso, invalidated a patent over a method for the administration of taxol on the ground that it was not a ‘manner of manufacture’. Taxol was a well known chemotherapeutic, first discovered in 1977, but which was not approved for use in the treatment of breast cancer until 1994. It is important to appreciate that there was nothing new in taxol *per se* nor in its use as a chemotherapeutic drug.

3.6 Claim 1 was as follows:

A method for treating cancer in a patient suffering therefrom including infusing from 135 to 175 mg/m<sup>2</sup> of taxol over a duration less than 6 hours wherein said method results in a reduction of hematological toxicity and neurotoxicity compared with infusing greater than 170 mg/m<sup>2</sup> of taxol over a duration of 24 hours.

3.7 The claim was to a method of human treatment defined by (a) the length of time over which taxol was administered and (b) the actual dosage. Apparently, the new dosage regime provided some benefits to patients but it was, at best, an incremental advance not a medical breakthrough.

3.8 The trial judge, Heerey J., made that very point in deciding that it was not a ‘manner of manufacture’:

At the priority date the material (taxol) had been known for many years. *It is a naturally-occurring compound and thus in itself unpatentable*. In the words of the specification, taxol had “shown great promise as an anticancer drug” and “been found to be an active agent against drug-refractory ovarian cancer” ... . The properties which made taxol effective against cancer, that is to say its biological mechanism, were well known. They had been discussed in the articles referred to in the specification which were “incorporated by reference as if reproduced in full below” ... . Thus the specification is not merely a claim of a “new use of an old substance” ... but a claim for the same use of an old substance. (italics added)

3.9 It is important to note that the trial judge had made findings of fact based on the evidence presented at the trial that the patent sought to monopolise, via a method claim rather than a product claim, a substance (which was derived from a biological material found in the bark of a Pacific Yew tree) that was neither new nor inventive if the *use* of that substance was directed to a specific form of human treatment. In other words the trial judge had formed the view that there was no merit in the patent sufficient to warrant the grant of a patent monopoly.

3.10 The Full Court, however, disagreed. According to Black C.J. and Lehane J., “drawing a logical distinction which would justify allowing patentability for a product for treating the human body, but deny patentability for a method of treatment was an insurmountable problem”. Finklestein J. merely took the view that it was “not the function of a court [to adjudicate] on an issue such as this ... [and] if public policy requires a different result, it is for the Parliament to amend the 1990 Act”.

3.11 As a consequence of *Rescare* and *Bristol-Myer* decisions the Federal Court effectively repealed the proviso in s.6 of the *Statute of Monopolies, 1623* thereby negating an important check and balance in the patent system that had been a part of the ‘manner of manufacture’ test for nearly 400 years.

3.12 This result, however, was inconsistent with the Parliament’s intent. As the then Minister, the Hon Barry Jones MP, said during the second reading speech, one of the main objectives of the *Patents Bill, 1989* was to “make it harder” to get a patent. Another was to “maximise the *social* benefits and minimise the *social* costs to Australians”. (emphasis added) The fact that s.18(2) expressly banned patents over human cloning, introduced into what became the *Patents Act, 1990* by an amendment moved by Senator Harradine, did not, with respect, override these two central objectives nor provide the courts with a mandate to ignore the full scope of the ‘manner of manufacture’ test.

3.13 These two decisions did the exact opposite by first making it easier to get a patent and second by ignoring the net social impact on the Australian people.

3.14 Far from being “superfluous”, a charge made by Prof. Natalie Stoianoff, Dr. Ann Kurts and Dr. Mark Lutherborrow from the University of Technology, Sydney and relied on by the committee as a point of criticism, the passage of this aspect of the Bill will restore both the original intent of s.18(1)(a) *Patents Act, 1990* and full scope and operation of the ‘manner of manufacture’ test.

3.15 The committee in the report stated:

“Professor Dianne Nicol, Mr Johnathon Liddicoat, Dr Jane Nielsen and Mr Ben Mee considered that the change would “add nothing to the development or state of the law relating to ‘manner of manufacture’ and would not achieve any paradigm shift in the relevance of social and ethical dimensions to determinations of patentability’.”

3.16 But this criticism, respectfully, misses the point because this aspect of the Bill is not seeking to “add” something new or revolutionary to the operation of the *Patents Act, 1990*, rather it is merely seeking to restore an important check and balance and one that was never intended to be removed in the first place. Once it is restored this check and balance will, once again, be available to the courts and to apply the law, this time, with the benefit of an amendment that overrules these two Federal Court decisions.

3.17 In regards to the committee’s reference to the joint submission by the DIISR and IP Australia and to the ACIP Patentable Subject Matter Report, we are of the view for the reasons already provided that the IPAC and IPCRC reports and recommendations on this issue are to be preferred.

### ***Exclusion of biological materials***

3.18 The central criticism of the second or principle aspect of the Bill, which is contained in the proposed s.18(2)(b) to the *Patents Act, 1990*, is that the terms

‘derivatives’, components’ and ‘substantially identical’ are undefined and thereby open to a variety of judicial interpretations that could, according to Professor Dianne Nicol, Mr Johnathon Liddicoat, Dr Jane Nielsen and Mr Ben Mee “have far-reaching or limited effect”.

3.19 Related to that criticism is that the term ‘biological materials’, which is defined, would “introduce substantial and wide ranging uncertainty in the Patents Act 1990 arising principally from the scope and potential impact of these proposed amendments, particularly in relation to the ambiguity, or lack of clarity which exists in relation to most of the terminology to be introduced”.

3.20 We are, however, of the opinion that while the Bill provides the courts with scope to interpret and apply these terms in the context of the *Patents Act, 1990*, these criticisms are exaggerated. Every day in the Parliament legislation is passed that is open to judicial scrutiny and interpretation. The fact that there is no iron clad guarantee that the courts will necessarily apply the law as intended or proposed does not mean that Parliament does not pass legislation. Nor that it passes legislation that is so prescriptive so as to leave the courts with no ability to do their job. It is frankly absurd to suggest that the courts will not be able to, with the benefit of submissions from learned counsel, come to a workable definition of these terms that is also consistent with Parliament’s intention. Indeed, it does so happen, as we explain in the case of *Rescare* and *Bristol-Myers* decisions, that sometimes the courts do get it wrong. But when they do Parliament is always there to right that wrong if the Parliament deems it necessary to do so.

3.21 As Dr. Palombi explained, the term ‘substantially identical’ is undefined in the *Trade Marks Act, 1995* but that was not a reason not to pass that legislation, nor has the lack of a definition created legal uncertainty in the courts.

3.22 Regardless of the fact that we believe the Bill as originally introduced meets the criticisms, it was decided to reformulate s.18(2)(b) and the relevant definitions in s.18(5) in a new amendment. This amended version of the Bill is, as already stated, attached to this dissenting report.

3.23 In so doing the terms ‘derivatives’, ‘components’ and ‘substantially identical’ are deleted from s.18(2)(b) and a definition of ‘identical’ is inserted in s.18(5) so as to make it clear that the scope of the express exclusion is directed to only those biological materials that are structurally and functionally identical.

3.24 Accordingly, a biological material that is structurally identical to one that exists in nature but is functionally different will fall outside of the scope of the express prohibition. This means that if a biological material can be made to function in a way that it did not function in nature that biological material with its new function will be patent eligible.

3.25 This is the kind of outcome which we expect would have resulted with the original Bill had an Australian court been given the opportunity to interpret the term ‘substantially identical’.

***Increased possibility of litigation***

3.26 It follows, respectfully, that litigation goes hand-in-glove with legislation. Everyday the courts are called upon to adjudicate disputes involving litigants who take different approaches to the same legislation and invite the courts to prefer one interpretation over another. For this committee to take seriously the assertion by Ausbiotech that the Bill will lead to a “frenzy of legal activity” and use that to criticise the Bill is to ignore this fact.

3.27 In any event, patent litigation is not new. In fact the patent system heavily relies on patent litigation to filter out patents that may be invalid. The *Patents Act, 1990* in s. 20(1) expressly denies any guarantee of validity in regard to a granted patent so as to encourage the use of the courts as a filtering process.

3.28 The claim by Prof. Dianne Nicol, Mr. Johnathon Liddicoat, Dr. Jane Nielsen and Mr. Ben Mee that the Bill will be the subject of “protracted and expensive litigation” appears to ignore the fact that nearly all patent litigation is protracted and expensive. The criticism by the patent attorney and law firm Griffith Hack, that “there will be many millions of dollars wasted on patent attorney and lawyers’ fees debating the interpretation of the exclusion, money that would be better spent on research and commercialisation”, appears to ignore the significant costs already inherent within the patent system.

3.29 Millions and millions of dollars each year are spent by litigants embroiled in patent litigation, yet this is probably the first time that the cost of patent litigation has been seriously advanced as an excuse not to pass patent-related legislation.

***Efficacy of the Bill***

3.30 What are the Bill’s objectives? First to restore the ‘manner of manufacture’ test to how it was originally intended by overturning *Rescare* and *Bristol-Myers*. Second, to prohibit the patenting of any biological material that is identical or substantially identical to what exists in nature. In our opinion, the Bill achieves both of these objectives.

***Need for the Bill***

3.31 Since 1988 IP Australia has pursued a policy leading to the grant of thousands of patents over biological materials that no one invented. These materials have been isolated from their natural environments or have been synthetically duplicated through some biotechnological process. Either way, in these states the biological materials are identical or substantially identical to those that exist in nature either structurally or functionally.

3.32 The submissions referred to earlier (paras 2.3 – 2.14) provide evidence of the problems caused by these patents. In addition evidence provided to the Senate Community Affairs References Committee also showed specifically how patents of

this kind have delayed or interfered with medical and scientific research into BRCA 1 and BRCA 2 genetic testing. The majority report simply ignores this evidence and prefers the submissions of Ausbiotech and GlaxoSmithKline. We, however, do not. In our opinion, there is ample evidence to show that patents of the kind in issue have been and continue to be problematic particularly when they interfere with the provision of medical services.

3.33 The majority report did not appear to take account the evidence that clearly pointed to serious and fundamentally important health security concerns. For example, Dr. Palombi, in submissions made to the Senate Community Affairs References Committee and to this Committee, gave evidence of a number of instances of how patents of this kind have interfered with or restricted access to diagnostic tests or medical treatment going back to the early 1990s when Chiron Corporation was granted patents over the hepatitis C virus (HCV). In this case the Australian patent over HCV prevented Australia doctors and clinicians from developing their own diagnostics. The patentee simply refused to permit anyone other than its licensing partners from making HCV diagnostics, but there was a serious issue of the reliability of the Chiron licensed HCV tests. In fact, so serious was the issue that the Ass. Prof. Locarnini, the then Director of the Fairfield Infectious Diseases Hospital, said at the time (1995):

Blood banks in Australia and elsewhere are losing blood donors permanently. This means that the source of blood needed on a daily basis by the Australian community and other communities, is being seriously threatened. Once a blood donor is labelled as an HCV-indeterminate or HCV positive, their blood is excluded from the blood supply, even though they maybe truly negative for HCV. In other words, blood donors are being falsely labelled as 'HCV positive' when in fact they are not because of the inadequacies of the present anti-HCV test kits.

The fact that third generation anti-HCV test kits are giving such results is really saying something: it means in a low risk group such as blood donors, the present generation anti-HCV tests are detecting something other than HCV and giving false positive results in up to 75% of cases. It has been five years since the first anti-HCV test kits were first used in Australia and the manufacturers of these kits have not yet produced a kit which is as sensitive and specific as the test kits for HIV. This is clearly unsatisfactory.

3.34 In another example, Dr. Palombi provided evidence about the denial of medical services to infants at Westmead Hospital, western-Sydney's main public hospital. In this case infants were denied access to a genetic test for Dravet syndrome, a severe form of epilepsy, because of a patent over the genetic mutations to the human SCN1A gene linked to the disease. The patent was granted by IP Australia to Bionomics, an Australian company, which in turn granted an exclusive license to Genetic Technologies, another Australian company. The denial of service occurred in spite of the fact that over \$1 million of Australian taxpayer funds had been provided to both an Australian University in the research leading to the identification of the relevant genetic mutations and to Bionomics for the subsequent development of a genetic test. Part of the evidence provided by Dr. Palombi was an article published in the Sydney

Morning Herald on 29 November 2008. An excerpt from that article, entitled, ‘Sick babies denied treatment in DNA row’ is as follows:

Specialists are sending blood samples to Scotland, and only babies whose seizure patterns closely resemble Dravet syndrome are tested. This means children with slightly different symptoms may be treated with the wrong medicines for months, potentially retarding their development. “It’s frustrating that we can’t get the test done readily,” Dr. Gill said. “If we could include it as part of the work-up, we could identify them early.” At present the diagnosis is often delayed until the child is 12 to 18 months old. This is after the optimum time for treatment with strong drugs that are unsuitable for most babies with epilepsy but are used for infants with Dravet’s to control severe seizures that can damage the brain. Standard childhood epilepsy medications are ineffective with Dravet’s and may worsen it, Dr. Gill said.

SCN1A is the most important epilepsy gene discovered, Dr. Gill said, and is abnormal in about 70 per cent of children with Dravet syndrome, which affects about one in 30,000 babies - almost 10 per cent of infant epilepsy cases. About one in 20 children have a seizure when they develop a fever, though only a minority had epilepsy, Dr. Gill said.

3.35 Far from being a diminishing problem, Prof. Ian Olver OA, CEO of Cancer Council Australia, believes the problem is only going to get worse as medical treatments become tailored to an individual patient’s genetic make up. In evidence he gave to the Senate Community Affairs References Committee in August 2010, Prof. Olver stated:

The position of the Cancer Council of Australia and the Clinical Oncological Society of Australia is that ... we need to change the law to reflect what we regard as a common sense approach. The timing of this is absolutely critical since genes and their products are increasingly going to become the targets of new treatments for a range of diseases. If I stick to cancer, we are seeing a paradigm shift in cancer treatments towards targeted therapies—and the targets are genes and gene products. We are going to see hundreds more of these over the next decade, so a change now would protect us before the floodgates open.

***Investment in research and development in pharmaceuticals and biotechnology – the need for patent protection***

3.36 The majority report relies heavily on evidence from DIISR, IP Australia, Ausbiotech, Medicines Australia, CropLife, Roche, Pfizer, Chemskill, the Institute of Patent and Trade Mark Attorneys and Prof. Dianne Nicol, Mr. Johnathon Liddicoat, Dr. Jane Nielsen and Mr. Ben Mee to criticise the Bill on the basis that it will have a negative impact on investment in research and development in the pharmaceutical and biotechnology industry in Australia.

3.37 Medicines Australia, for instance, produced a list of 28 medicines which it asserts would be threatened by the Bill.

3.38 Pfizer asserts that “a ban on the patenting of all genetic material and derivatives in Australia would halt commercial development and supply and access to a wide range of innovative medicines and health technologies in Australia”.

3.39 Roche asserts that clinical trials would be threatened in Australia.

3.40 Ausbiotech asserts that “the absence of patents for biological materials will be a serious disincentive for foreign and domestic private investors and others interested in commercialising innovation in Australia.”

3.41 However, these assertions are misleading, exaggerated and are made without any objective analysis of the scope of the Bill or the kinds of patents that which will be impacted by the Bill. And unfortunately the majority report has been led into drawing erroneous conclusions based on this evidence.

3.42 For example, the list of medicines provided by Medicines Australia (Table 1 at para 4.87, majority report) is supposed to back up the claim, made by Medicines Australia, that “it is uncertain whether these medicines would be eligible for patents in Australia if this bill becomes law”. The assertion is, however, made without any explanation as to how precisely the Bill, if passed, would preclude these medicines from being be patent eligible. The language of the Bill in the proposed s.18(2)(b) is not directed to medicines. It does not say that a medicine which can treat a human being suffering from a specific disease or ailment is precluded from patentability. Rather the proposed s.18(2)(b) refers only to “biological materials ... *which are identical or substantially identical to such materials as they exist in nature.*” The words in italics qualify and narrow the scope of the prohibition to only biological materials that meet that specific criteria. Accordingly, biological materials that are materially different to what exists in nature, or medicines that contain such biological materials, would not be excluded from patentability.

3.43 Indeed, neither would medicines that contain naturally occurring biological materials, even if identical or substantially identical to those that exist in nature as a component, because medicines used to treat a specific human disease or ailment do not exist in nature. The majority report appears not to have taken account of this information and has instead relied on many unsubstantiated claims or comments that have provided little substantive analysis.

3.44 In 1618 (before the genesis of the modern Anglo-American patent system in 1624) the London *Pharmacopoeia* taught that natural biological materials could be used as medicines when isolated (that is, when removed from their natural environment) and purified (subjected to a process of purification). Strychnine, morphine, atropine and colchicines were all developed during the 19th century applying this very idea. The active ingredient of Aspirin, the famous trade mark applied to a drug containing acetylsalicylic acid, is a derivative of salicin, a substance found naturally in the bark of a willow tree. Salicin-rich plants had been known for thousands of years to be useful in the treatment of fever, pain and inflammation. However, in 1838, the Italian organic chemist, Raffaele Piria, converted salicin into

salicylic acid and although more effective (as a medicinal ingredient) than salicin it produced unpleasant side effects. It was not until 1897, when Bayer chemist Felix Hoffmann converted salicylic acid into acetylsalicylic acid, that the side effects were eradicated. In 1898 Bayer applied for patents over acetylsalicylic acid and in February 1900 the United States Patent and Trade Mark Office (USPTO) granted Bayer US patent 644,077. In the Bayer patent Hoffmann did not claim to have invented salicin; indeed, no mention is made of salicin nor the natural source of salicin. Rather, Hoffmann describes his invention by distinguishing it from an earlier attempt by another German chemist, Karl Kraut, to produce acetylsalicylic acid. Hoffmann declared in the patent:

According to my researches the body obtained by means of my new process is undoubtedly the real acetylsalicylic acid. Therefore the compound described by Kraut cannot be the real acetylsalicylic acid, but is another compound. In the following I point out specifically the principal differences between my new compound and the body described by Kraut.

It is important to note that Hoffmann was describing a new product that did not exist in nature. It was not merely a matter of isolating and purifying salicin from the bark of the willow tree. Apart from the fact that this kind of extraction had been done for thousands of years and therefore was not inventive, Hoffmann's claim to invention focused on the new process which when applied to salicylic acid (an artificial derivative of salicin) produced "the real acetylsalicylic acid". Thus the invention was a new artificial product produced by a new artificial process. The two were inseparable and Hoffmann's patent was to acetylsalicylic acid manufactured by the specific process he had invented and disclosed in his patent. It was not to acetylsalicylic acid *per se*. And, as already noted, it most certainly was not to salicin, that natural source of acetylsalicylic acid. This is an important point of distinction in the context of the patents in issue because the inventions which are claimed by these patents, and which the Bill is directed to, are to nothing more than isolated genes, proteins and other naturally occurring biological materials. The genes and the proteins which they code for are, apart from being in an artificial environment, substantially identical structurally and functionally from those from which they have been derived.

3.45 It is important to understand that patents of the kind in issue contain claims that cover not merely biological materials *per se* which have been isolated or purified or synthesised by some biotechnological process. These claims are merely the beginning. And it should be noted that the biological materials covered by these claims have no prophylactic, therapeutic or curative properties in themselves. They are claims to either to isolated or purified nucleic acids or amino acids that are identical or substantially identical to those that exist in nature.

3.46 For example, the claim at para 1.13 is reproduced to illustrate the point:

Australian Patent 686004 entitled, *In vivo mutations and polymorphisms in the 17q-linked breast and ovarian cancer susceptibility gene*:

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Claim 1: An isolated nucleic acid coding for a mutant or polymorphic BRCA 1 polypeptide, said nucleic acid containing in comparison to the BRCA 1 polypeptide encoding sequences set forth in SEQ.ID No: 1 one or more mutations or polymorphisms selected from the mutations set forth in Tables 12, 12A and 14 and the polymorphisms set forth in Tables 18 and 19.

This is not a claim to a medicine. In fact, the genetic sequence defined in the claim is linked to breast cancer. Essentially, this claim defines the invention to be a genetic trigger of breast cancer.

3.47 This claim, however, is only 1 of 30 claims. In addition to this claim are claims to the use of the biological material in genetic tests as well as other claims to methods and other biological materials which are not identical or substantially identical to those that exist in nature. These claims would not be affected by the Bill. In fact, if the Bill had been in operation at the time this patent was filed, 24 of the 30 claims would have been untouched by the Bill. (See Schedule A)

3.48 The 24 remaining claims enable Myriad Genetics, the patent owner, to exploit the invention as defined in each of these claims.

3.49 Neither will the Bill prevent the patenting of new, novel and inventive uses of naturally occurring biological materials in products, methods or processes. The freedom to operate and patent inventive medicines, therapeutics, diagnostics and cures remain untouched by the Bill.

3.50 Whatever incentive is provided by the Australian patent system in regards new and inventive medicines, therapeutics, diagnostics and cures remain open and available.

3.51 Further support for our view comes from the U.S. government's amicus brief (para 1.19) particularly as the United States is home to some of the world's largest biotechnology and pharmaceutical companies including Amgen, Genentech (owned by Roche), Novartis, Merck and Monsanto.

3.52 Despite the CAFC decision, handed down in the United States on 29 July 2011 reversing the earlier decision of Judge Sweet invalidating U.S. patents granted to Myriad Genetics over the mutant BRCA nucleic acids and proteins, the issue is far from being legally resolved.

3.53 On 25 August 2011 the American Civil Liberties Union (ACLU) acting for the plaintiffs in *Association for Molecular Pathology et al v Myriad Genetics and others* filed a Petition for Panel Rehearing with the CAFC. As a result the CAFC decision of 29 July is neither final nor definitive as a matter of U.S. law.

3.54 The Petition for Panel Rehearing summarises the grounds as follows:

... the majority erred in analyzing the chemical structure of the patented genes and gene fragments without considering (1) that the language of the

patents defines the function, not the structure of the patented genes and gene fragments; (2) that gene fragments with the altered chemical structure identified by the Court exist in nature.

3.55 The issues raised by the Petition for Panel Rehearing is precisely the issue that the Bill attempts to resolve through legislative means in Australia. And the U.S. government supports this position.

3.56 The U.S. government stated in the U.S. Department of Justice's Amicus Curiae Brief to the CAFC the following:

The extent to which basic discoveries in genetics may be patented is *a question of great importance to the national economy, to medical science, and to the public health*. This appeal consequently implicates the expertise and responsibilities of a wide array of federal agencies and components, including the Patent and Trademark Office (PTO), the National Institutes of Health (NIH), the Antitrust Division of the Department of Justice, the Centers for Disease Control and Prevention, the Office of Science and Technology Policy, and the National Economic Council, among others. (emphasis added)

3.57 We believe that the U.S. government's concern that the resolution of this issue is a "matter of great importance", not just to the U.S. biotechnology industry and the legal, scientific and university communities that are associated with it, but to "the national economy, to medical science, and to the public health". This aspect has been brushed over or minimised in the majority report.

3.58 IP Australia's policy has, as the evidence presented to both to this committee and to the Senate Community Affairs References Committee shows, negatively and seriously impacted on Australia's national economy, medical science and public health. It is vitally important that the interest of the *entire* Australian community be balanced against the interests of one industry sector. This balancing act is critical to the future of this country, its people and cannot be resolved satisfactorily, as the majority report recommends, by ignoring the social and ethical problems it has caused on the basis of an unsubstantiated theory, that patents drive innovation, and the unfounded fear, that without patent protection the Australian biotechnology will ceased to be. Particularly when this policy has over the past 30 years permitted the grant of thousands of patents over naturally occurring biological materials, none of which have been invented, under the guise of untested legal reasoning

3.59 Moreover, as the U.S. government has argued, it is a matter of common sense that the biological materials which this Bill is directed to, are not patentable subject matter. The U.S. government's reasoning is summarised in the following passage from the Amicus Curiae Brief:

The discovery of any number of basic natural phenomena could be recharacterized as the "invention" of an isolated "manufacture" or "composition of matter" under section 101. For example, many highly reactive elements on the periodic table, such as lithium, occur in nature only in chemical compounds (i.e., salts). Not until 1818 was lithium, which has

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innumerable industrial applications, first isolated in metallic form by Sir Humphry Davy and W.T. Brande. See Krebs, *The History and Use of Our Earth's Chemical Elements: A Reference Guide* 48 (2d ed. 2006). That accomplishment marked a significant achievement in chemistry, but it did not entitle Davy and Brande to claim a patent on the third element in the periodic table. Cf. *Funk Brothers*, 333 U.S. at 130 (the “qualities of metals” are “part of the storehouse of knowledge of all men”). Courts in the early part of the 20th century repeatedly rejected claims for isolated natural elements as new “manufactures.” See *Gen. Electric Co. v. De Forest Radio Co.*, 28 F.2d 641 (3d Cir. 1928) (pure ductile tungsten, though previously thought impossible to produce, held unpatentable as a product of nature); *In re Marden*, 47 F.2d 957 (CCPA 1931) (same, pure ductile uranium); *In re Marden*, 47 F.2d 958 (CCPA 1931) (same, pure ductile vanadium); cf. *In re Seaborg*, 328 F.2d 996 (CCPA 1964) (upholding patent for element 75, americium, which does not occur in nature). The unacceptable implication of appellants’ argument is that these cases were wrongly decided.

3.60 The U.S. government’s reasoning, once again, fortifies us in our dissent and should be a reminder to the majority that no matter how bleak a picture those opposed to this Bill have painted in terms of the potential negative impact on the biotechnology sector, which we believe is grossly exaggerated, this Parliament should be comforted by the position of the U.S. government on this issue.

#### ***Australia’s international obligations***

3.61 For the same reasons it is unlikely the U.S. government would have adopted the position it has on the issue, if there was any merit to the argument that its position would contravene either TRIPS or the AUSFTA.

3.62 Prof. Drahos and Dr. Palombi have explained to this Committee, both in submissions and in evidence, that TRIPS and the AUSFTA provide a minimum requirement that patents be granted for what is an ‘invention’ and then only if the invention is novel, involves an inventive step and is industrially applicable.

3.63 It is common sense, for the reasons stated earlier, that biological materials identical or substantially identical to what exists in nature, regardless of their physical state, are not inventions in themselves.

#### ***The European Biotechnology Directive***

3.64 This Committee was referred the European Parliament’s passage, in 1998, of the European Biotechnology Directive. The Directive mandated E.U. members to amend their patent laws so that an isolated but otherwise identical biological material or those synthesised through a “technical process”, are to be deemed to be patentable subject matter under art. 52.1 of the European Patent Convention.

3.65 While it is a matter for the European Parliament to make laws as it sees fit for the E.U., it is a matter for the Australian Parliament to make laws as it sees fit for Australia, subject to meeting Australia’s international obligations for Australia. We,

therefore, are cautious of arguments advanced to this Committee that the Directive is persuasive, or should be, on this Parliament given the U.S. government's stand on the issue.

3.66 Moreover, it must be appreciated that the Directive mandated a change of law in 1998, amid great controversy that was unresolved until 2006 and 10 years after the decision of the U.K. Court of Appeal in *Genentech v Wellcome* [1989] RPC 147, in this case the entire patent, granted to Genentech over a synthetic human protein, human tissue plasminogen activator (t-PA) and its process of manufacture, was wholly invalidated.

3.67 The principal product claim of Genentech's t-PA patent defined the invention to be "recombinant human tissue plasminogen activator essentially free of other protein of human origin". It was a claim to synthetic t-PA. And it clearly was a claim to both purified and isolated t-PA. Yet the Court held that synthetic T-PA was not something that could be patented under the European Patent Convention (as it was prior to the Directive). And, reinforcing the point, Lord Justice Mustill held that the word "recombinant" did not describe "the product itself, but its history". In his opinion, to differentiate t-PA produced by recombinant means from naturally occurring t-PA was misleading because it suggested that "[the] protein molecules with the amino acid sequences shown ... and the functional characteristics set out in the [patent] specification" were new, when in fact they "have existed since far into the distant past". Neither was he convinced that the technical process used to mass produce purified t-PA resulted in a product that was any different from the t-PA produced by the human body, concluding: "[t]he t-PA which Genentech made [was] neither more nor less than t-PA".

3.68 The Appellate Committee House of Lords cited *Genentech v Wellcome* with approval in another biotechnology patent case, *Biogen v Medeva* [1997] RPC 1. Lord Mustill, as he then was, held as follows:

Certainly, in the great majority of cases, there will be no need to complicate the enquiry by looking outside the four conditions. The traditional law of patents is, however, in the course of adapting itself to new technologies, beyond contemplation when the foundations of that law were established. This process is not without strain, and I believe that in some instances a close conceptual analysis of the nature of patentability will not be a waste of time. Such a case was *Genentech Inc's Patent where the claim was for a product already existing in nature*, a subject far distant from the mechanical and chemical inventions to which so much of traditional patent law relates. There may well be others in the future. (italics added)

3.69 Again, the Appellate Committee House of Lords in *Kirin-Amgen Inc v Hoechst Marion Roussel Ltd* [2005] RPC 169 held that a claim to a synthetic human protein, erythropoietin, was invalid because it was not new in that it already existed in the human body.

3.70 In regards to the structure of human protein erythropoietin, a 1989 decision of a U.S. Federal Court makes it unquestionably clear that the identity of the synthetic protein to the natural protein is exactly the same. The Court held:

... the overwhelming evidence, including Amgen's own admissions, establishes that [natural erythropoietin] and [recombinant erythropoietin] are the same product. The [erythropoietin] gene used to produce [recombinant erythropoietin] is the same [erythropoietin] gene as the human body uses to produce [natural erythropoietin]. The amino acid sequences of human [natural erythropoietin] and [recombinant erythropoietin] are identical. ... There are no known differences between the secondary structure of [recombinant erythropoietin] produced in a Chinese hamster cell and [erythropoietin] produced in a human kidney. Amgen's own scientists have concluded that by all criteria examined, [recombinant erythropoietin] is the "equivalent to the natural hormone."

3.71 In other words, the Directive was a legislative enactment of the joint USPTO, EPO and JPO policy – a policy that was not at the time it was formulated in accordance with the European Patent Convention as interpreted and applied by the U.K. Court of Appeal and the Appellate Committee of the House of Lords.

3.72 This suggests to us, absent a similar amendment to the *Patents Act, 1990*, as effected by the Directive in terms of European patent law, the Bill is consistent with current Australian patent law.

#### ***Crown use, compulsory licensing and experimental use – freedom to operate***

3.73 Crown Use and Compulsory Licensing provisions have been contained in all three Australian patent legislations since Federation. The origin of the policy for these provisions is to be found in the patent laws of Great Britain – laws that provided the template for the *Patents Act, 1903* and the *Patents Act, 1952*. The legal connection between Australian and British law, however, was severed in 1977 when the British Parliament passed the *Patents Act, 1977 (U.K.)* as a result of Great Britain joining the European Community in 1973.

3.74 The *Patents Act, 1990* therefore represented a break from its legislative predecessors. Nonetheless, the Crown Use and Compulsory Licensing provisions were retained. In regards compulsory licensing the IPAC report stated the following:

The next matter considered is the focus of compulsory licensing provisions in patent law on what are permissible or desirable ways in which a patent may be exploited, and in particular on local manufacture or "working" as against importation. *We conclude that the existing provisions should be retained, observing that they take account of both the possible desirability of local working and the fact that local demand may be met satisfactorily by importation.* In addition, a compulsory licence ought to be available notwithstanding that the prospective licensee wishes to exercise the licence by importation. The court should have a discretion to order transfer of related know-how as part of the reasonable terms on which a compulsory

licence is granted. Compulsory licences should be made a remedy available in actions under the Trade Practices Act.

3.75 However, in 1995 Australia joined the World Trade Organization (WTO). Accordingly, Australia accepted TRIPS and since then has signed and ratified AUSFTA. Both of these international agreements have imposed stringent limitations on the scope of compulsory licensing.

3.76 Prof. Drahos, a recognised world leader on the subject of intellectual property and trade law advised the Committee as follows:

Relying on crown use/compulsory licensing provisions is not a politically feasible strategy. The US has been a great critic of the use of these provisions and has brought trade pressure to bear on countries that have gone down this path (eg Thailand). It is true that China and Brazil have been prepared to confront the US in the WTO over trade disputes concerning intellectual property, but one wonders whether Australian political leaders would be prepared to tread this same confrontational path. By enacting the Bill, Australia would be taking an option that is supported by the US administration. It follows that it would also minimize the risks of a trade confrontation with the US over the patenting of biological materials.

3.77 We are of the opinion that Prof Drahos is correct in his assessment and, accordingly, the possibility that any Australian government will make use of crown use or compulsory licensing to ameliorate the worst effects of these kinds of patents is very low. While we accept that there may be exceptional circumstances where an Australian government may be persuaded to use these provisions, for example, in the event of a pandemic or military hostilities, the historical evidence does not support the majority report's conclusion that these provisions "can effectively influence patent-holder behavior".

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## CONCLUSION

The Australian patent system has operated since 1903. Since that time no Australian government has undertaken a thorough economic assessment of its net effects on the Australian economy. The latest iteration of the patent system, in the form of the *Patents Act, 1990*, came from a review that was criticised by the only economist on the panel of experts. Despite the concerns that he raised about the lack of any empirical data or analysis, the then Australian government decided to maintain the patent system. Since then there has been an explosion in the growth of intellectual property around the world and since 1995 intellectual property has been included in international trade talks. Throughout this Inquiry the Committee received many submissions about the Australian patent system, how it operates to encourage innovation and how patent protection is seen as vital to medical and scientific research. The problem, however, is that there is no data to substantiate any of these claims or counter-claims.

Regardless, patents are today recognised as a form of property, albeit with a 20 year sunset clause. And as a form of property can be valued, traded and transferred, it follows that they are legal instruments that provide their owners with the power to exclude all others from exploiting the property defined in the patent claims. That said, what can be made the subject of this form of property is limited to something that is an invention. Indeed, it is the act of invention that provides the justification for the grant of a property right.

But since 1988 that justification has been the subject of potential abuse. The patenting of naturally occurring biological materials on the pretext that they are in an artificial state or artificially made has stretched the credibility of the patent system and now poses a threat to its very existence. It is for this reason that this Bill is so important. It seeks to recalibrate the system in one specific way. In doing so it does not address many other issues that hang, unresolved, over the patent system. And it is not meant to. Ultimately whether the patent system continues and on what terms is a matter for decision after a thorough economic assessment has been undertaken and completed. However, until that assessment has occurred, we must work with what we have. Accordingly, to the extent that it is possible for this Parliament to put the Australian patent system back on track it should do so. It is for this reason that we dissent and recommend to the Parliament that it pass the Bill.

**Recommendation: The Senate should pass the Bill with the attached amendment.**

**Senator the Hon Bill Heffernan**  
**Liberal Senator for New South Wales**

**Senator Rachel Siewert**  
**Greens Senator for Western Australia**

**Senator Nick Xenophon**  
**Independent Senator for South Australia**

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**Appendix A**  
**Schedule 1— (New) Amendment of the Patents Act 1990**

**1 Paragraph 18(1)(a)**

Repeal the paragraph, substitute:

(a) is a manner of manufacture within the full meaning, including the proviso, of section 6 of the Statute of Monopolies; and

**2 Paragraph 18(1A)(a)**

Repeal the paragraph, substitute:

(a) is a manner of manufacture within the full meaning, including the proviso, of section 6 of the Statute of Monopolies; and

**3 Subsection 18(2)**

Repeal the subsection, substitute:

(2) The following are not patentable inventions:

(a) human beings, and the biological processes for their generation; and

(b) biological materials, whether isolated or not and however made, which are identical to such materials as they exist in nature.

**4 After subsection 18(4)**

Insert:

(5) In this section:

*biological materials*, in section 18, includes DNA, RNA, proteins, cells and fluids and their components.

*identical*, in section 18, means a biological material which is structurally and functionally identical

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## Appendix B

August 24, 2011

### **Despite Gene Patent Victory, Myriad Genetics Faces Challenges** By **ANDREW POLLACK**

<http://www.nytimes.com/2011/08/25/business/despite-gene-patent-victory-myriad-genetics-faces-challenges.html?pagewanted=all>

Myriad Genetics retained its monopoly on a lucrative genetic test for breast cancer risk when a federal appeals court recently upheld the company's patents on two human genes — and the validity of gene patents in general.

But it is only a matter of time before the company's business faces severe challenges, some experts say, because that \$3,340 test is technologically outmoded, incomplete and too costly.

"Science has moved beyond what these folks do," said Mary-Claire King, a professor of genome sciences and medicine at the University of Washington. "It's not good for the science and it's not good for the patients and their clinicians if they cannot have the most complete, up-to-date information."

Myriad sequences the two patented genes, known as BRCA1 and BRCA2, for mutations that raise the risk of a woman getting breast and ovarian cancer.

But newer DNA-sequencing techniques are far faster and only a fraction of the cost of the 1990s technology that Myriad uses. Indeed, it will soon be possible to sequence a person's entire genome, all 22,000 or so genes, for less than Myriad charges for just two genes.

Executives at Myriad say they are preparing for changes. Although its major patents start expiring in 2014, the executives say the company's patent protection should last until at least 2018.

They say that will give the company time to adopt new technology and to diversify beyond the breast cancer test, which accounted for \$353 million, or 88 percent, of Myriad's \$402 million in revenue in the fiscal year that ended in June.

The company also plans to rely less on patents and more on trade secrets. Because it has done so much more testing than anyone else, Myriad has more information on

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which of the thousands of possible mutations in the two genes actually raise the risk of getting [cancer](#).

Myriad used to share such information with a public database maintained by the National Institutes of Health, and it cooperated with academic scientists trying to analyze the mutations. But a few years ago, the company quietly stopped contributing and cooperating, in favor of building its own database.

An academic consortium, relying on data from European labs or from individual patients, is trying to catch up, but “it’s kind of slow going,” said Sean Tavtigian, a former Myriad scientist who is now an associate professor of oncological sciences at the University of Utah and is involved in the consortium.

Myriad, which is based in Salt Lake City, is hoping to use that advantage first in Europe, where it will open a testing laboratory next year.

“If I had my druthers, I would not want to go into a new market in a heavy-handed fashion, trying to enforce patents,” Peter D. Meldrum, Myriad’s chief executive, told analysts in January. Instead, he said the company would exploit its quicker turnaround time for testing and its “vastly superior information.”

Myriad executives have said that when a European laboratory finds a mutation in either of the two genes, 20 to 40 percent of the time it does not know if the mutation raises the cancer risk. They say that Myriad’s rate of uncertain findings is just 3 percent.

Daniel B. Vorhaus, a New York lawyer and editor of the [Genomics Law Report](#), a Web site, said there were ethical questions about whether Myriad should be withholding the mutation information, important for public health, that it has gathered by dint of its patents to essentially extend its monopoly beyond the life of the patents.

Mark C. Capone, the president of Myriad’s laboratory division, said in an interview that the company had invested heavily in characterizing the various mutations. He said that the company became uncomfortable sharing its information with a public database when it realized the information might be used to compete against it.

Ever since Myriad and its partner, the University of Utah, beat other researchers, including Professor King of the University of Washington, in identifying the BRCA1 gene in 1994, Myriad has been the target of those opposed to the patenting of genes.

In 2009, the American Civil Liberties Union and the Public Patent Foundation filed a lawsuit challenging Myriad's patents on behalf of various medical researchers, medical societies and patients.

A federal district judge last year said genes could not be patented. But his decision was reversed in late July by a 2-1 decision from the Court of Appeals for the Federal Circuit. The plaintiffs are considering appealing to the Supreme Court.

The lawsuit contends that the patents, by giving Myriad a monopoly, have limited testing options for patients and led to lower-quality tests.

The latest controversy concerns a supplemental test that Myriad is offering.

In 2006, Professor King and colleagues [published a paper](#) showing that Myriad's test, known as the Comprehensive BRCAAnalysis, actually failed to detect a significant number of genetic alterations in the two genes.

Myriad then developed a test for these alterations. But instead of incorporating it into its main product, it offered it as a supplemental test at a price of \$700. Many insurers do not pay for it, and therefore many women do not get it.

Myriad's data shows that for Latina women in particular, 20 percent of all mutations found are detectable only by the supplemental test.

"The comprehensive testing they are advertising is not really comprehensive," said Ellen T. Matloff, director of cancer genetic counseling at Yale, who is also a plaintiff in the patent lawsuit. "This would not happen in a competitive market. It simply would be unacceptable."

More than 200 doctors, genetic counselors and other health care professionals have signed an open letter to Myriad urging it to incorporate the supplemental testing into the main test.

Kathleen Maxian says that if that had been done earlier, she might not be fighting for her life against ovarian cancer.

Her sister developed breast cancer at age 40 about five years ago, but tested negative for mutations on Myriad's main test. She was not offered the supplemental test.

Two years ago, Ms. Maxian developed ovarian cancer. It turned out that both she and her sister had genetic alterations that were detectable only by the supplemental test.

"If my sister had had that test and had gotten a positive result, I would have gone to a genetic counselor and have been tested," said Ms. Maxian, who is 49 and lives in Pendleton, N.Y., near Buffalo. She would then have had the option of having her ovaries removed to avoid getting ovarian cancer.

"I don't want to see this happen to anyone else," she said. "Women should have this test."

Mr. Capone of Myriad said the company kept the test separate because insurers would not pay for it. The company has now compiled the data necessary to arrange for reimbursement and is moving to incorporate that testing into its main product.

He said only 1 percent of women over all would have a mutation detected only by the supplemental test.

The future challenge for Myriad is from new sequencing machines and techniques. Last year, Professor King and colleagues [published a paper](#) on a technique that can test BRCA1 and BRCA2, as well as 20 other genes that contribute to breast cancer risk, and at a cost much lower than Myriad's.

Some companies [like Knome](#) already offer sequencing of a person's full genome. Prices are still high — [Illumina](#), for instance, charges \$9,500 — but are dropping rapidly. Others, like GenomeQuest, are developing [software tools to analyze](#) the genetic information.

Lawyers say it is not clear if sequencing a person's whole genome and then providing information on mutations in the BRCA genes would violate Myriad's patents on the isolated genes.

Mr. Capone said that full genome sequencing did not yet meet the requirements for accuracy required of a medical diagnostic test. And the reported cost of sequencing a human genome does not include the significant cost of analyzing the data.

“It will probably take four years or more before whole genome sequencing can be done clinically,” Mr. Capone said. By then, Myriad will have developed its test using new sequencers that will judge the risk of all hereditary cancers, not just hereditary breast and ovarian cancers.

Many analysts like the stock, though Isaac Ro of Goldman Sachs rates it a sell, saying the price of the breast-cancer risk test is unsustainable.

For now, sales of the breast cancer risk test continue to grow, rising 10 percent in the last fiscal year. Mr. Capone said that many women who were eligible for testing under medical guidelines were still not getting tested, leaving a large untapped market.

Myriad is also trying to diversify. It sells seven other tests, including one for the risk of inherited [colon cancer](#) and one that helps guide [prostate cancer](#) treatment by gauging a [tumor](#)'s aggressiveness.

It has at least 13 other tests in development and is moving into so-called companion diagnostics, which are tests to show whether a particular drug is appropriate for a particular patient.

But so far, the other tests pale beside the one for breast cancer. Professor Tavgian said Myriad insiders refer to the company's product portfolio as Snow White and the Seven Dwarfs. END

# APPENDIX 1

## SUBMISSIONS RECEIVED

<b>Submission Number</b>	<b>Submitter</b>
1	Dr Charles Lawson
2	Professor Judy Kirk
3	Mr Adam Johnston
4	The Royal College of Pathologists of Australia
5	Human Genetics Society of Australasia
6	Mr Christopher Aitchison
7	Bayer CropScience
8	Cancer Voices NSW
9	The Royal Australasian College of Physicians
10	Mr Paul McCormack
11	Cancer Voices Australia
12	Amgen Australia
13	Perth Bone and Tissue Bank
14	Abbott Australasia
15	South Australian Government
16	Consumers Health Forum of Australia
17	Davies Collison Cave
18	Dr Ann Kurts, Dr Mark Lutherborrow and Professor Natalie Stoianoff
19	Professor Andrew Christie
20	Dr Malcolm Lyons
21	Mr Doug Calhoun
22	Australian Medical Association
23	SciVentures
24	Peter MacCallum Cancer Centre
25	Professor Peter Drahos
26	Liberty Victoria
27	Australian Reproductive Health Alliance
28	Group of Eight
29	Dr Hazel Moir
30	Australian Law Reform Commission
31	ChemSkill
32	Sanofi-Aventis
33	National Coalition of Public Pathology
34	Australian Institute for Innovation
35	International Federation of Intellectual Property Attorneys
36	Foursight Associates
37	Ms Stephanie Gleeson
38	Metabolic Pharmaceuticals

39 Professor Dianne Nicol, Mr Johnathon Liddicoat, Dr Jane Nielsen and  
Mr Ben Mee

40 Dr Chris Dent

41 La Trobe University

42 Roche

43 Ms Elizabeth Gleeson

44 St Vincent's Institute of Medical Research

45 Grasslanz Technology Limited

46 National Health and Medical Research Council

47 Griffith Hack and Griffith Hack Lawyers

48 Law Council of Australia

49 Institute of Patent and Trade Mark Attorneys of Australia

50 Dr Teresa Schafer, Mr Tim Clark and Mr George Raitt (partners in  
Piper Alderman)

51 Agrifood Awareness Australia

52 Eli Lilly Australia

53 James and Wells Intellectual Property

54 University of Western Sydney, University of Sydney, University of  
New South Wales, Macquarie University, University of Wollongong  
and Newcastle University

55 Ms Anna George

56 CSL

57 IVD Australia

58 Hexima

59 Walter and Eliza Hall Institute of Medical Research

60 Pfizer Australia

61 Dr Jennifer Leary

62 Knowledge Commercialisation Australasia

63 Association of Australian Medical Research Institutes

64 Garvan Institute of Medical Research

65 CropLife Australia

66 Sydnovate

67 BioMelbourne Network

68 Department of Health and Ageing

69 GlaxoSmithKline Australia

70 Mylan

71 Generic Medicines Industry Association

72 Cancer Council Australia and Clinical Oncological Society of  
Australia

73 Prima BioMed

74 Mr Geoffrey Burton

75 Alphapharm

76 Merck Serono Australia

77 FB Rice and Co

78 CSIRO

79 Mr Craig Patterson

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80	ResMed
81	Genetic Technologies
82	Merck Sharp and Dohme Australia
83	Dr Mark Summerfield
84	Breast Cancer Action Group NSW
85	Biomedical Consulting Services
86	Biotechnology Industry Organization
87	Shelston IP
88	Murdoch Childrens Research Institute
89	Medicines Australia
90	Grains Research and Development Corporation
91	Baxter Healthcare
92	Professor Ian Frazer
93	Bristol-Myers Squibb Australia
94	Department of Innovation, Industry, Science and Research and IP Australia
95	Licensing Executives Society of Australia and New Zealand
96	Tasmanian Government
97	AusBiotech
98	Australian Academy of Technological Sciences and Engineering
99	Mooroolbark Technology
100	Australian Academy of Science
101	Janssen, Pharmaceutical Companies of Johnson and Johnson
102	Meat and Livestock Australia
103	Dr Luigi Palombi
104	MS Research Australia
105	Industry and Investment NSW
106	Gene Ethics
107	Confidential
108	Confidential
109	The Burnet Institute
110	American Intellectual Property Law Association
111	Dr Warwick Neville FM, Dr Luigi Palombi, Dr Buddhima Lokuge
112	Victorian Government
113	Ms Katrina Howard
114	Genzyme Australasia
115	Mr John Wood
116	Ms Joanne Mulcahy
117	Ms Lin Stuart
118	Mrs Emily Wallis
119	Ms Wilma Western
120	Name Withheld
121	Name Withheld
122	Greenpeace Australia Pacific

## **ADDITIONAL INFORMATION RECEIVED**

- 1 Amendment to the Bill tabled by Senator the Hon Bill Heffernan on 28 April 2011
- 2 Answer to Question on Notice provided by the Royal College of Pathologists of Australasia on 3 May 2011
- 3 Answer to Question on Notice provided by Professor Dianne Nicol and Mr Johnathon Liddicoat on 12 May 2011
- 4 Answer to Question on Notice provided by Dr Luigi Palombi on 12 May 2011
- 5 Answer to Question on Notice provided by Generic Medicines Industry Association on 12 May 2011
- 6 Answer to Question on Notice provided by CropLife Australia on 13 May 2011
- 7 Answer to Question on Notice provided by Walter and Eliza Hall Institute of Medical Research on 13 May 2011
- 8 Answer to Question on Notice provided by Medicines Australia on 17 May 2011
- 9 Clarification of evidence provided by CropLife Australia on 31 May 2011
- 10 Correspondence received from Government of Brazil on 8 June 2011

## **APPENDIX 2**

### **WITNESSES WHO APPEARED BEFORE THE COMMITTEE**

**Canberra, 28 April 2011**

CLARK, Dr Julian, Head of Business Development, Walter and Eliza Hall Institute of Medical Research

CROSS, Dr Martin, Chairman, Generic Medicines Industry Association

DAVIES, Dr Trevor, Councillor, Institute of Patent and Trade Mark Attorneys

DRAHOS, Professor Peter, Director, Centre for Governance of Knowledge and Development, Australian National University

HAMER, Mr Richard, Deputy Chairman, Intellectual Property Committee, Business Law Section, Law Council of Australia

HANNAH, Mr Colin, Vice President, Australia and New Zealand, Hospira Pty Ltd; Board Member, Generic Medicines Industry Association

HILTON, Professor Douglas, Director, Walter and Eliza Hall Institute of Medical Research

JARVIS, Mr Richard, Member, Intellectual Property Committee, Law Council of Australia

LIDDICOAT, Mr Johnathon, Private capacity

LOFTHOUSE, Dr Shari, Manager of Intellectual Property and Development and Acting Director of Commercialisation, Peter MacCullum Cancer Centre

MITCHELL, Dr Gillian, Clinical Oncologist and Director, Familial Cancer Centre, Peter MacCallum Cancer Centre

MONK, Ms Deborah, Director, Innovation and Industry Policy, Medicines Australia

MURPHY, Mr Tim, Co-Chair, Innovation Strategic Committee, Medicines Australia; Head, Government Affairs and Policy, GlaxoSmithKline Australia

NICOL, Professor Dianne, Private capacity

OBANOVICH, Dr Tania, Fellow, Institute of Patent and Trade Mark Attorneys

OLVER, Professor Ian, Chief Executive Officer, Cancer Council Australia

SHAW, Dr Brendan, Chief Executive, Medicines Australia

SUTHERS, Dr Graeme, Chair, Genetics Advisory Committee, Royal College of Pathologists of Australasia

**Canberra, 29 April 2011**

BEATTIE, Mrs Fatima, Deputy Director-General, IP Australia

CHRISTIE, Professor Andrew, Private capacity

COSSEY, Mr Matthew, Chief Executive Officer, CropLife Australia

HALTON, Ms Jane, Secretary, Department of Health and Ageing

LAVELLE, Dr Anna, Chief Executive Officer, AusBiotech

LUNN, Mr Peter, Manager, Pharmaceuticals and Health Technologies Section, Department of Innovation, Industry, Science and Research

McDONALD, Ms Mary, First Assistant Secretary, Regulatory Policy and Governance Division, Department of Health and Ageing

MOORE, Ms Terry, Director, Domestic Policy, IP Australia

PALOMBI, Dr Luigi, Private capacity

PETERS, Dr Kirrily, Manager, Pharmaceuticals Industry Strategy and Environment Section, Department of Innovation, Industry, Science and Research

PRESS, Ms Lexie, Examiner of Patents, IP Australia

QUINN, Mr Daniel, Policy Manager, Biotechnology, and Policy Manager, Minor Use, CropLife Australia

REID, Mr Chris, General Counsel, Department of Health and Ageing

*Patents Act 1990 – Summary of Private Member’s Bills - Proposed amendments to 18(2) and 18(4)*

Bill	Proposed amendments	Outcome
<p>Patent Amendment (Human Genes and Biological Materials) Bill 2010</p> <p><b>Person/s proposing amendments</b> Senator the Hon Helen Coonan, Senator the Hon Bill Heffernan, Senator Rachel Siewert and Senator Nick Xenophon</p>	<p>ss. 18(2) - Repeal the subsection, substitute</p> <p>(2) The following are not patentable inventions:</p> <p>(a) human beings, and the biological processes for their generation; and</p> <p>(b) <b><i>biological materials</i></b> including their components and derivatives, whether isolated or purified or not and however made, which are identical or substantially identical to such materials as they exist in nature.</p> <p>After ss. 18(4) - Insert</p> <p>(5) In this section: <b><i>biological materials</i></b> includes DNA, RNA, proteins, cells and fluids.</p>	<p>In September 2011, the Senate Legal and Constitutional Affairs Committee recommended the Bill not be passed.</p>
<p>Patent Amendment (Human Genes and Biological Materials) Bill 2010</p> <p><b>Person/s proposing amendments</b> Mr Dutton, Mr Oakeshott, Mr Forrest and Mr Turnbull</p>	<p>Identical Bill to the above private member’s Bill.</p>	<p>Not proceeding.</p>
<p>Patents Amendment (Genetic Materials) Bill 2012</p> <p><b>Person proposing amendments – in letter of 13 March 2012 to Minister Combet Ms Parke</b></p>	<p>ss. 18(2) – Repeal the subsection, substitute</p> <p>(2) The following are not patentable inventions:</p> <p>(a) human beings, and the biological processes for their generation;</p> <p>(b) <b><i>genetic materials that exist in nature, or are the same as or not markedly different from those existing in nature,</i></b> whether such materials are in situ, isolated or purified;</p> <p>(c) any <b><i>method that involves the mere comparison of genetic materials or genetic sequences in the provision of a diagnosis for a human being.</i></b></p> <p>(2A) A reference in subsection (2) to genetic materials includes, but is not limited to, DNA or RNA whether in whole or in part or in fragments, however made.</p>	<p>Subject of this brief.</p>

<p><b>Note</b> that Ms Parke also proposed amendments in the course of debate: Intellectual Property Laws Amendment (Raising the Bar Bill) 2011</p> <p><b>Person/s proposing amendments</b> Ms Parke</p>	<p>ss.18(2) - Repeal the subsection, substitute (2) The following are not patentable inventions: (a) human beings, and the biological processes for their generation; and (b) any <u><i>natural phenomena</i></u> whether isolated or purified or not and howsoever made.</p> <p>Schedule 1 (Dictionary) – Insert <u><i>natural phenomena</i></u> for the purposes of ss. 18(2) include a composition of matter not markedly different to anything found in nature.</p>	<p>Issues analogous to Ms Parke’s proposal were considered as part of the Senate Legal and Constitutional Affairs Committee’s deliberations.</p>
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# Response to C12/911 - Reply to Melissa Parke MP, Private Members Bill[SEC=UNCLASSIFIED] - Notes Memo

**From:** [Julie.Baxter@ipaaustralia.gov.au](mailto:Julie.Baxter@ipaaustralia.gov.au)  
**To:** Frances.Roden@ipaaustralia.gov.au  
**Sent:** 19-03-2012 09:26:14 AM

Good morning MLO

Here is our response to C12/911 - including brief, letter in response and attachments. It has been cleared by Director General Philip Noonan.

Cheers,  
Julie

<Attachment: 12-03-16 C12-911 Attachment A Reply.doc> <Attachment: 12-03-16 C12-911 Attachment B .pdf> <Attachment: 12-03-16 C12-911 Attachment C.pdf> <Attachment: 12-03-16 C12-911 Attachment D.pdf> <Attachment: 12-03-16 C12-911 Attachment E.pdf> <Attachment: 12-03-16 C12-911 Attachment F.doc> <Attachment: 12-03-16 C12-911 DB Ms Parke Private Member's Bill.doc>

Kind Regards,

## Ministerial Support Team

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Please consider the environment before printing this email

**Minister for Industry and Innovation:** Decision  
 cc: Parliamentary Secretary Dreyfus and Minister Evans

**Brief No:** C12/911  
**Division/Agency:** IP Australia

**PROPOSAL BY MS MELISSA PARKE MP TO INTRODUCE A PRIVATE MEMBERS BILL, THE PATENTS AMENDMENT (GENETIC MATERIALS) BILL 2012**

**Timing:** 4 April 2012

Recommendation/s:	Approved/Noted
1. That you do not support Ms Melissa Parke MP's proposed introduction of a private member's Bill, the <i>Patents Amendment (Genetic Materials) Bill 2012</i> .	Yes / No
2. That you sign the letter ( <b>Attachment A</b> ) to Ms Parke indicating the Government does not support the proposed Bill.	Yes / No
<b>Minister's signature:</b>	<b>Date:</b>

**Key Points**

- Ms Melissa Parke MP (Ms Parke) intends to introduce a private member's Bill *Patents Amendment (Genetic Materials) Bill 2012* (proposed Bill) into the House of Representatives (**Attachment B**). While the proposed Bill is more detailed than previous similar Bills, it has primarily the same effect - a prospective ban on gene patents.
- A previous private member's Bill, the *Patent Amendment (Human Genes & Biological Materials) Bill 2010* (Sen Heffernan's Bill) (**Attachment C**) was introduced into the Senate on 24 November by Senators Heffernan, Coonan, Xenophon and Siewart. An identical Bill (Mr Dutton's Bill) was introduced into the House of Representatives on 21 February 2011 by the Hon Peter Dutton MP, the Hon Rob Oakeshott MP, Mr John Forrest MP and the Hon Malcolm Turnbull MP (**Attachment D**).
  - The Senate referred Sen Heffernan's Bill to the Senate Legal and Constitutional Affairs Committee for inquiry and report. Over 100 submissions were received by the inquiry, the majority of which opposed the Bill. Also Medicines Australia and Ausbiotech actively opposed it in a variety of ways.
  - In September 2011 the Committee (in a majority report) recommended the Senate should not pass Sen Heffernan's Bill (**Attachment E**). The Committee concluded that the Bill "could have a large number of unintended consequences across the entire patent system with indeterminate impacts on a range of industries and sectors."
- The considerable adverse impact of the proposed Bill and previous similar Bills (Sen Heffernan's Bill and Mr Dutton's Bill) would primarily be on pharmaceutical and biotechnology sectors, including on industrial biotechnology sectors.
- These are sectors of the future that have high paid, high skilled, high value-added jobs that leverage from the quality research capacity that exists in Australian universities, public research bodies and medical research institutes. The growth potential of these sectors is

enormous, and industrial biotechnology in particular can increase the productivity of existing industries.

- **Attachment F** provides a comparison between the Sen Heffernan/Mr Dutton's Bills and Ms Parke's proposed Bill.
  - The Sen Heffernan/Mr Dutton Bills were narrower in the subject matter of the exclusion, namely products, while the proposed exclusion in Ms Parke's Bill extends to products and diagnostic methods.
  - The product exclusion in Ms Parke's Bill could potentially be narrower, being directed to 'genetic' rather than 'biological' products. However, this in itself introduces definitional uncertainties as to what falls within 'genetic' in addition to uncertainty around what constitutes 'markedly different'. Ms Parke's Bill seeks to exclude an area of technology *per se* which may not be compliant with the Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement obligations.
- The granting of patents over biological material, including genetic material, derived from nature has been a long standing aspect of Australian law. This has facilitated the development and access to important drugs, diagnostics and medical treatments, and other industrial products and processes.
- Australian law on this issue is consistent with that of our major trading partners. It also adheres to the TRIPS and the Australia-United States Free Trade Agreement.
- Over recent years there have been a number of reports into the patenting of genetic material: The Australian Law Reform Commission's 2004 report on *Genes and Ingenuity: Gene Patenting and Human Health*; The Senate Community Affairs Committee's *Gene Patents* Report released on 26 November 2010; and the Advisory Council on Intellectual Property's 2011 report on patentable subject matter.
- On 23 November 2011 the Government released its response to the Senate Community Affairs Committee's report, addressing recommendations made in all the above three reports. The majority of the reports' recommendations were accepted by Government, including that there be no ban on gene patents at this time.
- The issue of gene patents is the subject of legal action in the Federal Court of Australia. On 8 June 2010, Cancer Voices Australia instigated legal action against Myriad Genetic Inc and others in respect of the validity of one of Myriad's patents. This matter was heard on 20-24 February and judgement is reserved.

### Issues/sensitivities

- Innovation Division and IP Australia are responsible for implementing a number of the key recommendations in the Government's response. In particular, reforms to patent law, through the *Intellectual Property Laws Amendment (Raising the Bar) Bill 2011* (RTB Bill), which passed the Senate in February and is before the House of Representatives.
- The RTB Bill includes the introduction of a research exemption and raises the criteria for granting of patents. These reforms apply to all technologies and will make it clear that researchers will not infringe a patent when carrying out further research on the patented invention. This will address many of the issues Ms Parke raises around access to patented materials for research. These reforms also raise the threshold for inventive step, which will make it harder to obtain a patent and should address concerns about patents for biotechnology developments being too easy to obtain in Australia.

**Consultation**

- Pharmaceuticals, Health Industries and Enabling Technologies Branch, Innovation Division, Department of Industry, Innovation, Science, Research and Tertiary Education.

Philip Noonan  
Director General  
IP Australia  
(02) 6283 2000  
March 2012

s47F

Contact Officer:  
Frances Roden  
(02) 6283 2151

**Attachments**

- Attachment A: Response to Ms Parke.
- Attachment B: Private Member's Bill *Patents Amendment (Genetic Materials) Bill 2012*, proposed by Ms Parke.
- Attachment C: Private Member's Bill *Patents Amendment (Human Genes & Biological Materials) Bill 2010*, proposed by Senators Heffernan, Coonan, Xenophon and Siewart.
- Attachment D: Private Member's Bill *Patents Amendment (Human Genes & Biological Materials) Bill 2010*, proposed by Messrs Dutton, Oakeshott, Forrest and Turnbull.
- Attachment E: Senate Legal and Constitutional Affairs Committee report on the private member's Bill *Patents Amendment (Human Genes & Biological Materials) Bill 2010*.
- Attachment F: Comparison of the three private member's Bills.

## Background

The Government released its response to the Senate Community Affairs Committee's review of Gene Patents on 23 November 2011 as part of a combined response to the Senate Committee's *Gene Patents* report, the Australian Law Reform Commission's 2004 report on *Genes and Ingenuity* and the Advisory Council on Intellectual Property's 2011 report on Patentable Subject Matter.

The issue of gene patents is one which raises very strong views. Opponents of patenting of gene sequences argue that patents should not be granted over things that are found in nature and that these patents restrict further research and patient access to medical tests and treatments. A number of the reviews gave detailed consideration to the impact of gene patents on research and access to medical tests and treatments but found no empirical evidence that gene patents are having an adverse impact on research or access to medical treatment or technologies.

Supporters of gene patents argue that patents in this area are essential to encourage innovation and protect the investment made in finding new medical treatments. They also argue that banning patenting of gene sequences would put Australia out of step with the rest of its major trading partners which allow these patents. The reviews found some evidence that the incentive provided by the patent system can assist access to funding.

The reviews made a number of recommendations for improvements to the patent system but did not recommend banning or restricting gene patents.

A number of the proposed changes accepted by the Government are already being implemented in the RTB Bill. The key focus of these changes is to raise patent standards and introduce an exemption from infringement for researcher activities.

Other key changes accepted by the Government are a rewording of the test for patentable subject matter, introduction of an objectives statement into the *Patents Act 1990*, a review of the existing compulsory licensing provisions, raise awareness of crown use provisions amongst the health sector and vary the membership of the Advisory Council on Intellectual Property to better represent wider consumer/community interests. These recommendations are directed at improving the clarity of patents legislation and ensuring public access to essential patented technologies. Innovation Division and IP Australia will work on implementation of these recommendations reflecting their joint policy responsibility for patent policy.

Cancer Voices Australia is currently challenging the validity of Myriad Genetics Inc's breast cancer antigen (BRCA) patents in the Federal Court. (It was Myriad's actions in relation to these patents that generated the concerns about gene patents.) The case was heard on 20-24 February 2012 and judgement is reserved. It may reopen the gene patents debate in Australia.

The BRCA patent has also been the subject of court action in the US, where the American Civil Liberties Union has challenged Myriad's US patent. In July 2011 the US Court of Appeals for the Federal Circuit upheld the validity of Myriad's patent. As at March 2012, the US Supreme Court is yet to decide whether it will hear the case.

# B12/1051 - Potential Implications for Gene Patents in Australia of the US Supreme Court Patent Decision *Mayo Collaborative Services v Prometheus Laboratories, Inc.* [SEC=IN-CONFIDENCE] - Notes Memo

**From:** [Andrea.Blazsev@ipaaustralia.gov.au](mailto:Andrea.Blazsev@ipaaustralia.gov.au)  
**To:** mlobriefs@innovation.gov.au, kaye.fisk@innovation.gov.au  
**Cc:** Frances.Roden@ipaaustralia.gov.au  
**Sent:** 30-03-2012 08:47:32 AM

MLO

Please find attached information brief B12/1051 - Potential Implications for Gene Patents in Australia of the US Supreme Court Patent Decision *Mayo Collaborative Services v Prometheus Laboratories, Inc.*

The brief has been cleared by Philip Noonan, Director-General, IP Australia and was already emailed directly to the office of Parliamentary Secretary Dreyfus late yesterday afternoon (for a meeting they have this morning).

Please upload to Slipstream.

<Attachment: 2012-03-29 B12-1051 IB Implications of Prometheus decision.doc>

Thank you  
Andrea

Kind Regards,

## Ministerial Support Team

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IP Australia

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Noted in office by  
 adviser  31.3.12

**IN-CONFIDENCE**

**BRIEF**

**Parliamentary Secretary:** Information  
**cc:** Minister Combet  
 Minister Evans

**Brief No:** B12/1051  
**Division/Agency:** IP Australia

**POTENTIAL IMPLICATIONS FOR GENE PATENTS IN AUSTRALIA OF THE UNITED STATES SUPREME COURT PATENT DECISION *MAYO COLLABORATIVE SERVICES V PROMETHEUS LABORATORIES, INC.***

**Timing:** 27 April 2012

<b>Recommendation/s:</b>	<b>Approved/Noted</b>
1. That you note possible implications arising from the United States Supreme Court decision in <i>Mayo Collaborative Services v Prometheus Laboratories, Inc.</i> for the patenting of genes and the biotechnology sector in Australia.	Yes / No
<b>Parliamentary Secretary's signature:</b>	<b>Date:</b>

**Key Points**

- On 20 March 2012 the Supreme Court of the United States issued a decision in *Mayo Collaborative Services v Prometheus Laboratories, Inc.* (*Mayo* case). The decision was that two patents relating to optimising the dosage of a drug for treatment of autoimmune diseases were invalid. The patents sought to use information about the body's reaction to a certain drug to indicate whether the dosage of a drug should be increased or decreased, in accordance with the current concentration of the drug in the bloodstream. The Supreme Court held that information about the body's reaction to the drug was a "law of nature" and therefore not eligible to be patented under US law. The additional information about dosage alterations was insufficient to allow the overall patent to constitute an "application of a law of nature", which would be eligible to be patented.
- This case has potential implications for the treatment in the US of patents relating to isolated gene sequences. The court may take the view that the gene sequence is a law of nature and that isolating the sequence is insufficient to make the isolated gene sequence eligible for a patent.
- To date, the position in the US on gene patents has been unclear. The *Association for Molecular Pathology v Myriad Genetics* case (US *Myriad* case) has been heard in two lower courts, the decisions on which have been divided. On 27 March 2012, the US Supreme Court remitted the US *Myriad* case to the Court of Appeal for the Federal Circuit for further consideration 'in light of the *Mayo* decision'.
- It seems very possible that the Federal Circuit's decision on the US *Myriad* case will result in isolated gene patents not being patentable in the US.
- While this decision would not be binding in Australia, Australian courts may well take guidance from the decision in applying Australia's test for patent eligibility, which is not quite the same as the US test, but which often leads to similar results. This may be

particularly relevant to the Australian *Cancer Voices Australia v Myriad Genetics* case, judgement in which is currently reserved.

**Issues/sensitivities**

There are a number of pertinent issues relating to potential economic impacts for Australia:

- If the US courts decide that genetic technologies are not patentable, there may be an immediate adverse impact on the Australian biotechnology sector. Patents covering isolated genes are an important factor for investors in medical tests or treatments based on those genes. Without the security of patent rights in the US, the value of Australian biotechnology companies may decline.
- If the US courts decide that isolated gene sequences *per se* are not patentable subject matter (because they are considered a law of nature), the patentability of genetic diagnostic tests may remain uncertain. This is because the test set out in *Mayo* asks the question whether the claimed invention adds sufficiently to a law of nature. It is not clear how much ‘addition’ is required in order to patent a diagnostic test that compares gene sequences. This uncertainty may adversely impact on investment in new diagnostic tests.
- With this extra perspective as background, the table below provides commentary on the following two options:

**Option 1:** The Government awaits the outcome of the Australian court proceedings.

**Option 2:** The Government introduces or supports a Bill along the lines proposed by Ms Melissa Parke MP (C12/911 refers).

<b>Option 1 – await outcome of court decisions</b>	<b>Option 2 – introduce a Government Bill</b>
<p>Consistent with the Government’s response to the Gene Patents reports (B11/4524 refers), which agreed to implement recommendations such as a review of compulsory licensing, but not to ban gene patents at this time.</p>	<p>Pre-empts court decisions.</p>
<p>Consistent with the Senate Community Affairs Committee’s recommendation to wait for the outcome of other activities before deciding whether or not to amend the <i>Patents Act 1990</i> to ban gene patents.</p> <p>In their <i>Gene Patents</i> report the Senate Community Affairs Committee explained that one of the reasons for not recommending a ban on gene patents, at this stage, was the court cases currently afoot in Australia and the US. The Committee noted that if the outcome of these cases was that the courts founds that gene sequences are not patentable there would be less need for a legislative solution. (<i>Gene Patents</i> report, para 4.130.)</p>	<p>Inconsistent with the Senate Community Affairs Committee’s recommendation.</p>

Changes would be prospective and retrospective i.e. if the court found that isolated gene sequences were not patentable, then this would apply to existing and future patents, rendering existing patents unenforceable.	Changes would be prospective only, unless constitutional compensation was offered (section 51(xxxi) of the Constitution provides for acquisition of property on just terms.)
The Government would be able to keep its options open until the legal position was clear.	The Government would be committed to a position.

Philip Noonan  
Director General  
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29 March 2012

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Contact Officer:  
Frances Roden  
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**Parliamentary Secretary:** Information  
 cc: Minister Combet  
 Minister Evans

**Brief No:** B12/1051  
**Division/Agency:** IP Australia

**POTENTIAL IMPLICATIONS FOR GENE PATENTS IN AUSTRALIA OF THE UNITED STATES SUPREME COURT PATENT DECISION *MAYO COLLABORATIVE SERVICES V PROMETHEUS LABORATORIES, INC.***

**Timing:** 27 April 2012

<b>Recommendation/s:</b>	<b>Approved/Noted</b>
1. That you note possible implications arising from the United States Supreme Court decision in <i>Mayo Collaborative Services v Prometheus Laboratories, Inc.</i> for the patenting of genes and the biotechnology sector in Australia.	Yes / No
<b>Parliamentary Secretary's signature:</b>	<b>Date:</b>

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- This case has potential implications for the treatment in the US of patents relating to isolated gene sequences. The court may take the view that the gene sequence is a law of nature and that isolating the sequence is insufficient to make the isolated gene sequence eligible for a patent.
- To date, the position in the US on gene patents has been unclear. The *Association for Molecular Pathology v Myriad Genetics* case (US *Myriad* case) has been heard in two lower courts, the decisions on which have been divided. On 27 March 2012, the US Supreme Court remitted the US *Myriad* case to the Court of Appeal for the Federal Circuit for further consideration 'in light of the *Mayo* decision'.
- It seems very possible that the Federal Circuit's decision on the US *Myriad* case will result in isolated gene patents not being patentable in the US.
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particularly relevant to the Australian *Cancer Voices Australia v Myriad Genetics* case, judgement in which is currently reserved.

**Issues/sensitivities**

There are a number of pertinent issues relating to potential economic impacts for Australia:

- If the US courts decide that genetic technologies are not patentable, there may be an immediate adverse impact on the Australian biotechnology sector. Patents covering isolated genes are an important factor for investors in medical tests or treatments based on those genes. Without the security of patent rights in the US, the value of Australian biotechnology companies may decline.
- If the US courts decide that isolated gene sequences *per se* are not patentable subject matter (because they are considered a law of nature), the patentability of genetic diagnostic tests may remain uncertain. This is because the test set out in *Mayo* asks the question whether the claimed invention adds sufficiently to a law of nature. It is not clear how much ‘addition’ is required in order to patent a diagnostic test that compares gene sequences. This uncertainty may adversely impact on investment in new diagnostic tests.
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<p>The Government would be able to keep its options open until the legal position was clear.</p>	<p>The Government would be committed to a position.</p>

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29 March 2012

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Australian Government  
Department of Industry, Innovation, Science,  
Research and Tertiary Education

Please provide further information on the progress of the US Myriad case, including the rationale for the suggestion below that it is "very possible" that the Court will find that genes are not patentable

IN-CONFIDENCE

BRIEF

Parliamentary Secretary: Information  
cc: Minister Combet  
Minister Evans

Brief No: B12/1051

Division/Agency: IP Australia

2. Please provide further information on the Australian case.

POTENTIAL IMPLICATIONS FOR GENE PATENTS IN AUSTRALIA OF THE UNITED STATES SUPREME COURT PATENT DECISION *MAYO COLLABORATIVE SERVICES V PROMETHEUS LABORATORIES, INC.*

Timing: 27 April 2012

Recommendation/s:	Approved/Noted
1. That you note possible implications arising from the United States Supreme Court decision in <i>Mayo Collaborative Services v Prometheus Laboratories, Inc.</i> for the patenting of genes and the biotechnology sector in Australia.	Yes / No
Parliamentary Secretary's signature: 	Date: 22/5/12

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IN-CONFIDENCE

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29 March 2012

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File C2012/12966 FOI 288  
Ministerial Coversheet

<b>Date Due in MLO:</b>	3/04/2012	<b>Ministerial Item:</b>	B12/1051
<b>Action Division:</b>	IP Aust	<b>Current Division:</b>	IP Aust
<b>Action:</b>	Information - Request MO	<b>Minister Office:</b>	Dreyfus
<b>Signatories:</b>	DREYFUS QC MP, MARK		
<b>Subject:</b>	Myriad and Prometheus cases		

<b>Ministerial Type:</b>	Brief	<b>Attachments:</b>	N
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<b>Critical Date:</b>	<b>Talking Points:</b>	N
<b>Critical Date Reason:</b>	<b>Sensitivities Involved:</b>	N

**Summary:**

**Instructions:**

**Officer:** Parsonson, Emerson  
**Date:** 28 Mar 2012 13:15  
**Text:** Matters to be addressed in Brief: The progression and implications of these cases. The intersections for Australia. Suggested Action Officer: Baxter, Julie Requesting Adviser: Round, Jim (Dreyfus)

**Officer:**

File C2012/12966 FOI 289  
Ministerial Coversheet

<b>Date Due in MLO:</b>	3/04/2012	<b>Ministerial Item:</b>	B12/1051
<b>Action Division:</b>	IP Aust	<b>Current Division:</b>	IP Aust
<b>Action:</b>	Information - Request MO	<b>Minister Office:</b>	Dreyfus
<b>Signatories:</b>	DREYFUS QC MP, MARK		
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<b>Critical Date:</b>	<b>Talking Points:</b>	N
<b>Critical Date Reason:</b>	<b>Sensitivities Involved:</b>	N
<b>Summary:</b>		

<b>Instructions:</b>	
<b>Officer:</b>	Parsonson, Emerson
<b>Date:</b>	28 Mar 2012 13:15
<b>Text:</b>	Matters to be addressed in Brief: The progression and implications of these cases. The intersections for Australia. Suggested Action Officer: Baxter, Julie Requesting Adviser: Round, Jim (Dreyfus)
<b>Officer:</b>	

## **Additional background and examples**

### **Inventive step standards:**

Inventive step is considered in light of the ‘common general knowledge’ (CGK), which is the knowledge that every worker in the art may be expected to have. Currently, CGK for inventive step is restricted to what is known in Australia. This geographical restriction is not present in the patent laws of Australia’s major trading partners or under the Patent Cooperation Treaty (PCT)<sup>1</sup>: it is the CGK of the worker in the relevant art that is taken into account, not the knowledge of the worker in a specific geographical location.

Implementation of the changes in the Raising the Bar Bill will remove this geographical restriction, which raises the standard for inventive step. The CGK in a particular technical field may be more advanced outside of Australia. So the invention in question may be obvious (and therefore non-inventive) in light of the CGK in another region, but not in light of the more limited CGK in Australia. As a result of the amendments, the Commissioner and the courts will not be precluded from taking into account the more advanced CGK outside of Australia.

Inventive step is also considered against the ‘prior art base’, which is, broadly, the publicly available information in the relevant technical field. In countries that are our major trading partners, and under the PCT, inventive step is assessed against a prior art base including all information available to the public before the priority date of the application. In contrast, in Australia, publicly available information is restricted to only that information that the skilled person could be reasonably expected to have ‘ascertained, understood and regarded as relevant’. Inventive step is then assessed against this restricted pool of information.

Implementation of the Raising the Bar Bill will remove the terms ‘ascertained, understood and regarded as relevant’. Thus the prior art base for inventive step will be information made publicly available before the relevant priority date. This will raise the standard for inventive step. Information that may render the invention obvious (and therefore non-inventive) has previously been excluded from consideration because it would not have been ‘ascertained’<sup>2</sup>. The Commissioner and the courts will no longer be precluded from considering such information in assessing inventive step.

### **Options to strengthen the Research Exemption in *Raising the Bar*:**

Both the Australian Law Reform Commission and the Senate Community Affairs Committee’s Gene Patents Report found there was uncertainty about the scope of any pre-existing common law research exemption, as it has never been tested by the courts and there is no precedent in Australia for how it might be applied. The research exemption in the Raising the Bar Bill provides researchers with certainty about where they have freedom to operate.

<sup>1</sup> The PCT is an international treaty, administered by the World Intellectual Property Organization (WIPO), between more than 140 countries. The PCT makes it possible to seek patent protection for an invention simultaneously in each of a large number of countries by filing a single “international” patent application instead of filing several separate national or regional patent applications. The granting of patents remains under the control of the national or regional patent Offices in what is called the “national phase”. [http://www.wipo.int/pct/en/basic\\_facts/faqs\\_about\\_the\\_pct.pdf](http://www.wipo.int/pct/en/basic_facts/faqs_about_the_pct.pdf)

<sup>2</sup> See *Commissioner of Patents v Emperor Sports Pty Ltd* [2006] FCAFC 26.

In response to Ms Melissa Parke MP's suggestions that the research exemption does not go far enough:

*She believes the exemption is too narrow as it does not include non-experimental or other non-commercial purposes such as clinical, educational, teaching or applied scientific purposes.* The research exemption introduced in Raising the Bar includes clinical and applied scientific purposes where they are carried out to improve or test, for example, clinical trials to test the effectiveness or safety of a patented invention, or to compare it with another invention. However, the exemption will not apply when an invention is being used as a research or teaching tool if that is the use for which the invention is patented. If an inventor has invested in developing a research tool, for example, a better microscope, then they should be able to recoup the costs of developing this new technology and making it available to the research community. Similarly, researchers who have invested in developing new and better teaching tools and have made them available to teachers and students should be able to benefit from the patent reward.

*Ms Parke also suggested it is very difficult to prove that research has no commercial interest.* The exemption does allow for some degree of commercial activity, as long as the predominant purpose of the activity is for research or experimentation. This means the exemption applies regardless of whether the research is carried out by a university or a commercial entity. The exemption will also apply even where there is a commercial goal to the research. This draws a clear line between research work to develop and test an invention, and the manufacture of the invention for sale, which will not be exempt.

*Ms Parke noted that if a researcher using a patented genetic material under the exemption invents a useful application relating to that material, they would then need to obtain a licence from the patent holder in order to commercialise their invention.* If a researcher using a patented genetic material under the exemption invents a useful application then generally the researcher will need to obtain a license if they wish to move from research to commercialisation of the invention they have developed by improving on a patented invention. It is reasonable that when they wish to gain a commercial advantage from their own invention that they provide some compensation to the original inventor.

#### Patent pools:

Cumulative technologies, inventions made up of several components or elements, often result in 'patent thickets' because different parties may have patented the various components.

Patent pools consist of an agreement between two or more patent owners to license one or more of their patents to one another and/or third parties. Patent pools have proven successful in solving patent thickets in the field of electronic technologies, a field in which the need to standardise technologies for interoperability creates an incentive to pool. Patent pools have been quite successful in the software and consumer electronics industries, for example, involving inventions whose use is essential to comply with a particular technical standard such as the DVD-ROM and

DVD-Video formats. The MPEG-2 patent pool relating to a digital video compression standard has helped to reduce the cost and burden of individual licensing of more than 425 essential patents owned by more than 20 patent holders.

Generally the need to standardise technologies for interoperability does not exist in biotechnology. Nonetheless, a few patent pools have been formed, particularly in the agricultural arena, including one pool involving crucial patents for 'Golden Rice'. However, even in agriculture, pools have yet to provide a full solution to the patent thicket problem.

Recently, the World Health Organization (WHO) has encouraged creation of patent pools in cases where there is a significant public interest. For example, it is currently developing a patent pool relating to patent rights over gene sequences for the SARS virus. While genetic testing is not currently subject to 'technical' standards similar to those in the software industry, some standardisation is evident with the WHO announcement in 2007 of the first international standard for a human genetic test, Factor V Leiden. If more biotechnology based standards become officially endorsed they could become organising principles around which patent pools could be formed.

The World Intellectual Property Organisation (WIPO) Re:Search is an initiative that aims to accelerate the discovery and product development of medicines, vaccines and diagnostics to develop new solutions for people affected by neglected tropical diseases, tuberculosis, and malaria. It makes intellectual property available to the global health research community. WIPO Re:Search provides a searchable, public database of available intellectual property assets and resources. It also facilitates new partnerships to support organisations that conduct research on treatments for neglected tropical diseases.

Possible Memorandum of Understanding (MoU) between pharmaceutical/biotechnology companies and health/consumer lobby groups:

Providing patent protection for innovators and researchers – while ensuring reasonable access to new technologies and medical treatments – are the key aims of the Government's Response in November 2011 to three gene patent reports. The policy aim is to use incentives provided by the patent system to encourage the development of new gene based technologies. But the Government stated that it "will not allow patent owners to block reasonable access to affordable medical treatments and essential diagnostic tests, nor to stifle legitimate research".

The existing safeguards of the compulsory licensing provisions and crown use can be used to ensure access to essential services and treatments are not blocked by patent holders.

The Consumers Health Forum (CHF) is a major peak national body representing the interests of Australian healthcare consumers. It appears to be the body most likely to enter into any Memorandum of Understanding (MoU) that may be developed between consumers and pharmaceutical/biotechnology industries concerning reasonable access to health solutions. CHF generally supports Raising the Bar and the Bill's aim 'to put in place the appropriate regulatory safeguards to support consumer access to the medical services they require'. They also state that this 'Bill takes into consideration

many of the recommendations made in previous inquiries relevant to patentable material'.

It appears to be reasonable for the Government to support an appropriate MoU if developed between the pharmaceutical/biotechnology industries and health/consumer organisations in order to ensure consumers have reasonable access to health services. This aim is consistent with the Government policy aims stated above.

## **ADDITIONAL INFORMATION REGARDING CHANGING INVENTIVE STEP STANDARDS IN AUSTRALIA**

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### **Introduction**

In economic terms, patent rights encourage innovation by providing both an incentive for industry investment and industry innovation assistance through publication of patents. The patent system addresses a potential market failure between ensuring effective knowledge diffusion and providing incentives for industry associated with the cost of investing in innovations. However, the temporary monopoly provided by patent rights as a barrier to the use of industry knowledge imposes an additional production cost and opportunity for premium product prices. There are additionally social concerns around patents acting as barriers to access to technology, in particular genetic diagnostic technology.

There are a number of mechanisms available that assist in addressing these policy and economic tensions, either by increasing knowledge diffusion or providing supplementary incentives to industry. The recent Raising the Bar changes to the inventive step provisions are an example of a policy initiative to assist in obtaining an appropriate balance between demand for access to technology and incentivising industry. Supplementary incentive mechanisms such as patent pools and MoU development between for example, industry and consumer lobby groups are additional options for potentially addressing this balance.

Important themes in the economic debate on IP include: the ‘optimal’ inventive step, the deleterious consequences of patent thickets, the effect of exclusive marketing rights for pharmaceuticals, the merits of international IP law harmonization, the role of the IP system in facilitating markets for technology, and the benefits of research exemptions.

This paper chiefly explores issues raised by inventive step changes.

### **Inventive step background**

Previous research by the Intellectual Property Research Institute of Australia (IPRIA) on the impact of patents on medical biotechnology has looked generally at patent system changes, rather than examining the effect of inventive step in isolation. This study found a lack of available empirical evidence<sup>1</sup>.

However, the effect of raising the Australian statutory inventive step in isolation has been addressed by the IPRIA Occasional Paper No. 1/08 in August 2008<sup>2</sup>. The 2008 paper presents an analysis of the expected effect of a higher inventive step on domestic incentives to invent, on foreign industry intentions to invest in Australia, and on rival businesses.

The results are complex and dependent on the technology and the industry. In the short term, raising the inventive step was predicted to have variable but overall positive effects. Over the long term raising the inventive step threshold was predicted to raise the individual economic value of individual granted patents. A negative impact on the Australian incentive to invent was predicted for certain types of industries, which may include pharmaceutical and chemical industries, where patents are known to be important for eliminating imitation and research and

<sup>1</sup> <http://www.ipria.org/publications/reports/BiotechReportFinal.pdf>

<sup>2</sup> Jensen, P.H, Palangkaraya, A, Webster, E and Yong, A. *The Effect of Raising the Australian Statutory Inventive Step on the Australian Global Production System\** Intellectual Property Research Institute of Australia Melbourne Institute of Applied Economic and Social Research University of Melbourne IPRIA paper

development costs are high.

### **Innovation policy implications of the new enforceable inventive step standard**

Australia is a net importer of IP, it is therefore important that our legislation is in line with our major trading partners. Comparative patent examination standards were discussed in the Jensen et al<sup>3</sup> IPRIA paper. In that paper, Australian statutory inventive step standards were estimated to be between United States (lower) and European Union (higher). Subsequent changes under US law<sup>4</sup> relating to obviousness effectively raised the standard of patentability in the United States. Australia has implemented Raising the Bar changes which, among other changes, are intended to raise the Australian inventive step threshold to align Australia's standards more closely with those of Europe and the United States.

### **Innovation policy implications of further inventive step standard changes**

Before consideration of further inventive step changes, empirical evidence of economic utility of the current Raising the Bar amendments would need to be analysed and policy developed. However, raising the inventive step further may mean local inventors would struggle to meet the new higher test in Australia and this could impede their export opportunities. There could also be an adverse impact on foreign investment, since inventors needing to bring intellectual property into Australia would be unsure whether it would be protected. It will be important to evaluate the impact of the changes being made through Raising the Bar prior to any further policy or legislative change.

### **Inventive step in patent examination**

Under the *Patents Act 1990*, the grant and final sealing of a patent creates an inventor's statutory personal property right and a patent monopoly to exploit the invention for a fixed term of 20 years<sup>5</sup>. The patent application is assessed prior to grant by the Commissioner of Patents, under a statutory assessment process termed "examination". Examination of a patent application for inventive step (also termed "obviousness") under the *Patents Act 1990* takes place under section 7 (see also Manual of Practice and Procedure paragraph 2.5.1.2). If the patent application lacks an inventive step (also termed 'obvious') then it is not patentable. The patent application claims are commonly then amended by the applicant to avoid the objection of lack of inventive step.

The test for inventive step requires the examiner to consider what would be obvious to a person skilled in the relevant art (PSA)<sup>6</sup>. Inventive step is considered in light of the 'common

<sup>3</sup> Ibid Appendices

<sup>4</sup> *Teleflex Inc v KSR International Co* 119 Fed.Appx. 282

<sup>5</sup> However, one of the terms of the Commonwealth grant to the inventor is that the inventor's specification is also published. The public availability of patent applications assists industry innovation.

<sup>6</sup> Section 7 of the Patents Act 1990 (as in force from 1 April 2002) provides that:

"(2) ... an invention is taken to involve an **inventive step** when compared with the prior art base unless the invention would have been **obvious** to a person skilled in the relevant art in the light of the common general knowledge as it existed in the patent area before the priority date of the relevant claim, whether that knowledge is considered separately or together with the information mentioned in subsection (3).

(3) The information for the purposes of subsection (2) is:

(a) any single piece of prior art information; or  
(b) a combination of any 2 or more pieces of prior art information;

being information that the skilled person mentioned in subsection (2) could, before the priority date of the relevant claim, be reasonably expected to have ascertained, understood, regarded as relevant and, in the case of information mentioned in paragraph (b), combined as mentioned in that paragraph."

general knowledge' (CGK), which is the knowledge that every person skilled in the art (PSA) may be expected to have. Currently, CGK for inventive step is restricted to what is known in Australia, although this will change as a result of Raising the Bar.

To quote the detail of the Patent Examiner's Manual 2.5.1.1: "An objection to lack of inventive step occurs where the essential features of a claim have not been previously disclosed but where the claimed features would still naturally suggest themselves (be obvious) to the person skilled in the particular art. Examiners must consider the issue of inventive step in the context of the relevant person skilled in the art, appraised of their common general knowledge, trying to solve a predetermined problem. ... For an objection to arise, it is not sufficient to merely find that the difference (or the claim) is common general knowledge. It must be established that the prior art information (if any) would be relied upon by a person seeking a solution to a problem, and that any consideration of that common general knowledge with that prior art information would naturally suggest itself to that person. The objection also arises where there is no difference between the invention claimed and the prior art information. However in such circumstances a novelty objection will always apply."

### **Raising the Bar removes geographic restriction**

The Raising the Bar Amendment removes this Australian geographical restriction, so that examiners may consider the standard of CGK globally in the particular expertise or field that the PSA would be expected to have. This geographical restriction is no longer relevant because of increasingly globally available information, and is not present in the patent laws of Australia's major trading partners or under the Patent Cooperation Treaty (PCT)<sup>7</sup>.

Comparing the same case before and after the amendments, the invention would be more likely to be considered obvious by a PSA in light of this expanded CGK test. This is particularly the case in areas where the CGK of the PSA in a particular technical field, may be more advanced outside of Australia. These changes increase the range of material that is deemed obvious when a patent application is examined and in effect increases the inventive step threshold, which increases the likelihood of finding the patent application obvious and not patentable. Also for those patents that are granted following these amendments, there is a presumption of a higher level of inventiveness.

### **Raising the Bar Amendments also remove restrictions on the prior art base**

Inventive step is also considered against the 'prior art base', which is, broadly, the publicly available information in the relevant technical field. In countries that are our major trading partners, and under the PCT, inventive step is assessed against a prior art base including all information available to the public before the priority date of the application.

Prior to the Raising the Bar amendments, in Australia, publicly available information is restricted to only that information that the skilled person could be reasonably expected to have 'ascertained, understood and regarded as relevant'. Inventive step is therefore assessed against a restricted pool of information. Information that may render the invention obvious (and therefore non-inventive) has previously been excluded from consideration because it would not have been 'ascertained'<sup>8</sup> by the PSA. The prior art base for inventive step will now be

<sup>7</sup> The PCT is an international treaty, administered by the World Intellectual Property Organization (WIPO), between more than 140 countries. The PCT makes it possible to seek patent protection for an invention simultaneously in each of a large number of countries by filing a single "international" patent application instead of filing several separate national or regional patent applications. The granting of patents remains under the control of the national or regional patent Offices in what is called the "national phase". [http://www.wipo.int/pct/en/basic\\_facts/faqs\\_about\\_the\\_pct.pdf](http://www.wipo.int/pct/en/basic_facts/faqs_about_the_pct.pdf)

<sup>8</sup> See *Commissioner of Patents v Emperor Sports Pty Ltd* [2006] FCAFC 26.

information made publicly available before the relevant priority date. This will also raise the standard for inventive step by raising the inventive step threshold.

The amendments to inventive step are also predicted to change compliance and enforcement standards during examination under the Patents Act. Patents are also required to be new (termed ‘novel’ under the Cth *Patents Act*), as well as not obvious. Applications for patents that are too obvious to be patentable were also commonly not new as well. Following the amendments, it is possible that inventive step objections will more often be sustained during the examination process.

Overall, the effect of Raising the Bar, coupled with practice changes introduced by IP Australia in 2010 to increase the rigour with which inventive step is assessed during examination of patent applications, increase the level of inventiveness required for grant of a patent in Australia. These changes also bring Australian standards into better alignment with the standards of our major trading partners, as shown in the table below.

**Comparative international inventive step provisions**

<p><b>AU (before Raising the Bar)</b></p>	<p>s 7(2) For the purposes of this Act, an invention is taken to involve an inventive step when compared with the prior art base unless the invention would have been obvious to a person skilled in the relevant art in light of common general knowledge as it existed in the patent area before the priority date of the relevant claim....</p> <p>s 7(3) The information for purpose of subsection (2) is:</p> <p>(a) any single piece of prior art information; or</p> <p>(b) a combination of any 2 pieces of prior art information:</p> <p>Being information that the skilled person mentioned in subsection (2) could, before the priority date of the relevant claim, be reasonably expected to have ascertained, understood and regarded as relevant.....</p>
<p><b>AU (after Raising the Bar)</b></p>	<p>s 7(2) For the purposes of this Act, an invention is taken to involve an inventive step when compared with the prior art base unless the invention would have been obvious to a person skilled in the relevant art in light of common general knowledge as it existed <u>in the patent area, whether in or out of the patent area</u>, before the priority date of the relevant claim....</p> <p>s 7(3) The information for purpose of subsection (2) is:</p> <p>(a) any single piece of prior art information; or</p> <p>(b) a combination of any 2 pieces of prior art information that <del>the</del> <del>Being information that</del> the skilled person mentioned in subsection (2) could, before the priority date of the relevant claim, be reasonably expected to have <del>ascertained, understood and regarded as relevant</del> <u>combined</u>.</p>
<p><b>Europe</b></p>	<p>An invention shall be considered as involving an inventive step if, having regard to the state of the art, it is not obvious to a person skilled in the art. EPC (Art 56)</p>

	The state of the art for inventive step comprises “everything made available to the public by means of written or oral description, by use, or in any other way, before the date of filing of the EP patent application”. (Art 54(2))
<b>United Kingdom</b>	<p>An invention shall be taken to involve an inventive step if it is not obvious to a person skilled in the art, having regard to any matter which forms part of the state of the art ...UK Patents Act (s 3)</p> <p>The state of the art in the case of an invention shall be taken to comprise all matter (whether a product, a process, information about either, or anything else) which has at any time before the priority date of that invention been made available to the public (whether in the United Kingdom or elsewhere) by written or oral description, by use or in any other way. (UK s 2(2))</p>
<b>United States of America</b>	<p>A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. (35 USC 103)</p> <p>(Prior art is documents published in the US or a foreign country, public use or sale in the US. The common general knowledge is knowledge anywhere in the world.)</p>
<b>Japan</b>	Where an invention <i>could</i> easily have been made, prior to the filing of the patent application, by a person with ordinary skill in the art to which the invention pertains, on the basis of an invention or inventions [which were publicly known or worked in Japan or described in a publication anywhere], a patent shall not be granted for such an invention... (Patent Law Section 29(2))
<b>Patent Cooperation Treaty</b>	<p>A claimed invention shall be considered to have an inventive step if, having regard to the prior art as defined in the Regulations, it is not, at the prescribed relevant date, obvious to a person skilled in the relevant art. (Art 33)</p> <p>The prior art for the purposes of assessing the novelty and inventive step of an invention is defined as “everything made available to the public anywhere in the world by means of written disclosure (including drawings and other illustrations)” before the “relevant date.” (rule 64)</p>

**Conclusion**

The recent changes to the inventive step threshold in Australia aim to improve the balance between knowledge diffusion and providing industry incentive to innovate, and align Australia’s inventive step standards with those of our major trading partners.

FURTHER REFERENCES

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**Re: data:** Jensen, P. H. and Webster, E. (2008), Australian Innovation Data. *Australian Economic Review*, 41: 323–329. doi: 10.1111/j.1467-8462.2008.00516.x

**Re: inventive step effect of changes on Australian industry production and comparative international standards:** Jensen, P.H, Palangkaraya, A, Webster, E and Yong, A. *The Effect of Raising the Australian Statutory Inventive Step on the Australian Global Production System\** Intellectual Property Research Institute of Australia Melbourne Institute of Applied Economic and Social Research University of Melbourne IPRIA paper 2008

# B12/1068 - Raising the Bar - Research Exemption, Inventive Step Standards and Other Aspects of the Patent System [SEC=IN-CONFIDENCE] - Notes Memo

**From:** [Andrea.Blazsev@ipaaustralia.gov.au](mailto:Andrea.Blazsev@ipaaustralia.gov.au)  
**To:** mlobriefs@innovation.gov.au, kaye.fisk@innovation.gov.au  
**Cc:** Frances.Roden@ipaaustralia.gov.au  
**Sent:** 05-04-2012 09:08:08 AM

Good morning MLO

Please find attached information brief B12/1068 - Raising the Bar - Research Exemption, Inventive Step Standards and Other Aspects of the Patent System.

It has been cleared by Philip Noonan, Director General, IP Australia.

<Attachment: 12-04-04 B12-1068 IB Various aspects of the patent system.doc> <Attachment: 12-04-04 B12-1068 Attachment A.doc>

Kind Regards,

## Ministerial Support Team

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# B12/1068 Redraft - Various Aspects of the Patent System [SEC=IN-CONFIDENCE] - Notes Memo

**From:** [Andrea.Blazsev@ipaaustralia.gov.au](mailto:Andrea.Blazsev@ipaaustralia.gov.au)  
**To:** mlobriefs@innovation.gov.au, kaye.fisk@innovation.gov.au  
**Cc:** Matthew.Forno@ipaaustralia.gov.au, Frances.Roden@ipaaustralia.gov.au, Anthea.Harvie@ipaaustralia.gov.au  
**Sent:** 04-05-2012 09:07:44 AM

MLO

Please find attached the redraft of B12/1068 - Various Aspects of the Patent System. Please note that Attachments B and C are the new material and the brief itself has also been amended to include reference to these attachments. Attachment A remains the same.

The redraft has been cleared by Matt Forno, A/g General Manager - Business Development and Strategy Group, IP Australia.

<Attachment: 12-05-03 B12-1068 IB Various aspects of the patent system - redraft.doc> <Attachment: 12-04-04 B12-1068 IB Attachment A.doc> <Attachment: 12-05-03 B12-1068 IB Attachment B- additional information on inventive step.doc> <Attachment: 12-05-02 B12-1068 IB Attachment C IPRIA paper on inventive step.pdf>

Kind Regards,

## Ministerial Support Team

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## **Additional background and examples**

### **Inventive step standards:**

Inventive step is considered in light of the ‘common general knowledge’ (CGK), which is the knowledge that every worker in the art may be expected to have. Currently, CGK for inventive step is restricted to what is known in Australia. This geographical restriction is not present in the patent laws of Australia’s major trading partners or under the Patent Cooperation Treaty (PCT)<sup>1</sup>: it is the CGK of the worker in the relevant art that is taken into account, not the knowledge of the worker in a specific geographical location.

Implementation of the changes in the Raising the Bar Bill will remove this geographical restriction, which raises the standard for inventive step. The CGK in a particular technical field may be more advanced outside of Australia. So the invention in question may be obvious (and therefore non-inventive) in light of the CGK in another region, but not in light of the more limited CGK in Australia. As a result of the amendments, the Commissioner and the courts will not be precluded from taking into account the more advanced CGK outside of Australia.

Inventive step is also considered against the ‘prior art base’, which is, broadly, the publicly available information in the relevant technical field. In countries that are our major trading partners, and under the PCT, inventive step is assessed against a prior art base including all information available to the public before the priority date of the application. In contrast, in Australia publicly available information is restricted to only that information that the skilled person could be reasonably expected to have ‘ascertained, understood and regarded as relevant’. Inventive step is then assessed against this restricted pool of information.

Implementation of the Raising the Bar Bill will remove the terms ‘ascertained, understood and regarded as relevant’. Thus the prior art base for inventive step will be information made publicly available before the relevant priority date. This will raise the standard for inventive step. Information that may render the invention obvious (and therefore non-inventive) has previously been excluded from consideration because it would not have been ‘ascertained’<sup>2</sup>. The Commissioner and the courts will no longer be precluded from considering such information in assessing inventive step.

### **Options to strengthen the Research Exemption in *Raising the Bar*:**

Both the Australian Law Reform Commission and the Senate Community Affairs Committee’s Gene Patents Report found there was uncertainty about the scope of any pre-existing common law research exemption, as it has never been tested by the courts and there is no precedent in Australia for how it might be applied. The research exemption in the Raising the Bar Bill provides researchers with certainty about where they have freedom to operate.

<sup>1</sup> The PCT is an international treaty, administered by the World Intellectual Property Organization (WIPO), between more than 140 countries. The PCT makes it possible to seek patent protection for an invention simultaneously in each of a large number of countries by filing a single “international” patent application instead of filing several separate national or regional patent applications. The granting of patents remains under the control of the national or regional patent Offices in what is called the “national phase”. [http://www.wipo.int/pct/en/basic\\_facts/faqs\\_about\\_the\\_pct.pdf](http://www.wipo.int/pct/en/basic_facts/faqs_about_the_pct.pdf)

<sup>2</sup> See *Commissioner of Patents v Emperor Sports Pty Ltd* [2006] FCAFC 26.

In response to Ms Melissa Parke MP's suggestions that the research exemption does not go far enough:

*She believes the exemption is too narrow as it does not include non-experimental or other non-commercial purposes such as clinical, educational, teaching or applied scientific purposes.* The research exemption introduced in Raising the Bar includes clinical and applied scientific purposes where they are carried out to improve or test, for example, clinical trials to test the effectiveness or safety of a patented invention, or to compare it with another invention. However, the exemption will not apply when an invention is being used as a research or teaching tool if that is the use for which the invention is patented. If an inventor has invested in developing a research tool, for example, a better microscope, then they should be able to recoup the costs of developing this new technology and making it available to the research community. Similarly, researchers who have invested in developing new and better teaching tools and have made them available to teachers and students should be able to benefit from the patent reward.

*Ms Parke also suggested it is very difficult to prove that research has no commercial interest.* The exemption does allow for some degree of commercial activity, as long as the predominant purpose of the activity is for research or experimentation. This means the exemption applies regardless of whether the research is carried out by a university or a commercial entity. The exemption will also apply even where there is a commercial goal to the research. This draws a clear line between research work to develop and test an invention, and the manufacture of the invention for sale, which will not be exempt.

*Ms Parke noted that if a researcher using a patented genetic material under the exemption invents a useful application relating to that material, they would then need to obtain a licence from the patent holder in order to commercialise their invention.* If a researcher using a patented genetic material under the exemption invents a useful application then generally the researcher will need to obtain a license if they wish to move from research to commercialisation of the invention they have developed by improving on a patented invention. It is reasonable that when they wish to gain a commercial advantage from their own invention that they provide some compensation to the original inventor.

#### Patent pools:

Cumulative technologies, inventions made up of several components or elements, often result in 'patent thickets' because different parties may have patented the various components.

Patent pools consist of an agreement between two or more patent owners to license one or more of their patents to one another and/or third parties. Patent pools have proven successful in solving patent thickets in the field of electronic technologies, a field in which the need to standardise technologies for interoperability creates an incentive to pool. Patent pools have been quite successful in the software and consumer electronics industries, for example, involving inventions whose use is essential to comply with a particular technical standard such as the DVD-ROM and

DVD-Video formats. The MPEG-2 patent pool relating to a digital video compression standard has helped to reduce the cost and burden of individual licensing of more than 425 essential patents owned by more than 20 patent holders.

Generally the need to standardise technologies for interoperability does not exist in biotechnology. Nonetheless, a few patent pools have been formed, particularly in the agricultural arena, including one pool involving crucial patents for 'Golden Rice'. However, even in agriculture, pools have yet to provide a full solution to the patent thicket problem.

Recently, the World Health Organization (WHO) has encouraged creation of patent pools in cases where there is a significant public interest. For example, it is currently developing a patent pool relating to patent rights over gene sequences for the SARS virus. While genetic testing is not currently subject to 'technical' standards similar to those in the software industry, some standardisation is evident with the WHO announcement in 2007 of the first international standard for a human genetic test, Factor V Leiden. If more biotechnology based standards become officially endorsed they could become organising principles around which patent pools could be formed.

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Providing patent protection for innovators and researchers – while ensuring reasonable access to new technologies and medical treatments – are the key aims of the Government's Response in November 2011 to three gene patent reports. The policy aim is to use incentives provided by the patent system to encourage the development of new gene based technologies. But the Government stated that it "will not allow patent owners to block reasonable access to affordable medical treatments and essential diagnostic tests, nor to stifle legitimate research".

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many of the recommendations made in previous inquiries relevant to patentable material'.

It appears to be reasonable for the Government to support an appropriate MoU if developed between the pharmaceutical/biotechnology industries and health/consumer organisations in order to ensure consumers have reasonable access to health services. This aim is consistent with the Government policy aims stated above.

**Parliamentary Secretary:** Information  
 cc: Minister Combet  
 Minister Evans

**Brief No:** B12/1068  
**Division/Agency:** IP Australia

**RAISING THE BAR - RESEARCH EXEMPTION, INVENTIVE STEP STANDARDS AND OTHER ASPECTS OF THE PATENT SYSTEM**

**Timing:** Routine

<b>Recommendation/s:</b>	<b>Approved/Noted</b>
That you note the information provided on various aspects of the patent system, as requested by your office.	Yes / No
<b>Parliamentary Secretary's signature:</b>	<b>Date:</b>

**Key Points**

- Patent rights are a key feature of global knowledge-based economies. By providing innovators an exclusive title to an invention for a limited period of time, patent rights facilitate innovation, technology and knowledge transfer and inward investment.
- Research, development and commercialisation of products and services, particularly in cutting edge technology areas such as biotechnology, medical devices and communication technologies, can be time consuming, high risk and expensive. Without an incentive such as the patent system, which creates a secure environment for investment, many innovations would not be translated into new technologies that benefit Australian society. In return for this exclusive right the patent system requires innovators to publicly disclose their inventions, supporting follow-on research and innovation. Patent rights also increase the probability of public sector research being commercialised by industry. A robust patent system also ensures that new technologies, including medical treatments developed overseas, are made available in Australia.
- The Australian Law Reform Commission's 2004 report on *Genes and Ingenuity: Gene Patenting and Human Health*, the Senate Community Affairs Committee's *Gene Patents* Report released in November 2010 and the Advisory Council on Intellectual Property's 2011 report on patentable subject matter made recommendations for change to a number of aspects of the Australian patent system. The Government's response to these reports, released on 23 November 2011 accepted the majority of the recommendations in these reports (**B11/4524** refers).
- The *Intellectual Property Laws Amendment (Raising the Bar) Bill 2011* implements a number of these changes, ensuring Australia has strong and internationally aligned patenting criteria for novelty, inventive step, usefulness and description of the invention. The Bill also introduces a research exemption, providing certainty to researchers to research without fear of prosecution for patent infringement (**B12/827** and **B12/368** refer).
- Information on the specific issues raised in the briefing request is provided below and in **Attachment A**.

## Issues/sensitivities

### Inventive step standards:

Australia is a net importer of IP, it is therefore important that our legislation is in line with our major trading partners. The Raising the Bar Bill increases the inventive step standard in Australia, so it aligns with that of our major trading partners, through removing the geographical restriction on common general knowledge, and removing the requirement for the prior art base (the publicly available information in the relevant technical field) to have been 'ascertained, understood and regarded as relevant'. Further detail is provided at **Attachment A**.

Australia's test for inventive test considers whether the invention is 'obvious', if it is, then it is not patentable. The same test is applied in Europe. In the United States, a 'non-obvious' test is used, resulting in an invention that is non-obvious being patentable. Conversely, an 'obvious' invention is not patentable, as in Australia.

It would not be in Australia's interests to have a higher threshold for inventiveness than other countries have. Local inventors would struggle to meet the higher test in Australia and this would probably impede their export opportunities. There could also be an adverse impact on foreign investment, since inventors needing to bring intellectual property into Australia would be unsure whether it would be protected.

### Options to strengthen the Research Exemption in *Raising the Bar*:

Ms Melissa Parke MP in her Raising the Bar second reading speech to the House of Representatives on 19 March 2012 suggested the research exemption does not 'go far enough'. She raised a number of issues with the exemption, outlined further at **Attachment A**.

The exemption introduced includes clinical and applied scientific purposes where they are carried out to improve or test an invention. However, the exemption will not apply when an invention is being used as a research or teaching tool if that is the use for which the invention is patented.

This exemption allows for some degree of commercial activity, as long as the predominant purpose of the activity is for research or experimentation.

If a researcher using a patented genetic material under the exemption invents a useful application, then in many circumstances the researcher will need to obtain a license if they wish to move from research to commercialisation. However, the researcher has benefited from the original invention, so it is only reasonable that when they wish to commercialise their invention they provide some compensation to the original inventor.

On the other hand, if the new invention is sufficiently different from the original invention, the researcher will not need to obtain a license because their invention differs to an extent that does not infringe the original invention.

Under our current understanding of the law, if a new diagnostic test using a patented isolated gene sequence is commercialised, the owner of the new test, when taking it to market would need to negotiate licensing provisions with the patentee of the gene sequence. This is because the commercialisation of a new diagnostic test or treatment of disease based on a patented isolated genetic sequence does not constitute research, and as such does not fall under the research exemption.

### Patent pools:

Patent pools can be defined as an agreement between two or more patent owners to license one or more of their patents to one another and/or third parties. The key benefit of patent pools is in reducing transaction costs for users having to identify relevant patents and then seek cross licensing arrangements with multiple individual patent holders. Patent pools are particularly beneficial in cases where the relevant technology is subject to fragmented patent ownership, such as may be the case when a technology is developing very rapidly, as has been the case in recent years in IT technology. Examples of successful use of patent pools are at **Attachment A**.

The establishment of patent pools tends to be driven by industry on a voluntary basis, governments have little role in their creation. However, governments can create incentives and provide the appropriate institutional framework to actively encourage setting up of patent pools in any particular technology field.

To date there is little experience within governments to incentivise, facilitate or regulate patent pools.

Possible Memorandum of Understanding (MoU) between pharmaceutical/biotechnology companies and health/consumer lobby groups:

The Government recognises there needs to be a balance between achieving affordable access to healthcare and the ability to stimulate biomedical research and innovation.

The Australian patent system has existing safeguards such as the crown use and compulsory licensing provisions that can be used to ensure access to essential services and treatments are not blocked by patents.

As part of the implementation of the Government's response to the gene patent reports (**B11/4524** refers) a review of the compulsory licensing provisions will be undertaken (**B12/859** refers). Another recommendation is to improve the understanding of crown use. IP Australia is implementing this recommendation through an education and awareness program.

Additional information is provided at **Attachment A**.

Retrospectivity issues associated with banning gene patents:

If the Australian courts decide that isolated gene sequences are unpatentable, changes will likely be prospective and retrospective. This would be so because the court would probably decide that isolated gene sequences were never patentable, with the result that existing patents are invalid. Other parties wishing to use patented gene sequences would be able to either litigate, to have the patent in question revoked, or they may choose to simply use the patented sequence on the assumption that the patent is invalid.

If the government introduces a Bill that excludes isolated gene sequences from patentable subject matter, the changes would be prospective only, unless constitutional compensation was offered (section 51(xxxi) of the Constitution provides for acquisition of property on just terms). This is because it would be open to patent owners (in the absence of a court decision) to argue that the Government was acquiring an existing legal right.

Excluding isolated gene sequences from patentable subject matter may mean Australia is vulnerable to a claim of inconsistency with the Trade-Related Aspects of Intellectual Property Rights Protocol (TRIPS) and the Australia-United States Free Trade Agreement (AUSFTA). Under these agreements Australia is obliged to make patents available for 'any invention... in all fields of technology'.

**Consultation**

- Pharmaceutical, Health Industries and Enabling Technologies Branch, Department of Industry, Innovation, Science, Research and Tertiary Education.

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**Attachments**

Attachment A: Additional background and examples

# **The Effect of Raising the Australian Statutory Inventive Step on the Australian Global Production System\***

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## 1. INTRODUCTION

This paper analyses the effect of raising the inventive step requirements in the Patents Act 1990 on Australia's position in the global supply chain. In particular, we consider the likely effects on the intentions of foreign multinational enterprises (MNEs) to invest in Australia and the ability of Australian businesses to compete in the global market.

The design of the patent system – of which the examination threshold is an important component – has received substantial attention in the literature over the last 50 years or so, but there are still many gaps in our understanding. Here, we attempt to refine the literature by focusing our attention specifically on changing one aspect of the patent system: the effect of raising the size of the inventive step required to obtain a patent. Despite its importance, much of the literature has overlooked this issue in favour of other facets of the patent system such as changes to the enforcement regime.<sup>1</sup>

From an economic perspective, patent rights operate in inherently second-best markets and are crude attempts to address the potential market failure arising from the tension between providing sufficient incentives to invest in innovative activities and ensuring effective knowledge diffusion. That is, patents provide an incentive to invest but this comes at a cost since they result in higher prices and slower diffusion of knowledge (by creating a legal barrier to the free use of the knowledge). In order to concentrate patents in areas where the benefits from the incentive effect are greatest, and the costs from the slower-diffusion effect are smallest, a patented invention must satisfy three criteria: novelty, non-obviousness and utility.<sup>2</sup> The second requirement, non-obviousness, which means that an invention encompasses knowledge that is a step higher than existing knowledge, is the criterion of interest to us. There is, in principle, a step size such that the net benefits of knowledge creation and diffusion are maximised. This step is called the 'optimal' inventive step threshold.

However, in practice it is most probable that the optimal inventive step threshold is different across industries and technologies. In fact, Hunt (2007) argues that the size of the optimal inventive step is positively correlated with the productivity of R&D. Policy objectives aimed at protecting industries

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<sup>1</sup> Exceptions to this statement are Hunt (1999; 2007), Gallini (2002) and Encaoua et al. (2006) who do consider the effects of the size of the inventive step on innovation.

<sup>2</sup> These three fundamental tenets are enshrined in the legal system of all nations that are signatories to TRIPS.

where R&D is not very productive would be best served by having a low inventive step requirement, whereas a policy objective aimed at protecting industries where R&D is more productive would be best served by a high inventive step requirement. In the latter instance, although a smaller number of patents would be granted, innovation would be more rapid in those industries. The reason for this policy recommendation is based on the logic that, by making the prize in the form of a patent grant harder to obtain, it also becomes more valuable in that the financial reward becomes greater. Since the industry enjoys very productive R&D, the prize is not beyond the reach of inventors who are fully capable of leapfrogging the previous technology. However, to simplify the discussion here, we refrain from considering varying the inventive step requirements for different industries and simply consider the average effects of raising the inventive step requirement across all industries.<sup>3</sup> In particular, we consider the effects of raising the ‘revealed’ inventive step. By revealed, we mean the size of the step that in practice is required for a patent grant. In an ideal world, the optimal inventive step should coincide with the revealed inventive step. In practice, however, many factors could cause a wedge between the optimal and the revealed inventive steps.

Since the focus is on the incentives to invest by MNEs and Australian businesses competing in the world market, we first provide a brief background discussion on the nature of global production, that is, what determines whether an MNE will choose to undertake foreign direct investment (FDI) in Australia and the factors determining the revealed inventive step. For each affected party – domestic inventors, foreign MNEs and rivals of these two groups – we consider the likely effects on behaviour under four sets of stylised circumstances. A more comprehensive review of the literature is included in the Appendix.

## **2. THE NATURE OF GLOBAL PRODUCTION**

The success of a business often depends on the achievement of economies of scale. Scale economies can arise from the adoption of the most advanced physical technologies or by fully exploiting intangible assets. Whether a business needs to go international to achieve these economies depends on size of the domestic market and the nature of technology. At the limit, all businesses need to access global markets at some stage if they are to expand, hence their export focus depends on their stage of

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<sup>3</sup> We do, however, discuss reasons why patents maybe more effective in some technology areas than others.

maturity. Accordingly, there is no clear distinction between domestic-orientated versus export-orientated businesses. It is partly a matter of how successful they are and their history. All Australian businesses, even those in non-traditional sectors such as childcare, job placement, cafes and welfare, are potential multinationals. Accordingly, any change to the patent system should consider the effects on all businesses, not just current exporters.

### **3. GOING GLOBAL: FDI OR EXPORT?**

A foreign MNE wanting to supply the Australian market will make a choice between FDI in Australia or exporting (or a mix of both). Alternatively, a foreign MNE wanting to supply the world market in general will make a choice between FDI in Australia or FDI elsewhere. Both exporters and investors into Australia will require patent protection, if they have patentable products and processes. However, we expect that since FDI involves transferring the technology as well as the product, the requirements from the patenting system of MNEs considering FDI are greater. Hence, if the type and strength of protection offered by a country is critical to an FDI decision, this will have some impact on MNEs considering *how* to supply the Australian market (FDI versus export) but the impact would be even greater on MNEs considering *whether* to use Australia as a production base.

We conventionally think about FDI as an activity that involves the transfer of production facilities and its associated technologies. Historically, R&D has been kept close to headquarters and foreign-affiliate R&D was used mainly to adapt the product to local conditions (Cincera *et al.* 2005). However since the 1980s there has been an increase in the amount of FDI that is specifically R&D in nature (especially in automotive and pharmaceuticals). This trend towards Australian-based R&D (e.g., GM, Bosch) should not affect the FDI decision since what matters most is the ability to patent in the jurisdictions of the ultimate customer.

There is a considerable literature documenting the factors determining the choice between undertaking FDI and committing to export. Briefly, a foreign MNE will be more likely to undertake FDI in Australia instead of exporting to Australia or FDI elsewhere if:

- transporting the product to the consumer market is either costly relative to value or impractical, and consequently production needs to be proximate to customers (especially in services);
- cheaper production facilities exist in Australia (because of lower taxes, wages or raw materials);

- there is access to cheaper skilled labour in Australia;
- there is access to cheaper finance in Australia;
- there are lower costs in terms of accessing Australian knowledge spillovers; or
- there are lower costs in terms of controlling the seepage of knowledge into Australia (brand, patent, design protection).

In general, the first three points – transport, production and labour costs – are the most commonly cited factors. However, increasingly, there are more examples of businesses locating in high-wage countries in order to access the local knowledge base and venture capital finance. These examples refer almost exclusively to high-tech sector FDI. Nonetheless, it is the final factor above, the cost of preventing imitation of ideas (i.e., controlling outgoing knowledge spillovers), which is at the heart of our question. While preventing imitation is less commonly cited as a factor in FDI, our task is to evaluate its importance, at the margin, to decisions regarding FDI versus export, and FDI in Australia versus FDI elsewhere.

From the perspective of the patent applicant, there are four main factors affecting the ease with which to prevent imitation:

- the cost of the patent application;
- the probability of patent grant;
- the ability to detect imitation on patented ideas; and
- the effectiveness of the patent enforcement regime.

#### **4. DETERMINANTS OF THE REVEALED INVENTIVE STEP**

Changing the statutory inventive step threshold will affect the first two factors listed above: the patent application and examination processes.<sup>4</sup> However, the statutory inventive step is not the only factor in determining the proportion of applications that are granted. In addition to the wording of the statute, actual grant rates depend on common law and patent office protocols and procedures. We call the outcome of three interdependent forces what we call the ‘revealed inventive step’.

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<sup>4</sup> The inventive step criterion is arguably most decisive in whether or not a patent is granted. The other criteria – novelty and industrial applicability – are more easily met.

According to the legal interpretation of the statutes, Australia has lower inventive step criteria than both the USPTO and EPO, with the latter two considered comparable in this regard. However, according to studies comparing the actual grant rates across patent offices, the United States had the lowest inventive step, followed by Australia and then the EPO (Webster *et al.* 2007, Jensen *et al.* 2006<sup>5</sup>). These studies report what we call the revealed inventive step, that is, the overall outcome of the statute, common law and office protocols and procedures combined.

In this paper we discuss only the effects of increasing the statutory inventive step, however we assume that this has a clear positive relationship with the revealed inventive step. That is, whatever the interdependencies between the statute, common law and office protocols and procedures, the net effect of tightening the criteria under the statute is to raise the revealed inventive step.

## 5. EFFECT OF RAISING THE THRESHOLD ON AUSTRALIA'S POSITION IN THE GLOBAL SUPPLY CHAIN

We consider the effect of two distinct changes to the inventive step threshold on Australia's position in the global supply chain: first, the inventive step criteria in the Australian statute is made *parallel* or harmonised with the United States and European Union, and second, the inventive step criteria in the Australian statutes are made *stricter* than the in United States and European Union.

These changes imply two distinct effects:

1. Harmonising the law to be consistent with US or EU laws will reduce transaction costs if it reduces the duplication of patent attorney drafting work for multi-jurisdiction applicants. Reductions in transaction costs are unambiguously good for investment and economic efficiency, all other things considered. This benefit accrues to Australian inventors as the result of any unilateral decision to harmonise. An additional benefit will arise if international patent offices can share the results of at least one prior art search and accordingly the total cost of application falls. However, such a benefit accrues only in the event of a multilateral agreement. Harmonisation, *of itself*, may lead to more patents being granted as applications are cheaper and easier to file.

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<sup>5</sup> These studies only included examination decisions up until 2004 and would thereby not include the effects of the recent KSR vs Telflex decision in the US.

2. In the first instance, we expect that increasing the inventive step leads to a lower percentage of patent applications being granted. Accordingly, we need to consider the marginal economic effects of fewer patents being granted to Australian and foreign firms, which is not straightforward. We argue that these effects depend on the characteristics of the technology area of the marginal applicant, the most important of which we identify below. This ‘fewer patents’ effect will apply both where the Australian statute is made parallel or harmonised with the United States and European Union, and where it exceeds the US and EU standards.

The second point – the ‘fewer patents’ effect – needs closer examination as there can be subtle and countervailing forces at work. We do this by considering how we would expect players in the global business environment to behave in a hypothetical scenario where a patent is granted, compared with the counterfactual where it is not. In so doing we need to assume away other changes to the patent system. Accordingly, we assume that:

- it is patent applications with the smallest inventive step that would not be granted under the counterfactual (we assume that the inventive step can be measured accurately);
- the effectiveness of the enforcement regime remains unchanged; and
- other reasons for MNEs wanting to undertake FDI to Australia are unchanged.

## **6. EXAMINING THE ‘FEWER PATENTS’ EFFECT**

In the following tables, we use the available theoretical and empirical literature, as reviewed in the appendix, to try and identify the effect of ‘fewer patents’ on i) domestic businesses’ incentive to invent; ii) foreign MNEs’ intention to undertake technology transfer; and iii) the effects on rival businesses.

All investment decisions are guided by the expected economic return from the activity. In the case of a domestic invention, this return is a ratio of the net increment in the business’s profits to the costs of R&D. The importance of R&D costs is straightforward. The smaller are these costs, the greater is the rate of return to an invention for all levels of positive net increment in profits. The increment to business profits depends on how well patents prevent imitation, thereby enabling patentees to earn monopoly profits. In general, patents offer better protection against imitators:

- the more codified the technology and thus the easier it is technically to replicate the invention – the IT, chemical and pharmaceutical technologies are considered highly codified;

- where alternative ways to prevent imitation are prohibitively expensive; and
- in slow-moving technologies where inventions take a long time to become obsolete.

In the contrary case, patents are considered to add little to business profits since they have a minimal effect on imitation. These are cases where:

- the technology is tacit, or difficult to express in words, and can only be fully revealed, and thereby copied, through personal contact and interaction;
- where many alternative ways exist to prevent imitation such as the use of secrecy, brand names or the sheer technical difficulty of reproducing complex production systems; and
- the technology is rapidly changing so that even a well-protected patented invention will become obsolete in a short time.

Table 1 presents the expected effect of a higher inventive step on domestic incentives to invent. We consider the situation where a patent application which would have been granted under the old regime is now rejected under the new regime. It shows that the loss of patent protection only has an impact in instances where the patent is important in sustaining monopoly profits *and* the R&D costs underlying the invention are large. In all other cases, the effects are negligible or zero. These effects will be greatest when the domestic applicant is filing a patent *only* in Australia. For cases where Australia is one of several jurisdictions where applications are being filed, the relative effect of an Australian rejection is even smaller.

**Table 1: Marginal Investment effect on rejected domestic applicant’s incentive to invent**

Patent protection \ Cost of invention	High cost R&D	Low cost R&D
	<b>Patent gives good protection against imitators</b> - well-codified - no alternative forms of protection - slow moving technology	Negative
<b>Patent gives poor protection against imitators</b> - highly-tacit - other appropriation alternatives - fast moving technology	Negligible	None

In the case of a foreign MNE, the rate of return to investing in Australia depends on how well patents intrinsically prevent imitation (as defined above) and the erosion of the foreign MNE’s monopoly position through imitation in Australia. The latter is more likely to occur if Australia has strong capabilities in that technology area and is able to invent around or otherwise copy the foreign technology with ease.

Table 2 gives the four potential outcomes of this situation. As with the domestic situation, we can deduce that the effect of raising the inventive step on foreign MNE intentions to invest in Australia is significant only in technologies or industries where patents give good protection against imitators *and* Australia has strong R&D capabilities. Unless Australia builds up capabilities – a long term prospect – there should not be any effect on FDI in the weak-capability industries. Again, how much profits the MNE loses as a result of imitation of the rejected patent depends on how important the Australian market is for the MNE. This is because Australian imitators are not able to export products embodying the copied technology or idea to jurisdictions where the patent applies. A rejected surfboard patent is expected to have a large impact on foreign surfboard MNE profits, but a rejected automotive patent will not.

**Table 2: Marginal effect on rejected foreign applicant’s intention to invest in Australia**

Local capabilities Patent protection	Strong Australian capability	Weak Australian capability
<b>Patent gives good protection against imitators</b> - well-codified - no alternative forms of protection - slow moving technology	<b>Negative</b>	<b>None (medium term outlook)</b>
<b>Patent gives poor protection against imitators</b> - highly-tacit - other appropriation alternatives - fast moving technology	<b>Negligible</b>	<b>None (medium term outlook)</b>

Finally, Table 3 presents the effects on other patentees in proximate markets to the affected patent applicant. The effects on this group of competitors are often overlooked since the impact on them is



a positive effect on domestic innovation where patents are known to be effective in blocking rival R&D efforts. In the first two cases, the negative effects are smaller where the rejected patent application is more marginal and less economically significant. In addition, the less important the Australian market is for the MNE, the smaller is the effect on investment decisions.

Harmonising laws to minimise the need for the applicant to pay for multiple application drafts will have clear and unambiguously positive effects on both the domestic incentive to invent and MNE FDI into Australia.

We caution that the above analysis ignores the *long-term* impact of raising the inventive step on economic and inventive activities. While raising the inventive step would likely result in a decrease in the overall number of patents granted in the short run, it is less clear what would happen in the long term. It is worth noting that patents that are granted under a higher inventive step threshold ought to be more valuable to businesses, since there will be fewer competitors in the market place. Given that a patent in effect grants the inventor a monopoly position, this monopoly position is stronger if there are fewer competing products. That is, it raises the power of the patentee to appropriate returns from the invention (in other words, it increases the patent's economic value). In the long run this stronger monopoly position should provide a greater incentive to undertake R&D.

Furthermore, is it also not clear what would happen to patent granting *rates* in the long run. Increasing the inventive step threshold may result in the rejection of applications that would otherwise have been granted, which seems to imply that the patent granting rate would fall from, say, 80 per cent to 70 per cent. But this is not necessarily so in the long run, since it is quite likely that as applicants learn about the new inventive step threshold they will reduce the number of applications with low inventive steps (and therefore low probability of being granted). Thus the patent granting rate may in fact stay at its pre-existing level of 80 per cent (assuming this is some sort of equilibrium grant rate). This simple example highlights the importance of dynamics in any analysis of patent parameter changes.

## **APPENDIX: REVIEW OF THE LITERATURE**

Much of the empirical literature we consider in this report examines what happens when changes are made to one aspect or another of a country's patent regime. Such studies consider the effects of patent regime changes on variables such as R&D expenditure, trade flows and foreign direct investment (FDI). The usefulness of these empirical findings for policy purposes depends on how well the authors have understood and measured changes to the patent system. At best, the author(s) define and carefully detail the nature of the change in the patenting institutions and laws. However, more often than not authors simply use composite measures of a patent regime which typically conflate changes to the statute or administrative rules with changes in patent scope and enforcement mechanisms.

While there have been numerous examples of jurisdictions making changes to their enforcement mechanism and redefining the scope of patentable inventions, especially following the establishment of TRIPS, cases where the inventive step threshold has changed are more scarce. The most well recognised example occurred during the 1980s in the United States where the effect of the courts relaxing the non-obviousness requirement for all inventions was believed to have flowed through to the examination procedures at the USPTO (Hunt 1999; Barton 2000; Kingston, 2001; Merges, 1999).<sup>6</sup>

In fact, there are no empirical studies that actually measure the effect of changes in the inventive step threshold on economic performance, and only a limited number that consider the issue from a theoretical stand-point (Hunt 1999; Gallini 2002; Encaoua et al. 2006; Jensen and Webster 2004). Nevertheless, these theoretical studies enable us to gain some insight into how and why a change in the inventive step threshold may shape the pattern of R&D expenditure and other economic factors. One probable cause of the dearth of empirical studies on the effect of such changes is that inventiveness is difficult to observe: it is essentially a subjective measure. Patent examiners are provided with tools and techniques aimed at providing a rigorous basis for evaluating an application's inventiveness, but it still remains in the realm of a subjective measure.

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<sup>6</sup> Although the National Research Council makes the point that there is no rigorous evidence that the size of the inventive step had changed. The view that it had changed is based more on anecdotes (Cohen 2005).

## Defining the issues

There are many interpretations of ‘changing patent regimes’ in the literature.<sup>7</sup> Most of the studies consider ‘strengthening’, ‘broadening’ or ‘expanding’ an already existing patent regime. In general, the studies consider ‘strengthening’ rather than ‘weakening’ patent rights, since Lerner (2002) demonstrates that this has been the prevailing trend over the last 150 years. But ‘strengthening’ can be interpreted in various ways such as: increasing patent scope to cover new technologies; changing the patent scope to cover multi-claim applications; increasing the length of the patent term; or changing the conditions of legal enforcement of patents. In fact, most empirical studies consider this last issue: the effect of changing the enforcement conditions. In this report, we are not concerned with patent enforcement *per se*. Rather, we focus on the effect of a unilateral increase in the size of the inventive step requirement at the patent examination stage.

Having said this, it is not easy to separate the issue of patent examination (and the inventive step threshold) from patent enforcement. In fact, there is an important nexus between the two since changing the patent examination standards (including the inventive step threshold) may have no discernible effect if the courts don’t uphold the validity of granted patents. Nevertheless, we attempt to differentiate between the two here by focusing on the inventive step threshold solely and *assuming that the status quo prevails in the enforcement of patents*.<sup>8</sup> Given there are no empirical studies that consider the effects of increasing the inventive step threshold, we summarise the major findings from the broader literature where relevant if it has an indirect bearing on issues associated with the inventive step. Many studies of changing patent enforcement parameters, however, have no direct bearing on the issue we are addressing. We selectively include findings in our summary so the reader is clear about red-herring arguments.

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<sup>7</sup> A ‘patent regime’ refers to all aspects of the patent system such as the laws governing patent requirements, administrative procedures covering the patent examination process and judicial protocols.

<sup>8</sup> However, we acknowledge that it is difficult to separate the discussion of examination standards from patent enforcement even if we assume that the legal and institutional mechanisms of enforcement remain unchanged. To the extent that the inventive step threshold is increased, it should be easier for the patent owner to obtain a favourable outcome should a patent dispute occur. For example, if the dispute goes to the Court, one should expect that the Court is more likely to find the disputed patent valid, given that the patent was granted through a more stringent set of standards and there are likely to be fewer close patents in existence.

As mentioned, use of the term ‘strengthening patent rights’ is commonplace in the literature. It can, however, be quite confusing since it may refer, as we have just argued, to many different aspects of the patent system. This is unfortunate since it is important to highlight the differences between aspects such as inventive step threshold, scope of patentable subject matter and enforcement practices in terms of the effect on innovative activity. In talking about the complexities and confusion regarding the effects of different types of patent changes, Gallini (2002) stated that: ‘...the problem of patents being granted more easily highlights a recurring theme: the same policies that are perceived to have strengthened patent rights in certain ways have also weakened them’ (p.147). Encaoua et al. (2006) further highlights the confusion when stating that: ‘Some countries have arguably experienced a weakening of the standard criteria for granting patents (justified by the belief that “more patents is better”)’ (p.1424). For example, studies that make the simple assumption that increasing patent durations implies a strengthening of the patent regime are ignoring the negative effects of patent extension on other inventors. We believe that in general the use of the term ‘strengthening of the patent regime’ is suggestive and misleading. It implies that the ability of patentees – or even inventors as a whole – to appropriate profits has increased, whereas this is the actual proposition we are testing, not a prior assumption. Where possible, we avoid using the terms ‘strengthening’ and ‘patent regimes’ and instead define the actual specific change in the parameters of the patent system.

In general, there are two distinct approaches to examining the effects of a change in the parameters of the patent system on economic activity: one is a single country, case study-type approach (akin to a natural experiment) and the other is a cross-country approach (possibly with a time-series dimension as well) which utilises variations in patent protection across countries (and over time) to evaluate the effects of changes in the patent parameters on patenting activity. Such cross-country empirical studies often make use of two popular indices of the nature of patent protection: the indices of Rapp and Rozek (1990) and Ginarte and Park (1997). The Rapp and Rozek index is based on the adherence of each country's patent laws to the minimum standards proposed by the US Chamber of Commerce (1987), which include guidelines for patent examination procedures, term of protection, compulsory licensing, coverage of inventions, transferability of patent rights, and effective enforcement against infringement. The index ranks the level of patent protection for each country on a scale of zero to five. Ginarte and Park (1997) construct their index using similar criteria and values, but their scoring method differs

from that of Rapp and Rozek. Their index covers five equally-weighted aspects of the national patent laws: the extent of coverage (patentability), membership in international patent agreements, protection against loss rights (like compulsory licensing), enforcement mechanisms, and duration.

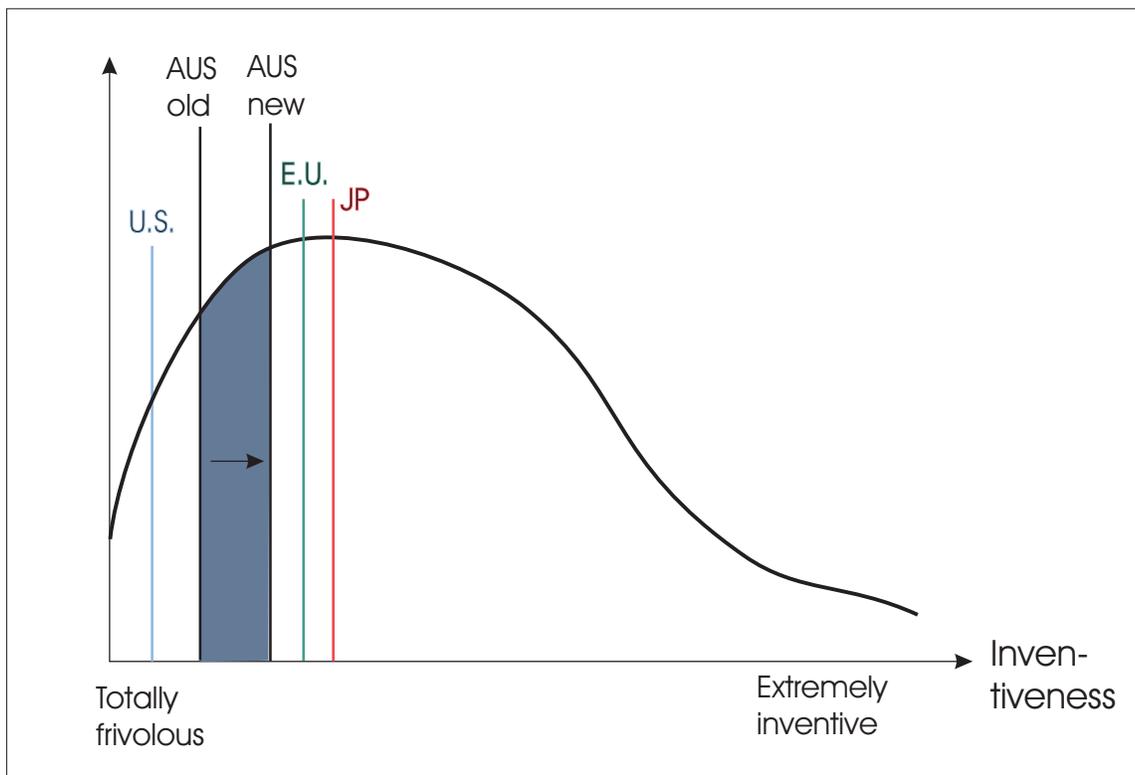
One difficulty with the Ginarte–Park approach is that there is clear evidence that a rise in R&D causes a rise in the index (Ginarte and Park, 1997). That is, the index is endogenous. Accordingly, studies which do not account in a satisfactory way for potential two-way causation will produce spurious findings. Over and above this our view is that the Ginarte–Park index is too broad-brush and conflates too many policy changes to provide useful policy recommendations. Furthermore, as discussed above, the use of the term ‘stronger patent regime’ for higher levels of the Ginarte–Park index is misleading. While a rise in the Ginarte–Park index implies stronger patent rights for some patentees (those who now get a bigger, longer or more enforceable patent), it can also imply weaker rights for other patentees and inventors, both current and prospective who are excluded from the patent system. For example, raising patent duration to 100 years may at first glance be increasing patentees’ rights, but the conclusion is less clear cut if we consider the effects on other inventors operating in the same technological space. Inventors wishing to undertake follow-on or related R&D can now only do so via licensing for 100 years and the power of ambiguously-related patents to stop infringement may remain ambiguous for 100 years, rather than the current 20.

### **The effects of raising the ‘revealed’ inventive step threshold**

Imagine a simplified world in which we are able to rank all patent applications according to their inventiveness, as in Figure 1. The degree of inventiveness ranges from ‘totally frivolous’ to ‘extremely inventive’. The solid curve in Figure 1 approximates the frequency distribution of patent applications. We imagine that the existing Australian revealed inventive step threshold can be represented by a vertical cut-off line labelled ‘AUS old’, to the left of which are applications that are deemed to have too low a degree of inventiveness for a patent to be granted. Conversely, to the right of the cut-off line are applications that are considered to have sufficient merit in terms of the inventiveness criteria for a patent to be granted. The revealed threshold is determined by how inventive a proposed invention has to be in practice in order to qualify for a grant. It represents the outcome of the statutory law, common law and patent office protocols and procedures.

For comparison, we have also included cut-off lines representing the revealed inventive step thresholds of the United States, Europe and Japan. Figure 1 depicts the approximate current standing of these three jurisdictions vis-à-vis Australia in terms of the stringency of their respective inventive step thresholds as estimated by Jensen *et al.* (2008), who consider the examination decisions for 7,000 unique inventions which were all sent to the USPTO, JPO, EPO and APO. Since the examination decisions at these offices were conducted on patent applications for the underlying inventions, this study provides us with a unique insight into the relative inventive steps in different national patent offices.<sup>9</sup> We also include in Figure 1 the idea that the proposed stronger examination standards will move Australia's cut-off from 'AUS old' to 'AUS new', which is still below the European and Japanese standards.

Figure 1: Australian patent examination standards vis-à-vis United States, Europe and Japan



<sup>9</sup> Note that we don't know the size of the *optimal* inventive step since that depends on the relationship between the inventive step and the intensity of innovative activity, which we discuss later.

## On the number and value of patents

The effect of the patent parameters on innovative activity depends on the degree of protection they give to inventors, taken as a whole, less the deadweight losses due to impediments to further R&D. Together this amounts to the ability of inventors to conduct R&D in a cost-effective manner and to appropriate monopoly revenues from their inventions (which can be thought of as the economic value of the patent). As shown in Figure 1, raising the inventive step threshold would in effect shift the cut-off line to the right, resulting in a decrease in the number of patents granted. Hunt (1999) refers to the fall in the probability of being granted a patent as the *static effect* of raising the inventive step threshold. For these 'marginal' inventions, raising the inventive step threshold in Australia implies a decline in patent protection. Thus, for prospective inventors who are yet to undertake an R&D project, the *expected return* of doing so is lower due to the static effect.

In contrast, for inventions on the right of the new cut-off line, raising the inventive step threshold effectively confers stronger patent protection, since there will be fewer competitors in the market place in which they operate. Given that a patent in effect grants the inventor a monopoly position, this monopoly position is stronger if there are fewer substitutes in the market. That is, it raises the power of the patentee to appropriate returns from the invention (in other words, it increases the patent's economic value) in the long term. Hunt (1999) refers to this as the *dynamic effect* of raising the inventive step threshold. Thus the expected return of undertaking an R&D project is now higher under the dynamic effect. It is not clear whether the static effect dominates the dynamic effect or vice versa. *Given that both these effects will operate when we raise the inventive step threshold, it is not possible to say that a rise in the threshold is akin to increasing or decreasing the profits of all inventors.*

To further clarify the issue, consider a hypothetical situation involving two countries, D (domestic) and F (foreign) and two inventions owned respectively by companies A and B. The two inventions can be developed into two distinct commercial products that are reasonably close substitutes. Suppose Company A obtains a patent in both countries, whereas Company B successfully gets a patent in Country F but has yet to obtain one in Country D. Now suppose that Country D raises its inventive step threshold so that Company B, which could obtain a patent under the previous standards, can no longer do so. From the perspective of Company B, there is less protection for his invention as his ability to

appropriate profits in Country D is reduced. From the perspective of Company A, however, its ability to appropriate profits has increased, since it does not need to compete with B in the Country D product market.<sup>10</sup> From Country D's perspective, whether the effect of raising the inventive step threshold is a desirable policy for that country's economy depends critically on the nationality of A and B.

It is also important to think of the relative position of a nation's inventive step threshold. For example, given that the United States operates a more liberal inventive step threshold than Australia, an increase in Australia's inventive step threshold (from 'AUS old' to 'AUS new') would decrease the number of patents granted in Australia (by the amount contained in the shaded region in Figure 1). The reference to the United States is of particular importance because although the United States does not lead in all technological fields, it leads in a significant number of areas.

Of course, patents are not the only (or even the most effective) means of appropriating returns from innovative investments. Other commonly used appropriation mechanisms include trade marks and brands, trade secrecy and organisational know-how. Following the seminal work of Levin *et al.* (1987), it is well known that the effectiveness of appropriability mechanisms varies across industries and that patents are typically rated as less effective than most other mechanisms. The effectiveness of an appropriation mechanism is likely to be affected by the underlying nature of knowledge: that is, whether the knowledge is tacit or has been codified. Inventions which are based on codified knowledge, for example, might be better protected using patents, while inventions based on tacit knowledge may be more naturally protected by trade secrecy and sheer complexity. Moreover, returns from investing in tacit technology may be easier to appropriate since the costs of imitation are typically high and may equal (or be close to) the cost of invention.

The available empirical evidence seems to support the contention that industries which rely on product inventions based on codifiable knowledge (such as the pharmaceutical industry) are relatively more likely to find patents an effective appropriation mechanism. On the other hand, industries relying on tacit knowledge are more likely to find trade secrets or organisational know-how more effective

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<sup>10</sup> This is only true, of course, if we assume that the product is not commercialised in the absence of a patent (or that it is commercialised but can't erode any of the patent owners' profits).

appropriation mechanisms (Harabi 1995; Arundel 2001). To the extent that non-patent forms of protection are effective, the full impact of changes to the inventive step threshold will be muted.

Thus far, we have ignored the *long-term* impact of raising the inventive step threshold on patent granting *rates*. For example, we state that raising the examination standards would in effect shift the cut-off line to the right, resulting in a decrease in the number of patents granted. While this is unambiguously true, it is less clear what would happen to patent granting *rates* in the long term. Increasing the inventive step threshold may result in the rejection of applications that would otherwise have been granted, which seems to imply that the patent granting rate would fall from, say, 80 per cent to 70 per cent. But this is not necessarily correct since it is quite likely that as applicants learn about the new inventive step threshold they will reduce the number of applications with low inventive steps (and therefore low probability of being granted). Thus the left tail of the distribution in Figure 1 may shrink, such that the patent granting rate may in fact stay at its pre-existing level of 80 per cent (assuming this is some sort of equilibrium grant rate). This simple example highlights the importance of dynamics in any analysis of patent parameter changes.

Existing cross-sectional evidence, however, suggests that changes to the inventiveness of underlying applications are unlikely to restore the grant rate to the former level following a change in the inventive step threshold. Jensen *et al.* (2008) and Webster *et al.* (2007) use matched samples of international patent applications to reveal clear differences in the size of inventive step threshold between jurisdictions. As shown in Figure 1, the rank order is – from lowest to highest – the United States, Australia, Europe and then Japan. However, it is also known that overall grant rates have the same rank order as exists for thresholds, which suggests that offices with higher thresholds simply reject a greater proportion of applications. It does appear that the effect of a higher inventive step threshold is not fully absorbed by a reduction in low step applications.

### **On domestic R&D and research output**

The fundamental economic rationale for the existence of patents is to increase the *ex ante* incentive to invest in inventive activity. Where inventors are unable to exclude others from profiting from their invention, the unfettered market will under-invest in the provision of inventive activity. In many ways, economists regard patents as a necessary evil: although they introduce static dead-weight loss

associated with allowing inventors to charge monopoly prices, they aid in the creation and diffusion of knowledge that otherwise may not occur.

There are many other ways to solve the under-investment problem: government grants, prizes and contests can all be used as alternative ways to stimulate investment. Consequently, there are numerous examples of inventive activity occurring in the absence of patents (say prior to 1850) and of inventive activity which occurred in the patent age (and involved substantial costs) but was not associated with a patent at all (e.g. penicillin, Salk polio vaccine). Thus, we know from casual empiricism that patents are not necessary for many types of invention. This is particularly true in the case of basic or abstract scientific research at universities, which is typically undertaken through the provision of government grants rather than via patents. Nevertheless, patents are widely used in the developed world to stimulate applied (private sector) research and pressure is often put on developing nations to recognize patented technologies.

In this light, we examine the empirical evidence regarding the relationship between patents and inventive activity: in particular, we ask the question, does the evidence suggest that changing the parameters of the patent system will stimulate inventive activity, and, if so, how? Although there are no specific studies on the relationship between increasing the inventive step and its effect of inventive activity (e.g. R&D expenditure), there are numerous other studies which can help us understand the broader issue of the relationship between patent system changes and inventive activity.

There are a number of summaries of the theoretical and empirical arguments regarding the relationship between the parameters of the patent system and local innovation (see Branstetter 2004; Encaoua et al. 2006; Gallini 2002; Hall 2007; Mazzoleni and Nelson 1998). If there is a non-linear relationship between these parameters and innovation, then the marginal effect of *changing* the patent system depends on the status quo. In a review of this literature, Branstetter (2004) concludes that, on balance, there is little evidence to support the notion that stronger patent laws increase domestic innovation; rather, stronger patents laws resulted in more foreign patent applications in the reforming country. These conclusions are based on a number of country-specific empirical studies, including those on the 1988 Japanese patent law reforms which enabled multi-claim patent applications, by Sakakibara and Branstetter (2001) and Branstetter and Nakamura (2003). In a similar vein, Kortum and Lerner (1997)

show that the recently observed surge in patenting in the United States is due to technological revolution rather than the stronger enforcement provided by the creation of the Court of Appeals of the Federal Circuit. Another country-specific study was conducted by Scherer and Weisburst (1995), who demonstrate that in a particularly patent-friendly industry like pharmaceuticals, changes in Italian patent laws had no effect on domestic innovation. These conclusions arrive largely from studies on developed countries where that status quo involves broad patent scope, a potential 20 year patent life and a relatively well developed enforcement system.

There has been a proliferation of cross-country studies seeking to find a casual relationship between national patent rights and domestic innovative effort. Most papers use the Ginarte–Park index of patent regime ‘strength’ described above. For the most part, these studies have demonstrated results contrary to the finding of the detailed country-specific studies mentioned above. That is, they find that higher levels of the Ginarte–Park index are associated with more innovative activity (Kanwar 2007; Kanwar and Evenson 2003; Schneider 2005; Varsakelis 2000; Allred and Park 2007).<sup>11</sup>

Better methods for dealing with the meaning of ‘patent regime’ and ‘innovation’ are to be found in studies that have defined a change in the parameters of the patent system more clearly. These include the studies by Qian (2007), Kortum and Lerner (2004), Sakakibara and Branstetter (1999) and Branstetter and Nakamura (2003). Qian (2007) uses a matched sample method and finds that R&D is related to the level of economic development, educational attainment and economic freedom but not the strength of national patent laws *per se*. She also finds there is an optimal level of protection above which a strengthening of patent laws reduces R&D. The absence of a positive relationship between the strength of the enforcement regime and innovation was also found by Kortum and Lerner (2004) for the United States and Sakakibara and Branstetter (1999), Branstetter and Nakamura (2003) in Japan. In a review of national patent law changes over the past 150 years, Lerner (2002) found that strengthening patent law did not have a notable effect on patent applications from local residents, but it did have an effect on applications from foreign residents.

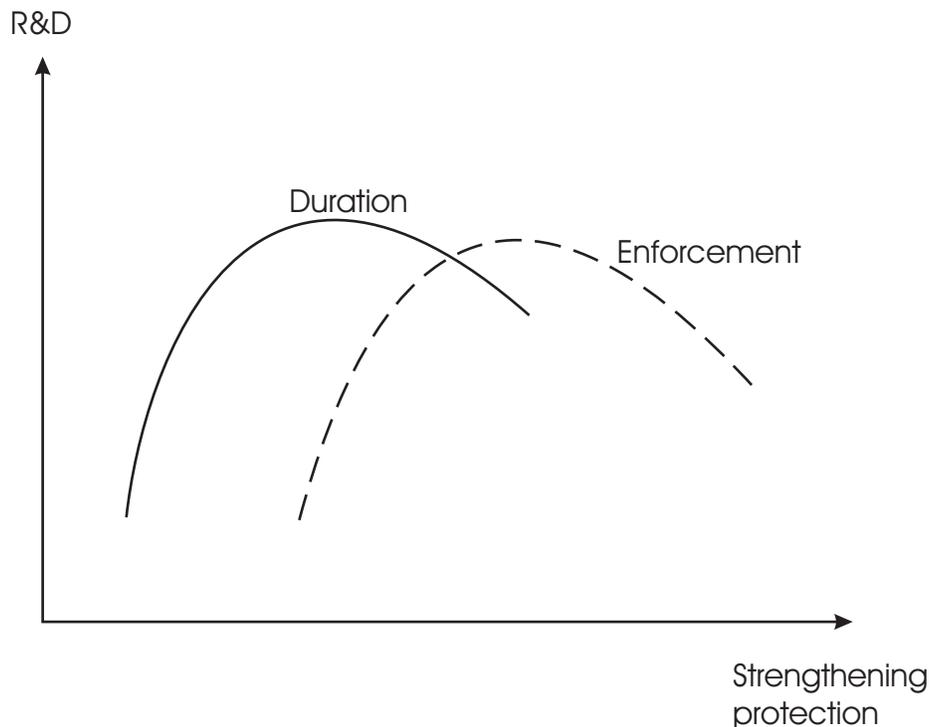
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<sup>11</sup> Note, however, that the relationship may not be a simple linear one: increasing patent regime strength may have a positive effect up to a point and then it decreases. This suggests that the relationship may in fact be U-shaped.

Branstetter (2004) points to a number of reasons why the *a priori* expectations regarding patent strength and innovation may not hold. First, R&D investments are cyclical and in order to invest, firms must have an expectation of a growing market. In the absence of this expectation, strong patent rights are simply insufficient to induce investment in the first place. Second, patents are not the only way to appropriate returns to investment. In the absence of strong patent rights, firms simply use other appropriation mechanisms and we have already seen that these can be quite effective. Third, strong patent rights can retard cumulative innovation if the first patentee in the chain blocks follow-on research by others. A number of theoretical models have demonstrated that strong patent rights can actually retard the level of innovation in technology areas where an innovation can be a crucial input into numerous other innovations (see Green and Scotchmer 1995; Bessen and Maskin 2000). On the empirical front, Hall and Ziedonis (2001) have shown that in an industry characterized by such cumulative innovation – for example, the semiconductor industry in the United States – stronger enforcement regimes have spawned entry by specialized firms but also encouraged more defensive patenting by large incumbent firms. Bessen and Hunt (2004) have shown that firms obtaining software patents experienced a significant decline in R&D intensity. Finally, if the local market is not perceived as being important, then changes to the local patent regime will not increase local incentive to invent.

Together, these studies suggest that the relationship between patent protection and R&D activity, if it exists, may not be linear. Figure 2 illustrates the non-linear relationship between R&D and two aspects of patent protection. Suppose there is an increase in patent duration, or additional enforcement mechanisms not previously provided for are created - this increase in patent protection has a non-linear effect on R&D, as represented by the solid curve for duration and dashed curve for enforcement. That is, an initial rise in the level of protection increases R&D, but eventually a point is reached such that the effect becomes negative – further strengthening of protection lowers R&D. The two curves also illustrate that the turning point may occur at different levels for different types of patent system change. As illustrated in Figure 2, the turning point for duration protection occurs earlier than that for enforcement, meaning that the lowering of R&D sets in earlier as compared with enforcement as the strength of duration protection is increased. From a policy perspective, this hypothetical situation implies that in order to increase R&D, it is desirable to introduce more enforcement mechanisms but not increase duration.

Figure 2: The relationship strengthening patent protection and R&D



### On domestic technology transfer and commercialisation

In the literature the role, or lack thereof, of patents in aiding domestic technology transfer has been discussed as it relates to small or specialised research organisations, large established firms and easily-imitated technologies. We summarise the findings below.

#### *Small or specialised research organisations*

When a firm is small or specialises in research (e.g. a university), the best option for development is often to attract external finance or find a partner with complementary assets (Mazzoleni and Nelson 1998, Arora and Merges 2004; Orsi and Coriat 2005). This generally involves selling a patent, licensing or making an initial public offering, *inter alia*. Patents are used in this process to demonstrate to external parties that the firm has made a recognisable invention over which it has surety of ownership.

There is general consensus in the literature that patents play a positive role in enabling the transfer and development of privately-financed research to privately-financed development partners (Arora,

Forsfuri, Gambardella 2003; Hall 2005). Nonetheless, it is less clear how many patents a firm needs to acquire to smooth the transfer process. There is likely to be diminishing returns from acquiring additional patents beyond a certain level. Mann and Sager (2007), for example, found that in the United States having one patent compared with no patents enhances the success of a start-up, but that additional patents have no incremental effect on the probability of success.

There is less consensus over whether it is desirable to encourage the use of patents for the development of *publicly* financed inventions (Arrow 1962; Dasgupta and David 1994; Eisenberg 1987; Heller and Eisenberg 1998).<sup>12</sup> Generally, the more upstream or fundamental the research, the more potential gains there are from free, unrestricted diffusion but there can also be cases where the development of a downstream product can benefit from unrestricted diffusion as well (such as a public health treatment). Put another way, patents should not be used as incentives for inventions when the dead-weight losses from monopoly power are large. Accordingly, basic science and broadly-applicable technologies should be financed through general government grants (Arrow 1962). Mazzoleni (2006) argues that the need to license and pay fees acts as a hindrance to negotiations and that the way to maximise transfers is to offer licenses, sometimes non-exclusively, for minimal fees. Other factors such as trust, geographic proximity and the flexibility of the university with respect to its IP policies (Santoro and Gopalakrishnan 2001), or provision of government financial support (Niosi 2006) matter most for the success of university technology transfer.

#### *Large established firms*

Surveys from a number of countries around the world have clearly shown that large, established firms are more likely to use lead time and complementary assets than patents to recoup their investments from development (Mazzoleni and Nelson 1998; Levin *et al.* 1987; Cohen *et al.* 2000; Arundel 2001; Harabi 1997; Jensen and Webster 2006; Branstetter and Nakamura 2003). Despite this, large firms are still just as likely to take out patents as smaller firms and it is likely that this apparent anomaly occurs because large firms patent for other reasons (Jensen and Webster 2006). In the United States, it has been argued that large firms often patent strategically rather than to protect a single invention from infringement. Either firms seek to obtain a wall of patents around a given invention (a patent thicket) to

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<sup>12</sup> Few people argue that the lure of future royalties should be an incentive to conduct research in the public sector since any attempt to exercise *ex post* monopoly power results in dead-weight losses.

hinder rivals' ability to invent around the idea, or they seek to obtain large portfolios of patents so they can make a credible threat to counter sue if a rival considers suing for infringement (a patent arms race) (Hall and Ziedonis 2001; Shapiro 2000; Blind *et al.* 2006). In both cases, the jurisdiction is flooded with patents, often of trivial value.

This flooding can act as a barrier to entry for new firms seeking to either conduct research or develop a technology, since they have to invest significant time to assess the scope of their freedom to operate. Established firms may circumvent this problem by forming a cartel and pooling knowledge within the cartel. A cartel is the best outcome from this scenario since it implies a high level of tacit consent among related parties to enable production.

A less successful outcome from this strategic patenting scenario occurs when the costs of obtaining agreements from all relevant patentees means that the product is priced out of the market. Thus, a product that is in great demand may not be produced simply because of the additional costs associated with negotiating many and varied licenses. This situation is called an 'anti-commons' (Heller and Eisenberg 1998; Cohen 2005). Under this scenario, patents and their associated registration, examination and litigation costs may be a more expensive way to induce commercialisation than other alternatives (Jaffe and Lerner 2004; Choi 2005).

### *Easily-imitated technologies*

When the invention is easy and cheap to imitate, patents may be the only way to achieve invention profits. It is generally thought that an invention is easy or cheap when the technology has been highly codified, such as in chemistry or pharmacology.<sup>13</sup> If knowledge transfer requires either personal contact, the replication of a large and complex number of processes or regular servicing from the originating firm, then patents are less important for appropriation. The inventing firm can simply withhold the transfer of personnel and knowledge about systems to prevent imitation. McCaughey, Liesch and Poulson (2000) document a case where a firm relied completely on the complexity of the production process to protect its product.

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<sup>13</sup> In a 1993 survey of 600 European manufacturing firms, Arundel and Kabala (1998) found that patent propensity rates were as low as 8 per cent in textile technologies (?). Only pharmaceuticals, chemicals, machinery and precision instruments industries apply for a patent for more than 50 per cent of their innovations.

### **On international trade flows**

In an open global economy, international exchanges including trade, FDI, and cross-border licensing spread the benefits of innovation beyond national boundaries. A country thus does not reap all the benefits that come from protecting patented technologies within its borders. The value of patent protection varies, depending on whether the country is a technology importing or exporting country, or whether one takes a global perspective that encompasses all countries. For example, technology importing countries not only incur higher import costs under a strong patent protection regime, but also face greater restrictions in developing local R&D via imitation. In contrast, technology exporting countries tend to gain not only via larger market shares but also greater monopoly power in the market place. From a global perspective, the net effect is ambiguous since there are gainers and losers; properly accounting for their gains and losses will require cross-country comparisons that are often contentious. Recent theoretical discussion investigating the impact of patent protection from various perspectives includes Branstetter, et al. (2007), Grossman and Lai (2004), McCalman (2002) and Helpman (1993). Maskus (1998, 2000) provides a summary of these arguments and the empirical evidence for and against them.

Given that changing patent protection could produce, in theory, effects that pull in different directions, the question then becomes an empirical one. Unfortunately, the empirical literature too produces mixed results. Many factors may contribute to the often contradictory empirical findings: data, measurement and aggregation differences are probably the obvious ones. Furthermore, most empirical studies measure IP protection using the indices of Rapp and Rozak (1990) and Ginarte and Park (1997). Thus, much of the evidence focuses on changes to the patent parameters that are unrelated to changes in the inventive step, so the results should be considered in this light. To be fair, however, the index does provide some indication of the extent of patent protection in cases when a developing country joins WTO or signs IP-related international treaties. A higher index in these cases indicates correctly that a greater degree of protection has been given to IP rights as compared with the pre-WTO or pre-treaty days.

The empirical literature on IP protection and trade began in the early 1990s with the pioneering work of Ferrantino (1993), who measured IP protection regimes according to national membership in IP rights treaties and found that importing countries' patent regimes have no significant effects on total US

exports. Maskus and Penubarti (1995) took the discussion one step further by distinguishing, conceptually, two opposing empirical effects of strengthening patent protection. First, stronger patent rights increase the imitation costs and lower the level of infringing activities, both of which increase the demand for the exporting firm's product. The increase in demand, called the *market expansion* effect, induces the exporting firm to supply more exports to the local market. Second, stronger patent rights enhance the market power of the exporting firm. This stronger market power, called the *market power* effect, induces the exporting firm to act monopolistically, and thus sell less to the local market.

Using the index of Rapp and Rozek (1990) to measure patent protection in their empirical investigation, Maskus and Penubarti (1995) found generally that a higher index induced greater trade flows across manufacturing sectors. However, for patent-intensive goods, they found that the market-expansion effect offset the market-power effect and as a result trade in these goods did not respond to differences in patent regimes. Later research tends to find that whether the market expansion effect dominates the market power effect depends on many factors, among which are the imitative capabilities of the importing country, characteristics of the technology, stage of development of the importing country, and R&D intensity of the exporting industries.

Smith (1999) demonstrated that the imitation capabilities of the importing country are an important consideration. A country with strong imitative capabilities poses a strong threat to the exporting firm, especially if the patent rights protection (in the local/importing country) is weak. Table 2 summarizes the possibilities. If a country has strong imitative capabilities and weak patent protection, an increase in its patent protection will have a positive effect on imports since the market expansion effect tends to dominate, i.e., exporting firms are likely to increase their exports to the country. In contrast, the opposite effect on trade occurs for a country with weak imitative abilities but strong patent protection; increasing its patent protection further will result in excessive market power for the foreign exporting firm, which could exploit its market power by restricting exports.

**Table 4: The threat of imitation and strengthening patent protection in local economy (adapted from Smith 1999)**

Imitative Capabilities in local/importing economy	Patent rights protection in local/importing economy	
	<i>Strong</i>	<i>Weak</i>
<i>Strong</i>	Moderate threat of imitation ambiguous effect (?)	Strong threat of imitation market expansion effect (+)
<i>Weak</i>	Weak threat of imitation market power effect (-)	Moderate threat of imitation Ambiguous effect (?)

Generally, the empirical literature lends support to the notion that the threat of imitation plays an important role in determining whether a higher degree of patent protection, in the sense of the Rapp–Rozak or Ginarte–Park index, affects trade flows (see Smith 1999 and Rafiquzzaman 2002). Smith (2001) further found a positive relationship not only for US exports, but also affiliate sales and licensing; and the effect is particularly large for countries with strong imitative capabilities. Co (2004) found that stronger patent protection had a positive effect on trade for R&D intensive goods, but negative effects for non-R&D intensive goods for a country with ‘average’ imitative capability in her sample. Liu and Lin (2005) also found, in relation to three knowledge-intensive industries, a positive relationship between foreign patent rights and exports when the importing country exhibits a strong threat of imitation. However, for agricultural trade, for which the imitation costs are low, Yang and Woo (2006) did not find any significant effects. It is worth pointing out that all these studies made use of either the Rapp-Rozak or Ginarte-Park index to measure the level of patent rights protection. It is not known whether and to what extent changes in the indices could be related to changes to the inventive step.

### **On FDI**

According to Dunning (1981), there are three necessary conditions for firms to be willing to undertake FDI abroad: (i) Ownership advantage – the firm must possess a non-rivalrous asset (know-how or brand names); (ii) location advantage – there is a potential market in the foreign location; (iii) internalisation advantage – the non-rivalrous asset requires personal transmission and is not suitable for arms-length licensing. Within this framework, patent rights protection in principle can have two opposing effects: on the one hand, it enhances the location advantage of the host country since the

foreign firm's investments are less likely to be undermined by imitation. On the other hand, stronger protection reduces the internalisation advantage of foreign firms undertaking FDI, as other forms of exploiting intellectual property (e.g., licensing) may become more attractive (see Javorcik 2004 and Smith 2001).

We briefly summarise the empirical literature below. We reiterate that that empirical studies of FDI are fraught with difficulty and the findings can be sensitive to issues such as: measurement problems related to patent protection, the use of highly aggregated FDI data, measures of industry and country characteristics, the nature of technologies, and substitution possibilities between FDI and other forms of patent use (e.g., licensing) beyond national borders. These limitations notwithstanding, empirical studies generally uncover a positive relationship between the Rapp–Rozak or Ginarte–Park index and FDI. An early example is Lee and Mansfield (1996), who conducted a survey of 100 US firms and found that a country's IP rights protection is positively correlated with the volume of US FDI inflows into that country. A more aggregate approach that came to the same conclusion is OECD (2003), which found that the patent rights index is positively associated with FDI. However, the same study also cautioned that the positive relationship appeared to be diminishing as the index increases. Thus, a higher index does not always raise FDI.

Several later studies examine not only the level but also the quality of FDI, technology characteristics of investments, country characteristics such as imitative capabilities and other variables. Nunnenkamp and Spatz (2004) noted that stronger IP rights protection may help induce high-quality FDI, where the quality of an investment was measured by the technology content, value added and exports generated by the FDI. Javorcik (2004) found that countries with more effective patent rights were more likely to be chosen as an investment location by multinationals, especially in high-technology sectors like chemicals or drugs, for which IP rights play an important role. Weak protection encouraged foreign investors to set up distribution facilities rather than to engage in local production. Branstetter et al. (2007) found that more rights for successful patent applicants slowed imitation and increased FDI from multinationals in the developed countries, particularly in technology-intensive industries.

However, there are also several studies that found either insignificant or no relationship between IP rights protection and FDI. For the chemical processing industries, Fosfuri (2004) found no evidence of

a significant impact from IP rights protection on international activity, including FDI. Pfister and Deffains (2005), in examining the location choice of French multinationals, found that stronger patent protection in countries with high GDP or a low R&D intensity tended to reduce the attractiveness of FDI for French firms. In a study that takes into account the substitution possibilities between FDI, direct exports and licensing among the decision variables of multinationals, Smith (2001) found that stronger patent rights protection had a stronger effect on FDI than on US exports, but the effect was less pronounced than that on licensing. These results were corroborated by Yang and Maskus (2001), who showed that royalties and license fees received by US companies rose with stronger IP rights protection in 23 partner countries.

Branstetter *et al.* (2006) investigated the effects of increases in the monopoly power of the patentee (i.e. reforms to reduce uncertainty over the grant decision, the expansion of patentable subject matter, increased control of patentee over licensing and imitation) on FDI from the United States to 16 mainly middle-income countries over the period 1982–1999. The results provide strong evidence that US multinationals respond to an increase in recipient-country patent reform by increasing technology transfer to reforming countries. The patterns in affiliate R&D spending, which complements the transfer of technology, indicate that at least some component of increased royalty payments reflects increases in the volume of technology transferred and not merely increases in the price of technology transferred. How well these effects translate to Australia as either a recipient or source of FDI is less clear.

On balance, the empirical evidence seems to suggest a positive but non-linear relationship, as depicted in Figure 2 above, between patent rights protection and FDI. More rights for successful applicants may induce more FDI initially, as exports are replaced with direct investments. However, as the level of protection is further strengthened, multinationals may prefer licensing to FDI. This explains the observation that, in advanced host countries with strong IP rights protection, FDI was increasingly replaced by licensing (Nunnenkamp and Spatz 2004). Thus, whether a strengthening of patent protection raises FDI depends, *inter alia*, on the initial level of IP protection in the host country and the substitutability between FDI, exports and licensing.

## Effects of the reduction in US inventive step threshold

As mentioned above, we believe that the decline in the US inventive step threshold during the 1980s is the only actual change to inventive step thresholds that has been analysed in the literature. Cohen (2005) presents an overview of this literature. He argues that the main effect of reducing the threshold was to increase uncertainty about the ultimate validity of any given patent, which in turn reduced investment in the development of the associated technology. It also diminished investment in competing technologies in cases where rivals believe that such investments may be at risk of infringing the existing (low quality) patent. That same uncertainty also generated litigation in instances where would-be infringers believed that it was worth the risk of ignoring a patent, given that the chance of a finding of invalidity in the event of a suit had increased.

Jaffe (2000) further argues that a lowering of the bar of non-obviousness creates more confusion over who owns what. On the one hand, a relaxed threshold permits other parties to patent an invention that is technologically close to the first patent – effectively limiting the scope of this first patent. However, by lowering the standard of non-obviousness, the technological space a firm can claim to be within its patent will likely be larger.

According to Levin and Levin (2003), patents on known or only trivially modified inventions confer potential market power to restrict access and raise prices, and enable the patent holder to use litigation as a competitive weapon without providing incentives for making genuine advances or disclosing such advances to the public. They offer no public benefit in exchange for the benefit given to the patentee. Granting patents for inventions that are not new, useful and non-obvious unjustly rewards the patent holder at the expense of consumers.

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**Parliamentary Secretary:** Information  
 cc: Minister Combet  
 Minister Evans

**Brief No:** B12/1068  
**Division/Agency:** IP Australia

**RAISING THE BAR - RESEARCH EXEMPTION, INVENTIVE STEP STANDARDS AND OTHER ASPECTS OF THE PATENT SYSTEM**

**Timing:** Routine

<b>Recommendation/s:</b>	<b>Approved/Noted</b>
That you note the information provided on various aspects of the patent system, as requested by your office.	Yes / No
<b>Parliamentary Secretary's signature:</b>	<b>Date:</b>

**Key Points**

- Patent rights are a key feature of global knowledge-based economies. By providing innovators an exclusive title to an invention for a limited period of time, patent rights facilitate innovation, technology and knowledge transfer and inward investment.
- Research, development and commercialisation of products and services, particularly in cutting edge technology areas such as biotechnology, medical devices and communication technologies, can be time consuming, high risk and expensive. Without an incentive such as the patent system, which creates a secure environment for investment, many innovations would not be translated into new technologies that benefit Australian society. In return for this exclusive right the patent system requires innovators to publicly disclose their inventions, supporting follow-on research and innovation. Patent rights also increase the probability of public sector research being commercialised by industry. A robust patent system also ensures that new technologies, including medical treatments developed overseas, are made available in Australia.
- The Australian Law Reform Commission's 2004 report on *Genes and Ingenuity: Gene Patenting and Human Health*, the Senate Community Affairs Committee's *Gene Patents* Report released in November 2010 and the Advisory Council on Intellectual Property's 2011 report on patentable subject matter made recommendations for change to a number of aspects of the Australian patent system. The Government's response to these reports, released on 23 November 2011 accepted the majority of the recommendations in these reports (**B11/4524** refers).
- The *Intellectual Property Laws Amendment (Raising the Bar) Act 2012* implements a number of these changes, ensuring Australia has strong and internationally aligned patenting criteria for novelty, inventive step, usefulness and description of the invention. The Act also introduces a research exemption, providing certainty to researchers to research without fear of prosecution for patent infringement (**B12/827** and **B12/368** refer).
- Information on the specific issues raised in the briefing request is provided below and in **Attachment A**.

## Issues/sensitivities

### Inventive step standards:

Australia is a net importer of IP, it is therefore important that our legislation is in line with our major trading partners. The Raising the Bar Act increases the inventive step standard in Australia, so it aligns with that of our major trading partners, through removing the geographical restriction on common general knowledge, and removing the requirement for the prior art base (the publicly available information in the relevant technical field) to have been 'ascertained, understood and regarded as relevant'. Further detail is provided at **Attachment A**, with additional information, as requested, at **Attachments B and C**.

Australia's test for inventive step considers whether the invention is 'obvious', if it is, then it is not patentable. The same test is applied in Europe. In the United States, a 'non-obvious' test is used, resulting in an invention that is non-obvious being patentable. Conversely, an 'obvious' invention is not patentable, as in Australia.

It would not be in Australia's interests to have a higher threshold for inventiveness than other countries have. Local inventors would struggle to meet the higher test in Australia and this would probably impede their export opportunities. There could also be an adverse impact on foreign investment, since inventors needing to bring intellectual property into Australia would be unsure whether it would be protected.

### Options to strengthen the Research Exemption in *Raising the Bar*:

Ms Melissa Parke MP in her Raising the Bar second reading speech to the House of Representatives on 19 March 2012 suggested the research exemption does not 'go far enough'. She raised a number of issues with the exemption, outlined further at **Attachment A**.

The exemption introduced includes clinical and applied scientific purposes where they are carried out to improve or test an invention. However, the exemption will not apply when an invention is being used as a research or teaching tool if that is the use for which the invention is patented.

This exemption allows for some degree of commercial activity, as long as the predominant purpose of the activity is for research or experimentation.

If a researcher using a patented genetic material under the exemption invents a useful application, then in many circumstances the researcher will need to obtain a license if they wish to move from research to commercialisation. However, the researcher has benefited from the original invention, so it is only reasonable that when they wish to commercialise their invention they provide some compensation to the original inventor.

On the other hand, if the new invention is sufficiently different from the original invention, the researcher will not need to obtain a license because their invention differs to an extent that does not infringe the original invention.

Under our current understanding of the law, if a new diagnostic test using a patented isolated gene sequence is commercialised, the owner of the new test, when taking it to market would need to negotiate licensing provisions with the patentee of the gene sequence. This is because the commercialisation of a new diagnostic test or treatment of disease based on a patented isolated genetic sequence does not constitute research, and as such does not fall under the research exemption.

Patent pools:

Patent pools can be defined as an agreement between two or more patent owners to license one or more of their patents to one another and/or third parties. The key benefit of patent pools is in reducing transaction costs for users having to identify relevant patents and then seek cross licensing arrangements with multiple individual patent holders. Patent pools are particularly beneficial in cases where the relevant technology is subject to fragmented patent ownership, such as may be the case when a technology is developing very rapidly, as has been the case in recent years in IT technology. Examples of successful use of patent pools are at **Attachment A**.

The establishment of patent pools tends to be driven by industry on a voluntary basis, governments have little role in their creation. However, governments can create incentives and provide the appropriate institutional framework to actively encourage setting up of patent pools in any particular technology field.

To date there is little experience within governments to incentivise, facilitate or regulate patent pools.

Possible Memorandum of Understanding (MoU) between pharmaceutical/biotechnology companies and health/consumer lobby groups:

The Government recognises there needs to be a balance between achieving affordable access to healthcare and the ability to stimulate biomedical research and innovation.

The Australian patent system has existing safeguards such as the crown use and compulsory licensing provisions that can be used to ensure access to essential services and treatments are not blocked by patents.

As part of the implementation of the Government's response to the gene patent reports (**B11/4524** refers) a review of the compulsory licensing provisions will be undertaken (**B12/859** refers). Another recommendation is to improve the understanding of crown use. IP Australia is implementing this recommendation through an education and awareness program.

Additional information is provided at **Attachment A**.

Retrospectivity issues associated with banning gene patents:

If the Australian courts decide that isolated gene sequences are unpatentable, changes will likely be prospective and retrospective. This would be so because the court would probably decide that isolated gene sequences were never patentable, with the result that existing patents are invalid. Other parties wishing to use patented gene sequences would be able to either litigate, to have the patent in question revoked, or they may choose to simply use the patented sequence on the assumption that the patent is invalid.

If the government introduces a Bill that excludes isolated gene sequences from patentable subject matter, the changes would be prospective only, unless constitutional compensation was offered (section 51(xxxi) of the Constitution provides for acquisition of property on just terms). This is because it would be open to patent owners (in the absence of a court decision) to argue that the Government was acquiring an existing legal right.

Excluding isolated gene sequences from patentable subject matter may mean Australia is vulnerable to a claim of inconsistency with the Trade-Related Aspects of Intellectual Property Rights Protocol (TRIPS) and the Australia-United States Free Trade Agreement (AUSFTA).

Under these agreements Australia is obliged to make patents available for ‘any invention... in all fields of technology’.

**Consultation**

- Pharmaceutical, Health Industries and Enabling Technologies Branch, Department of Industry, Innovation, Science, Research and Tertiary Education.

Clearing Officer

Matt Forno

A/g General Manager BDSG

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3 May 2012

s47F

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Frances Roden

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**Attachments**

Attachment A: Additional background and examples

Attachment B: Inventive Step – additional information, as requested

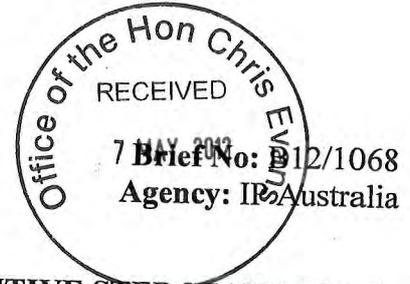
Attachment C: ‘The Effect of Raising the Australian Statutory Inventive Step on the Australian Global Production System’, P. H. Jensen et al, Intellectual Property Research Institute of Australia, Occasional Paper No. 1/08, August 2008



IN-CONFIDENCE

BRIEF

Parliamentary Secretary: Information  
 cc: Minister Combet  
 Minister Evans



**RAISING THE BAR - RESEARCH EXEMPTION, INVENTIVE STEP STANDARDS AND OTHER ASPECTS OF THE PATENT SYSTEM**

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#### **Consultation**

- Pharmaceutical, Health Industries and Enabling Technologies Branch, Department of Industry, Innovation, Science, Research and Tertiary Education.

*Slipstream version: 6 May 2012*

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3 May 2012

Contact Officer:  
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File C2012/12966 FOI 353  
Ministerial Coversheet

**Date Due in MLO:** 4/04/2012                      **Ministerial Item:** B12/1068  
**Action Division:** IP Aust                      **Current Division:** IP Aust  
**Action:** Information - Request MO           **Minister Office:** Dreyfus  
**Signatories:** DREYFUS QC MP, MARK  
**Subject:**  
Gene Patents: MOU; Patent Pools; Research exemption; banning gene patents; and inventive steps.

**Ministerial Type:** Brief                      **Attachments:** N

**Critical Date:**                                      **Talking Points:** N  
**Critical Date Reason:**                      **Sensitivities Involved:** N

**Summary:**

**Instructions:**  
**Officer:** Parsonson, Emerson  
**Date:** 29 Mar 2012 14:59  
**Text:** Suggested Action Officer: Baxter, Julie Requesting Adviser: Round, Jim (Dreyfus) Can the Department provide some advice by COB next Wednesday which includes?: – patent 'pools' (a patent sharing arrangement used OS), – a possible MoU between pharma/biotechs and health/consumer lobby groups about reasonable access to health solutions. – Options to strengthen the Research Exemption in the RTB bill. – consider further reviewing the 'inventive step' standards within the Patents Act (OS they use the term 'non-obvious step' rather than 'inventive'. It would be good to know if our is a higher or lower standard). also advice on any 'retrospectivity' issues associated with banning gene patents i.e. would a ban be likely to open up legal challenges to existing patents?  
**Officer:**



Australian Government  
 Department of Industry, Innovation, Science,  
 Research and Tertiary Education

*Please draft letters to:*  
 File C2012/12968 FOI 354  
 (1) Senator Evans seeking information  
 and feedback on the research  
 exemption; and  
 (2) Ms. Phibersch, seeking feedback  
 on the inventive step standards for  
 a health policy perspective.

**IN-CONFIDENCE**

**BRIEF**

Parliamentary Secretary: Information  
 cc: Minister Combet  
 Minister Evans

Brief No: B12/1068  
 Agency: IP Australia

**RAISING THE BAR - RESEARCH EXEMPTION, INVENTIVE STEP STANDARDS AND OTHER ASPECTS OF THE PATENT SYSTEM**

Timing: Routine

<b>Recommendation/s:</b>	<b>Approved/Noted</b>
That you note the information provided on various aspects of the patent system, as requested by your office.	<input checked="" type="radio"/> Yes / <input type="radio"/> No
Parliamentary Secretary's signature: <i>[Signature]</i>	Date: 2/7/12

**Key Points**

- Patent rights are a key feature of global knowledge-based economies. By providing innovators an exclusive title to an invention for a limited period of time, patent rights facilitate innovation, technology and knowledge transfer and inward investment.
- Research, development and commercialisation of products and services, particularly in cutting edge technology areas such as biotechnology, medical devices and communication technologies, can be time consuming, high risk and expensive. Without an incentive such as the patent system, which creates a secure environment for investment, many innovations would not be translated into new technologies that benefit Australian society. In return for this exclusive right the patent system requires innovators to publicly disclose their inventions, supporting follow-on research and innovation. Patent rights also increase the probability of public sector research being commercialised by industry. A robust patent system also ensures that new technologies, including medical treatments developed overseas, are made available in Australia.
- The Australian Law Reform Commission's 2004 report on *Genes and Ingenuity: Gene Patenting and Human Health*, the Senate Community Affairs Committee's *Gene Patents Report* released in November 2010 and the Advisory Council on Intellectual Property's 2011 report on patentable subject matter made recommendations for change to a number of aspects of the Australian patent system. The Government's response to these reports, released on 23 November 2011 accepted the majority of the recommendations in these reports (B11/4524 refers).
- The *Intellectual Property Laws Amendment (Raising the Bar) Act 2012* implements a number of these changes, ensuring Australia has strong and internationally aligned patenting criteria for novelty, inventive step, usefulness and description of the invention. The Act also introduces a research exemption, providing certainty to researchers to research without fear of prosecution for patent infringement (B12/827 and B12/368 refer).

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- Information on the specific issues raised in the briefing request is provided below and in **Attachment A**.

**Issues/sensitivities**

Inventive step standards:

Australia is a net importer of IP, it is therefore important that our legislation is in line with our major trading partners. The Raising the Bar Act increases the inventive step standard in Australia, so it aligns with that of our major trading partners, through removing the geographical restriction on common general knowledge, and removing the requirement for the prior art base (the publicly available information in the relevant technical field) to have been 'ascertained, understood and regarded as relevant'. Further detail is provided at **Attachment A**, with additional information, as requested, at **Attachments B and C**.

Australia's test for inventive step considers whether the invention is 'obvious', if it is, then it is not patentable. The same test is applied in Europe. In the United States, a 'non-obvious' test is used, resulting in an invention that is non-obvious being patentable. Conversely, an 'obvious' invention is not patentable, as in Australia.

It would not be in Australia's interests to have a higher threshold for inventiveness than other countries have. Local inventors would struggle to meet the higher test in Australia and this would probably impede their export opportunities. There could also be an adverse impact on foreign investment, since inventors needing to bring intellectual property into Australia would be unsure whether it would be protected.

Options to strengthen the Research Exemption in *Raising the Bar*:

Ms Melissa Parke MP, in her Raising the Bar second reading speech to the House of Representatives on 19 March 2012, suggested the research exemption does not 'go far enough'. She raised a number of issues with the exemption, outlined further at **Attachment A**.

The exemption introduced includes clinical and applied scientific purposes where they are carried out to improve or test an invention. However, the exemption will not apply when an invention is being used as a research or teaching tool if that is the use for which the invention is patented.

This exemption allows for some degree of commercial activity, as long as the predominant purpose of the activity is for research or experimentation.

If a researcher using a patented genetic material under the exemption invents a useful application, then in many circumstances the researcher will need to obtain a license if they wish to move from research to commercialisation. However, the researcher has benefited from the original invention, so it is only reasonable that when they wish to commercialise their invention they provide some compensation to the original inventor.

On the other hand, if the new invention is sufficiently different from the original invention, the researcher will not need to obtain a license because their invention differs to an extent that does not infringe the original invention.

Under our current understanding of the law, if a new diagnostic test using a patented isolated gene sequence is commercialised the owner of the new test, when taking it to market, would need to negotiate licensing provisions with the patentee of the gene sequence. This is because the commercialisation of a new diagnostic test or treatment of disease based on a patented

isolated genetic sequence does not constitute research, and as such does not fall under the research exemption.

Patent pools:

Patent pools can be defined as an agreement between two or more patent owners to license one or more of their patents to one another and/or third parties. The key benefit of patent pools is in reducing transaction costs for users having to identify relevant patents and then seek cross licensing arrangements with multiple individual patent holders. Patent pools are particularly beneficial in cases where the relevant technology is subject to fragmented patent ownership, such as may be the case when a technology is developing very rapidly, as has been the case in recent years in IT technology. Examples of successful use of patent pools are at **Attachment A**.

The establishment of patent pools tends to be driven by industry on a voluntary basis, governments have little role in their creation. However, governments can create incentives and provide the appropriate institutional framework to actively encourage setting up of patent pools in any particular technology field.

To date, there is little experience within governments to incentivise, facilitate or regulate patent pools.

Possible Memorandum of Understanding (MoU) between pharmaceutical/biotechnology companies and health/consumer lobby groups:

The Government recognises there needs to be a balance between achieving affordable access to healthcare and the ability to stimulate biomedical research and innovation.

The Australian patent system has existing safeguards such as the crown use and compulsory licensing provisions that can be used to ensure access to essential services and treatments are not blocked by patents.

As part of the implementation of the Government's response to the gene patent reports (B11/4524 refers) a review of the compulsory licensing provisions will be undertaken (B12/859 refers). Another recommendation is to improve the understanding of crown use. IP Australia is implementing this recommendation through an education and awareness program.

Additional information is provided at **Attachment A**.

Retrospectivity issues associated with banning gene patents:

If the Australian courts decide that isolated gene sequences are unpatentable, changes will likely be prospective and retrospective. This would be so because the court would probably decide that isolated gene sequences were never patentable, with the result that existing patents are invalid. Other parties wishing to use patented gene sequences would be able to either litigate, to have the patent in question revoked, or they may choose to simply use the patented sequence on the assumption that the patent is invalid.

If the government introduces a Bill that excludes isolated gene sequences from patentable subject matter, the changes would be prospective only, unless constitutional compensation was offered (section 51(xxxi) of the Constitution provides for acquisition of property on just

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terms). This is because it would be open to patent owners (in the absence of a court decision) to argue that the Government was acquiring an existing legal right.

Excluding isolated gene sequences from patentable subject matter may mean Australia is vulnerable to a claim of inconsistency with the Trade-Related Aspects of Intellectual Property Rights Protocol (TRIPS) and the Australia-United States Free Trade Agreement (AUSFTA). Under these agreements, Australia is obliged to make patents available for 'any invention... in all fields of technology'.

**Consultation**

- Pharmaceutical, Health Industries and Enabling Technologies Branch, Department of Industry, Innovation, Science, Research and Tertiary Education.

*Slipstream version: 6 May 2012*

Matt Forno

A/g General Manager BDSG

(02) 6283 2500

3 May 2012



Contact Officer:

Frances Roden

(02) 6283 2151

**Attachments**

Attachment A: Additional background and examples

Attachment B: Inventive Step – additional information, as requested

Attachment C: 'The Effect of Raising the Australian Statutory Inventive Step on the Australian Global Production System', P. H. Jensen et al, Intellectual Property Research Institute of Australia, Occasional Paper No. 1/08, August 2008

**Parliamentary Secretary Dreyfus for Action**

**Brief No:** B12/1630

**cc:** Minister Combet  
Minister Evans

**Division:** /Agency: IP Australia

**OPTIONS FOR ENHANCED EVIDENCE GATHERING AND THE  
CURRENT CASE AGAINST BANNING GENE PATENTS**

**Timing:** Routine

<b>Recommendation/s:</b>	<b>Approved</b>
1. That you agree to IP Australia engaging an external consultant to research and analyse the economic impact of gene patents.	Yes / No
<b>Parliamentary Secretary's signature:</b>	<b>Date:</b> / /

**Key Points:**

- Current patent law allows medical and other industrial inventions derived from nature to be patented. This is a long standing aspect of Australian law, which has enabled the development of important drugs, diagnostics and medical treatments, and other industrial products and processes. The law in Australia on this issue is consistent with that of our major trading partners.
- There have been a number of reviews into the patenting of genetic material in Australia. None have supported excluding isolated gene sequences from patent eligible subject matter, due at least in part to the possible effects this would have on innovation and access to innovative health care technology in Australia. A summary of issues relating to patenting of biological and genetic materials, including points made by IP Australia in submissions to these reviews, is at **Attachment A**.
- Both the Australian Law Reform Commission (ALRC) and the Senate Community Affairs Committee have recommended that further analysis be conducted into the impact of gene patents. It is clear that evidentiary gaps remain on the economic impact of patents for genetic material in Australia. This includes the effect of gene patents on the provision of health care services, on primary and incremental innovation, and on investment and commercialisation decisions. Availability of this evidence would assist in future policy decisions around gene patents.
- There are several options for conducting further economic research into the impact of gene patents in Australia, as outlined below. IP Australia recommends Option 1: to engage an external consultant with the expertise to undertake this complex economic analysis. While this option is likely to have the greatest financial cost, it will ensure an appropriate level of expertise and independence.
- IP Australia proposes, with your approval, to scope the proposed project, develop terms of reference and obtain quotes from a number of consultancies.

**Background:** See Attachment A.

**Key Issues / Sensitivities:**

*Options for undertaking economic research into the impact of gene patents:*

**Option 1 External Consultant**

An external consultancy could be engaged. This would allow the government to go to tender to select a provider that had the appropriate skills and capability to conduct a project of this nature, including expertise in economics and social policy. While this would potentially be the most expensive option, it is likely to provide the greatest transparency and impartiality in the eyes of stakeholders. This is IP Australia's preferred option.

**Option 2 Intellectual Property Research Institute of Australia (IPRIA)**

IPRIA was established to increase the understanding, creation, use and exploitation of intellectual property by Australian organisations and individuals. IPRIA's objectives are to:

- support and generate the development of high-level public policy in relation to IP issues;
- optimise the protection, management and exploitation of IP by all Australian stakeholders, including research institutions, public and private sector interests; and
- help create an informed environment for, and contribute to, on-going public debate in Australia about IP and related matters, including innovation policy and economic growth.

Engaging IPRIA to undertake the research may provide a lower cost option compared to engaging an external consultant, although this is not certain. Engaging an intellectual property research body directly may raise perceived concerns from critics of gene patents that any outcome will lack objectivity and be biased towards using the patents system.

If a tender process is used to select a provider under Option 1, it is possible that IPRIA will tender for the project. In this case, any tender documents could be assessed objectively against the tender criteria and against other competing tenders.

**Option 3 IP Australia Chief Economist**

IP Australia has recently created a new position of Chief Economist and is currently in the process of filling that position. The project envisaged is likely to be beyond the capability of one person, particularly in such a new role. This option is also likely to raise concerns about perceived objectivity.

**Option 4 Research by IP Australia**

IP Australia has previously commissioned economic work on aspects of the patent system. We could rely on this work together with other existing literature. This could be done by existing staff or under the direction of the new Chief Economist as per Option 3. However, the existing research does not directly address the identified gaps and would also raise perceived concerns about objectivity.

Clearing Officer  
Philip Noonan  
Director General  
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07 June 2012

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s47F

**Consultation:** NIL

**Attachments:**

Attachment A Summary of issues relating to patenting of biological and genetic material.

## Summary of issues relating to patenting of biological and genetic material

### *Reports on patenting of genetic material*

Over recent years there have been a number of reports into the patenting of genetic material: The Australian Law Reform Commission's 2004 report on *Genes and Ingenuity: Gene Patenting and Human Health*; The Senate Community Affairs Committee's *Gene Patents Report* released on 26 November 2010; and the Advisory Council on Intellectual Property's 2011 report on patentable subject matter. None of these reports recommended banning or restricting gene patents.

On 23 November 2011 the Government released its response to the Senate Community Affairs Committee's report, addressing recommendations made in all the above three reports. The majority of the reports' recommendations were accepted by Government, including that there be no ban on gene patents at this time.

IP Australia is responsible for implementing a number of the key recommendations in the Government's response. In particular, reforms to patent law, through the *Intellectual Property Laws Amendment (Raising the Bar) Act 2012*, a review of the compulsory licensing provisions, introducing a morality exclusion and a statement of objectives, and rewording the patentable subject matter test (**B12/1331** refers). These changes address a number of the major concerns expressed in the gene patent debate:

- The granting of overly broad and speculative patents will be addressed by changes to raise the standards that need to be met for grant of a patent.
- Certainty for researchers and facilitation of early entry into the market of generics will be addressed through the research and regulatory approval exemption from patent infringement.
- The claim that patents and restrictive licensing practices increase the costs of genetic diagnostic tests and medicines, and reduce equitable access to diagnostics, will be considered in the compulsory licensing review.

The ALRC report also included a recommendation that the Australian Health Ministers Advisory Council should establish processes for the examination of the financial impact of gene patents on the delivery of healthcare services in Australia. The Senate Community Affairs Committee report recommended that the Government support and expand on the collection of data, research, and analysis concerning genetic testing and treatment in Australia.

The Government accepted these recommendations in principle. Evidence on the value and impact of gene patents would greatly assist in future policy decisions on this issue. However, it must be noted that patenting of genetic material is a complex issue in which law, ethics, innovation, research, and healthcare policy intertwine. There are risks in considering any of those aspects in isolation as a change to address one aspect could have unexpected and significant consequences for Australian healthcare, business and trade interests. Any economic analysis should also consider the impact of gene patents on innovation, including research and development, investment and commercialisation.

### *Private member's Bills*

A private member's Bill, the *Patent Amendment (Human Genes & Biological Materials) Bill 2010* (Senator Heffernan's Bill), proposing to ban the patenting of biological material, was introduced into the Senate on 24 November 2010 by Senators Heffernan, Coonan, Xenophon

and Siewert. An identical Bill was introduced into the House of Representatives on 21 February 2011 by the Hon Peter Dutton MP, the Hon Rob Oakeshott MP, Mr John Forrest MP and the Hon Malcolm Turnbull MP.

The Senate referred Senator Heffernan's Bill to the Senate Legal and Constitutional Affairs Committee for inquiry and report. Over 100 submissions were received by the inquiry, the majority of which opposed the Bill. In September 2011 the Committee (in a majority report) recommended the Senate should not pass Senator Heffernan's Bill. The Committee concluded that the Bill "could have a large number of unintended consequences across the entire patent system with indeterminate impacts on a range of industries and sectors."

Ms Melissa Parke MP has recently canvassed a private member's Bill to exclude genetic material and diagnostic methods from patentable subject matter. While the proposed Bill is more detailed than previous similar Bills, it has primarily the same effect - a prospective ban on gene patents.

The considerable adverse impact of the proposed Bill and previous similar Bills would primarily be on the pharmaceutical and biotechnology sectors, including industrial biotechnology. These are sectors which have high paid, high skilled, high value-added jobs that leverage from the quality research capacity that exists in Australian universities, public research bodies and medical research institutes. The growth potential of these sectors is enormous, and industrial biotechnology in particular has the potential to increase the productivity of existing industries.

***Australia's position on the patenting of isolated biological material is consistent with most other countries***

All developed economies consider genetic and biological material to be eligible for patent protection. Brazil is a notable one among a small number of (predominantly South American) countries that do not.

Brazilian patent law does not permit the patenting of biological or genetic material isolated from natural sources, on the basis that such material is not an invention because it is "not new" - it "pre-exists" in nature. This exclusion is reportedly in place to prevent the legitimisation of patents granted in other countries and owned by foreign nationals, but that are based on biological material extracted from Brazilian biodiversity. Brazilian commentators have suggested that the social and economic loss from the current exclusion warrants reconsideration. The Brazilian Intellectual Property Association has proposed that the Brazilian patent law be amended in line with the approach of the developed countries. However, no change to the law concerning the patenting of biological material has been enacted to date.

In Europe, the Biotechnology Directive on the Legal Protection of Biotechnological inventions 98/44/EC requires that member states consider patents on biological material, including isolated gene sequences, no differently to inventions in any other technologies. The rules of the directive explicitly state "An element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element."

In contrast to the explicit EU biotech directive, the United States legislation regarding patent eligible subject matter defines four basic categories: process, machine, manufacture and composition of matter. In practice, isolated biological and genetic material (compositions of

matter) which is shown to be useful, new and non-obvious is presently deemed patent eligible by the United States Patent Office (USPTO).

In Australia the Manner of Manufacture requirement sets the boundary of what can be considered eligible subject matter. The High Court has determined in its 1959 watershed decision in *National Research and Development Corporation v Commissioner of Patents (NRDC)* this to be matter which requires an **artificially created state of affairs in a field of economic endeavour**.

In applying NRDC principles to assess whether a biological material qualifies as patent eligible subject matter, two essential requirements must be met. First, the material must be the result of a man-made process (or artificial state of affairs) - for example, an isolation, purification or synthesis process to yield the material in a useable form. Second, the material must have a specific use - for example, use in a specific industrial process or to treat or prevent a specific disease (field of economic endeavour). If no practical use is identified, then the material would be considered to be a discovery not an invention.

However, to date, no court decision in Australia has specifically considered whether isolated biological or genetic material is proper subject-matter for patents.

### ***Legal challenges to gene patents in the United States and Australia***

Gene patents are currently the subject of court action in Australia and the United States. The actions challenge the validity of Myriad's BRCA (breast cancer) patents. The central point of challenge in both court actions is that genetic material isolated from nature is not patent eligible under existing Australian and US patent law.

In the US, the Association for *Molecular Pathology v Myriad Genetics case (US Myriad case)* has been heard in two lower courts, the decisions on which have been divided. On 27 March 2012, the US Supreme Court remitted the US Myriad case to the Court of Appeal for the Federal Circuit for further consideration 'in light of the Mayo decision' (**B12/1051** refers).

On 8 June 2010, Cancer Voices Australia instigated legal action against Myriad Genetic Inc and others. This matter was heard on 20-24 February 2012 and judgement is currently reserved. A brief is currently being prepared to provide you with an update on these cases.

### ***Impact on Commonwealth government through possible non-compliance with international obligations***

Any exclusion from patentability of genetic or biological material needs to be considered in light of Australia's obligations to the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).

Provisions in TRIPS require patents to be available for 'inventions' in all fields of technology without discrimination. The term 'invention' is not defined in TRIPS. Australia is free to adopt its own definition of this term provided the characteristics that make certain subject matter not an 'invention' must be applied consistently to all subject matter that have those characteristics. For example, Australia could exclude human genetic material isolated from nature on the basis that such isolated material was not 'new' because it is 'pre-existing'. However, Australia would then also have to exclude all subject matter isolated from nature

including biological and non-biological material on that basis. The scope of such an exclusion is in large part represented by Senator Heffernan's Bill.

Adopting a narrow exclusion such as 'gene sequences or human gene sequences' risks non-compliance with TRIPS while a broad exclusion is more likely to lead to compliance but have more significant adverse impacts on industry as noted in the public submissions on Senator Heffernan's Bill.

### ***Healthcare and product access***

Reviews of gene patents in Australia and overseas have generally found a lack of evidence that gene patents systematically reduce patient access to healthcare or impede researchers' freedom to conduct research. Many of the concerns are speculative with the Myriad BRCA case being the prime source of evidence of adverse impact both during and since the 2004 ALRC inquiry.

The effect of gene patents on access to diagnostic and therapeutic procedures and research and development is not known. There are concerns that patenting could cause limitations on access to gene sequences. These proposals can be investigated; however there is no empirical evidence of the effect of gene patents on health outcomes.

An additional adverse consequence of any ban on gene or biological material is that there would be an incentive not to introduce new health treatments into the Australian market. Existing health treatments that are difficult to copy, such as biological and gene based drugs (which often have specific manufacturing processes that are not easily imitated), may become unavailable in Australia. This is because a major part of a drug's value is its patent value.

### ***Research activity***

The patenting of isolated biological and genetic material is the subject of much research and many commercial ventures in Australia. A ban on the patenting of this material will adversely impact on a broad range of industries including agriculture and animal health, food technologies and emerging "green" industries.

A number of research and development companies highlighted the potential adverse consequences to their operations in submissions to the Senate inquiries.

For example, the Victorian Government submission to the Senate inquiry on the Private Members Bill notes that "a ban on the patenting of biological materials threatens loss of jobs in the Life Science sector which currently contributes over 22,000 jobs in Victoria. In 2010, the Victorian Government spent more than \$637 million on research and development and raised \$2.16 billion in partnering deals".

It should also be noted that biological materials isolated from natural sources are a significant source of human medicines (47% of medicines approved in the last 25 years to 2006, were derived from natural sources; with respect to anti-cancer drugs almost 78% of those approved in the 25 years to 2006 were derived from natural sources or based upon material derived from natural sources.)

Examples of inventions underpinned by patents and patent applications covering isolated biological material include the Gardasil vaccine, the Hendra virus vaccine currently being

developed by the CSIRO in collaboration with the Henry M. Jackson Foundation; and CSIRO patents over bioleaching microorganisms which are useful for obtaining minerals from ores.

***Investment in development, commercialisation***

Patents mitigate the risks of new product development and allow researchers to attract investment. Patents can be used as a tool to get venture capital and negotiate with downstream pharmaceutical companies and suppliers. For example, the Adelaide based company Bionomics, recently signed a deal worth up to \$345 million with a US pharmaceutical company. According to Bionomics, this deal would not have occurred without their patents.

Biotechnology inventions are expensive to produce, with a high risk of failure over an extended period to market. However, they are comparatively inexpensive to reproduce or reverse engineer. According to IP Australia's submission to the Senate inquiry, current estimates of the full cost of bringing a new pharmaceutical (chemical or biological) entity to the market are around \$1.2 to \$1.3 billion. Given the high cost of conducting research and development (R&D) before commercialisation, it is crucial for businesses, particularly small start-ups, to attract private investment. Gene patents create certainty that encourages investment.

Many investment decisions are based on the availability of patent protection for "product patents" (i.e. the base molecule) and any ban on the patenting of genetic material would preclude patenting of these base molecules. Opponents of gene patents argue that the patent incentive should only be available on the pharmaceutical formulation and the method of isolation or manufacture, and not the base molecule itself. However, it is the base molecule that provides the pharmacological or biological activity; and it is this molecule for which safety and efficacy must be demonstrated through the risk based regulatory approval regime.

Gene patents also encourage foreign investment in Australia. IP Australia's concern is that if isolated genes are not patentable, research and investment will move offshore.

***US activity towards studying the impact of gene patents***

The US Congress has directed the USPTO to study effective ways to provide independent, confirming genetic diagnostic tests where gene patents and exclusive licensing for primary genetic diagnostic tests exist. This study includes examining the impact that independent second opinion testing has on: providing medical care to patients; the effect that providing independent second opinion genetic diagnostic testing would have on the existing patent and license holders of an exclusive genetic test; the impact of current practices on testing results and performance; and the role of insurance coverage on the provision of genetic diagnostic tests. The USPTO must report to Congress the findings of the study and provide recommendations for establishing the availability of independent confirming genetic diagnostic test activity by 16 June 2012.

# B12/1630 Options for Enhanced Evidence Gathering and the Current Case Against Banning Gene Patents [SEC=IN-CONFIDENCE] - Notes Memo

**From:** [Andrea.Blazsev@ipaaustralia.gov.au](mailto:Andrea.Blazsev@ipaaustralia.gov.au)  
**To:** mlobriefs@innovation.gov.au, kaye.fisk@innovation.gov.au  
**Cc:** Matthew.Forno@ipaaustralia.gov.au, Frances.Roden@ipaaustralia.gov.au  
**Sent:** 07-06-2012 4:01:34 PM

MLO

Please find attached B12/1630 Options for Enhanced Evidence Gathering and the Current Case Against Banning Gene Patents  
It has been cleared by Philip Noonan, Director General, IP Australia.

<Attachment: 12-06-07 B12-1630 AB Enhanced evidence gathering and case against banning gene patents.doc>

Kind Regards,

## Ministerial Support Team

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**Australian Government**  
Department of Industry, Innovation  
Science, Research and Tertiary Education

*Please consult with my  
office on the terms of reference  
for the consultant AD*

**Parliamentary Secretary Dreyfus for Action**

**Brief No:** B12/1630

**cc:** Minister Combet  
Minister Evans

**Division:** /Agency: IP Australia

**OPTIONS FOR ENHANCED EVIDENCE GATHERING AND THE  
CURRENT CASE AGAINST BANNING GENE PATENTS**

**Timing:** Routine

<b>Recommendation/s:</b>	<b>Approved</b>
1. That you agree to IP Australia engaging an external consultant to research and analyse the economic impact of gene patents.	<input checked="" type="radio"/> Yes / No
<b>Parliamentary Secretary's signature:</b>	<b>Date:</b> 4/6/12

**Key Points:**

- Current patent law allows medical and other industrial inventions derived from nature to be patented. This is a long standing aspect of Australian law, which has enabled the development of important drugs, diagnostics and medical treatments, and other industrial products and processes. The law in Australia on this issue is consistent with that of our major trading partners.
- There have been a number of reviews into the patenting of genetic material in Australia. None have supported excluding isolated gene sequences from patent eligible subject matter, due at least in part to the possible effects this would have on innovation and access to innovative health care technology in Australia. A summary of issues relating to patenting of biological and genetic materials, including points made by IP Australia in submissions to these reviews, is at **Attachment A**.
- Both the Australian Law Reform Commission (ALRC) and the Senate Community Affairs Committee have recommended that further analysis be conducted into the impact of gene patents. It is clear that evidentiary gaps remain on the economic impact of patents for genetic material in Australia. This includes the effect of gene patents on the provision of health care services, on primary and incremental innovation, and on investment and commercialisation decisions. Availability of this evidence would assist in future policy decisions around gene patents.
- There are several options for conducting further economic research into the impact of gene patents in Australia, as outlined below. IP Australia recommends Option 1: to engage an external consultant with the expertise to undertake this complex economic analysis. While this option is likely to have the greatest financial cost, it will ensure an appropriate level of expertise and independence.
- IP Australia proposes, with your approval, to scope the proposed project, develop terms of reference and obtain quotes from a number of consultancies.

**Background:** See Attachment A.

**Key Issues / Sensitivities:**

*Options for undertaking economic research into the impact of gene patents:*

**Option 1 External Consultant**

An external consultancy could be engaged. This would allow the government to go to tender to select a provider that had the appropriate skills and capability to conduct a project of this nature, including expertise in economics and social policy. While this would potentially be the most expensive option, it is likely to provide the greatest transparency and impartiality in the eyes of stakeholders. This is IP Australia's preferred option.

**Option 2 Intellectual Property Research Institute of Australia (IPRIA)**

IPRIA was established to increase the understanding, creation, use and exploitation of intellectual property by Australian organisations and individuals. IPRIA's objectives are to:

- support and generate the development of high-level public policy in relation to IP issues;
- optimise the protection, management and exploitation of IP by all Australian stakeholders, including research institutions, public and private sector interests; and
- help create an informed environment for, and contribute to, on-going public debate in Australia about IP and related matters, including innovation policy and economic growth.

Engaging IPRIA to undertake the research may provide a lower cost option compared to engaging an external consultant, although this is not certain. Engaging an intellectual property research body directly may raise perceived concerns from critics of gene patents that any outcome will lack objectivity and be biased towards using the patents system.

If a tender process is used to select a provider under Option 1, it is possible that IPRIA will tender for the project. In this case, any tender documents could be assessed objectively against the tender criteria and against other competing tenders.

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*Slipstream Version 8 June 2012*

Clearing Officer

Philip Noonan

Director General

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07 June 2012

Contact Officer:

Frances Roden

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**Consultation:** NIL

**Attachments:**

Attachment A Summary of issues relating to patenting of biological and genetic material.

## Summary of issues relating to patenting of biological and genetic material

### *Reports on patenting of genetic material*

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The Government accepted these recommendations in principle. Evidence on the value and impact of gene patents would greatly assist in future policy decisions on this issue. However, it must be noted that patenting of genetic material is a complex issue in which law, ethics, innovation, research, and healthcare policy intertwine. There are risks in considering any of those aspects in isolation as a change to address one aspect could have unexpected and significant consequences for Australian healthcare, business and trade interests. Any economic analysis should also consider the impact of gene patents on innovation, including research and development, investment and commercialisation.

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Ms Melissa Parke MP has recently canvassed a private member's Bill to exclude genetic material and diagnostic methods from patentable subject matter. While the proposed Bill is more detailed than previous similar Bills, it has primarily the same effect - a prospective ban on gene patents.

The considerable adverse impact of the proposed Bill and previous similar Bills would primarily be on the pharmaceutical and biotechnology sectors, including industrial biotechnology. These are sectors which have high paid, high skilled, high value-added jobs that leverage from the quality research capacity that exists in Australian universities, public research bodies and medical research institutes. The growth potential of these sectors is enormous, and industrial biotechnology in particular has the potential to increase the productivity of existing industries.

***Australia's position on the patenting of isolated biological material is consistent with most other countries***

All developed economies consider genetic and biological material to be eligible for patent protection. Brazil is a notable one among a small number of (predominantly South American) countries that do not.

Brazilian patent law does not permit the patenting of biological or genetic material isolated from natural sources, on the basis that such material is not an invention because it is "not new" - it "pre-exists" in nature. This exclusion is reportedly in place to prevent the legitimisation of patents granted in other countries and owned by foreign nationals, but that are based on biological material extracted from Brazilian biodiversity. Brazilian commentators have suggested that the social and economic loss from the current exclusion warrants reconsideration. The Brazilian Intellectual Property Association has proposed that the Brazilian patent law be amended in line with the approach of the developed countries. However, no change to the law concerning the patenting of biological material has been enacted to date.

In Europe, the Biotechnology Directive on the Legal Protection of Biotechnological inventions 98/44/EC requires that member states consider patents on biological material, including isolated gene sequences, no differently to inventions in any other technologies. The rules of the directive explicitly state "An element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element."

In contrast to the explicit EU biotech directive, the United States legislation regarding patent eligible subject matter defines four basic categories: process, machine, manufacture and

composition of matter. In practice, isolated biological and genetic material (compositions of matter) which is shown to be useful, new and non-obvious is presently deemed patent eligible by the United States Patent Office (USPTO).

In Australia the Manner of Manufacture requirement sets the boundary of what can be considered eligible subject matter. The High Court has determined in its 1959 watershed decision in *National Research and Development Corporation v Commissioner of Patents (NRDC)* this to be matter which requires an **artificially created state of affairs in a field of economic endeavour**.

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However, to date, no court decision in Australia has specifically considered whether isolated biological or genetic material is proper subject-matter for patents.

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Gene patents are currently the subject of court action in Australia and the United States. The actions challenge the validity of Myriad's BRCA (breast cancer) patents. The central point of challenge in both court actions is that genetic material isolated from nature is not patent eligible under existing Australian and US patent law.

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Provisions in TRIPS require patents to be available for 'inventions' in all fields of technology without discrimination. The term 'invention' is not defined in TRIPS. Australia is free to adopt its own definition of this term provided the characteristics that make certain subject matter not an 'invention' must be applied consistently to all subject matter that have those characteristics. For example, Australia could exclude human genetic material isolated from nature on the basis that such isolated material was not 'new' because it is 'pre-existing'. However, Australia would then also have to exclude all subject matter isolated from nature

including biological and non-biological material on that basis. The scope of such an exclusion is in large part represented by Senator Heffernan's Bill.

Adopting a narrow exclusion such as 'gene sequences or human gene sequences' risks non-compliance with TRIPS while a broad exclusion is more likely to lead to compliance but have more significant adverse impacts on industry as noted in the public submissions on Senator Heffernan's Bill.

### ***Healthcare and product access***

Reviews of gene patents in Australia and overseas have generally found a lack of evidence that gene patents systematically reduce patient access to healthcare or impede researchers' freedom to conduct research. Many of the concerns are speculative with the Myriad BRCA case being the prime source of evidence of adverse impact both during and since the 2004 ALRC inquiry.

The effect of gene patents on access to diagnostic and therapeutic procedures and research and development is not known. There are concerns that patenting could cause limitations on access to gene sequences. These proposals can be investigated; however there is no empirical evidence of the effect of gene patents on health outcomes.

An additional adverse consequence of any ban on gene or biological material is that there would be an incentive not to introduce new health treatments into the Australian market. Existing health treatments that are difficult to copy, such as biological and gene based drugs (which often have specific manufacturing processes that are not easily imitated), may become unavailable in Australia. This is because a major part of a drug's value is its patent value.

### ***Research activity***

The patenting of isolated biological and genetic material is the subject of much research and many commercial ventures in Australia. A ban on the patenting of this material will adversely impact on a broad range of industries including agriculture and animal health, food technologies and emerging "green" industries.

A number of research and development companies highlighted the potential adverse consequences to their operations in submissions to the Senate inquiries.

For example, the Victorian Government submission to the Senate inquiry on the Private Members Bill notes that "a ban on the patenting of biological materials threatens loss of jobs in the Life Science sector which currently contributes over 22,000 jobs in Victoria. In 2010, the Victorian Government spent more than \$637 million on research and development and raised \$2.16 billion in partnering deals".

It should also be noted that biological materials isolated from natural sources are a significant source of human medicines (47% of medicines approved in the last 25 years to 2006, were derived from natural sources; with respect to anti-cancer drugs almost 78% of those approved in the 25 years to 2006 were derived from natural sources or based upon material derived from natural sources.)

Examples of inventions underpinned by patents and patent applications covering isolated biological material include the Gardasil vaccine, the Hendra virus vaccine currently being

developed by the CSIRO in collaboration with the Henry M. Jackson Foundation; and CSIRO patents over bioleaching microorganisms which are useful for obtaining minerals from ores.

### ***Investment in development, commercialisation***

Patents mitigate the risks of new product development and allow researchers to attract investment. Patents can be used as a tool to get venture capital and negotiate with downstream pharmaceutical companies and suppliers. For example, the Adelaide based company Bionomics, recently signed a deal worth up to \$345 million with a US pharmaceutical company. According to Bionomics, this deal would not have occurred without their patents.

Biotechnology inventions are expensive to produce, with a high risk of failure over an extended period to market. However, they are comparatively inexpensive to reproduce or reverse engineer. According to IP Australia's submission to the Senate inquiry, current estimates of the full cost of bringing a new pharmaceutical (chemical or biological) entity to the market are around \$1.2 to \$1.3 billion. Given the high cost of conducting research and development (R&D) before commercialisation, it is crucial for businesses, particularly small start-ups, to attract private investment. Gene patents create certainty that encourages investment.

Many investment decisions are based on the availability of patent protection for "product patents" (i.e. the base molecule) and any ban on the patenting of genetic material would preclude patenting of these base molecules. Opponents of gene patents argue that the patent incentive should only be available on the pharmaceutical formulation and the method of isolation or manufacture, and not the base molecule itself. However, it is the base molecule that provides the pharmacological or biological activity; and it is this molecule for which safety and efficacy must be demonstrated through the risk based regulatory approval regime.

Gene patents also encourage foreign investment in Australia. IP Australia's concern is that if isolated genes are not patentable, research and investment will move offshore.

### ***US activity towards studying the impact of gene patents***

The US Congress has directed the USPTO to study effective ways to provide independent, confirming genetic diagnostic tests where gene patents and exclusive licensing for primary genetic diagnostic tests exist. This study includes examining the impact that independent second opinion testing has on: providing medical care to patients; the effect that providing independent second opinion genetic diagnostic testing would have on the existing patent and license holders of an exclusive genetic test; the impact of current practices on testing results and performance; and the role of insurance coverage on the provision of genetic diagnostic tests. The USPTO must report to Congress the findings of the study and provide recommendations for establishing the availability of independent confirming genetic diagnostic test activity by 16 June 2012.

**IN-CONFIDENCE**

**Australian Government**  
 Department of Industry, Innovation  
 Science, Research and Tertiary Education



**Parliamentary Secretary Dreyfus for Action**

cc: Minister Combet  
 Minister Evans

**Brief No: B12/1630**

**Division: /Agency: IP Australia**

**OPTIONS FOR ENHANCED EVIDENCE GATHERING AND THE  
 CURRENT CASE AGAINST BANNING GENE PATENTS**

**Timing:** Routine

<b>Recommendation/s:</b>	<b>Approved</b>
1. That you agree to IP Australia engaging an external consultant to research and analyse the economic impact of gene patents.	Yes / No
<b>Parliamentary Secretary's signature:</b>	<b>Date:</b> / /

**Key Points:**

- Current patent law allows medical and other industrial inventions derived from nature to be patented. This is a long standing aspect of Australian law, which has enabled the development of important drugs, diagnostics and medical treatments, and other industrial products and processes. The law in Australia on this issue is consistent with that of our major trading partners.
- There have been a number of reviews into the patenting of genetic material in Australia. None have supported excluding isolated gene sequences from patent eligible subject matter, due at least in part to the possible effects this would have on innovation and access to innovative health care technology in Australia. A summary of issues relating to patenting of biological and genetic materials, including points made by IP Australia in submissions to these reviews, is at **Attachment A**.
- Both the Australian Law Reform Commission (ALRC) and the Senate Community Affairs Committee have recommended that further analysis be conducted into the impact of gene patents. It is clear that evidentiary gaps remain on the economic impact of patents for genetic material in Australia. This includes the effect of gene patents on the provision of health care services, on primary and incremental innovation, and on investment and commercialisation decisions. Availability of this evidence would assist in future policy decisions around gene patents.
- There are several options for conducting further economic research into the impact of gene patents in Australia, as outlined below. IP Australia recommends Option 1: to engage an external consultant with the expertise to undertake this complex economic analysis. While this option is likely to have the greatest financial cost, it will ensure an appropriate level of expertise and independence.
- IP Australia proposes, with your approval, to scope the proposed project, develop terms of reference and obtain quotes from a number of consultancies.

**Background: See Attachment A.**

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**Key Issues / Sensitivities:**

*Options for undertaking economic research into the impact of gene patents:*

**Option 1 External Consultant**

An external consultancy could be engaged. This would allow the government to go to tender to select a provider that had the appropriate skills and capability to conduct a project of this nature, including expertise in economics and social policy. While this would potentially be the most expensive option, it is likely to provide the greatest transparency and impartiality in the eyes of stakeholders. This is IP Australia's preferred option.

**Option 2 Intellectual Property Research Institute of Australia (IPRIA)**

IPRIA was established to increase the understanding, creation, use and exploitation of intellectual property by Australian organisations and individuals. IPRIA's objectives are to:

- support and generate the development of high-level public policy in relation to IP issues;
- optimise the protection, management and exploitation of IP by all Australian stakeholders, including research institutions, public and private sector interests; and
- help create an informed environment for, and contribute to, on-going public debate in Australia about IP and related matters, including innovation policy and economic growth.

Engaging IPRIA to undertake the research may provide a lower cost option compared to engaging an external consultant, although this is not certain. Engaging an intellectual property research body directly may raise perceived concerns from critics of gene patents that any outcome will lack objectivity and be biased towards using the patents system.

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*Slipstream Version 8 June 2012*

Clearing Officer

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07 June 2012

Contact Officer:

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**Consultation: NIL**

**Attachments:**

Attachment A Summary of issues relating to patenting of biological and genetic material.

## Summary of issues relating to patenting of biological and genetic material

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File C2012/12966 FOI 380  
**Ministerial Coversheet**

<b>Date Due in MLO:</b>	8/06/2012	<b>Ministerial Item:</b>	B12/1630
<b>Action Division:</b>	IP Aust	<b>Current Division:</b>	IP Aust
<b>Action:</b>	Information - Request MO	<b>Minister Office:</b>	Dreyfus
<b>Signatories:</b>	DREYFUS QC MP, MARK		
<b>Subject:</b>	Assessment of options for enhanced evidence gathering on gene patents		

<b>Ministerial Type:</b>	Brief	<b>Attachments:</b>	N
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<b>Critical Date:</b>		<b>Talking Points:</b>	N
<b>Critical Date Reason:</b>		<b>Sensitivities Involved:</b>	N

**Summary:**

**Instructions:**

**Officer:** Wright, Adam  
**Date:** 21 May 2012 17:40  
**Text:** Matters to be addressed in Brief. Assess options available to instigate work on the impacts of gene patents. Refer to recommendation 1 of the Senate Gene Patents Report and recommendation 19-1 of the ALRC report Genes and Ingenuity. However, the evidence gathering will have a broader focus, including the impacts on 'initial' innovation and 'follow-on' innovation. Options may include: engagement of a consultancy; a review constituted by the Parliamentary Secretary. Requesting Adviser: Round, Jim (Dreyfus)

**Officer:**



ABN 38 113 072 755

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.....

5 June 2012

s47F

s47F

Thank you for your email of 15 May 2012 to the Prime Minister, in which you expressed concerns about the gene patent issues discussed on ABC's Lateline program of 14 May 2012. In that program, Ms Melissa Parke MP and Senator the Hon Bill Heffernan spoke about potential legislation aimed at banning gene patents. Your email has been referred to me at IP Australia, as this agency has responsibility for patent matters.

Because Ms Parke's legislation has not been introduced to Parliament, I am unable to comment on specific proposals. Nevertheless, IP Australia is mindful of the debate in Australia about patents for genetic material, and I am familiar with the issues covered during that edition of Lateline. I hope to reassure you about some of the main points that were raised, including questions about whether Australians will continue to have access to the latest medical advances, and how patent legislation affects the freedom of research in Australia.

By way of background, concerns about gene patents have been comprehensively investigated by the Australian Law Reform Commission (2004), the Advisory Council on Intellectual Property (2010), the Senate Community Affairs References Committee (2010) and the Senate Legal and Constitution Affairs Committee (2011). None of these reports recommended a ban on the patenting of isolated gene sequences.

There are already limits upon what can be patented in Australia. For example, genetic material in its natural state is not patentable. In particular, Australia does not allow patents over human beings and biological processes for their generation. However, Australia's patent system does allow the patenting of substances isolated from nature (for example, chemical compounds) and for which a new, practical application has been identified. These are the circumstances under which isolated gene sequences can be patented. Even then, a patent over an isolated gene sequence does not equate to ownership of that gene, and in no way impinges on the freedom of individuals to use their own DNA.

Community concerns about any potential for patents to deny access to medical care are understandable. To address that issue, the *Patents Act 1990* contains safeguards such as compulsory licensing and Crown use to ensure access to patented technology should problems arise. Notwithstanding, the Australian Government has committed to review existing compulsory licence provisions to ensure that they can be invoked efficiently and operate effectively as a safeguard.

The new *Intellectual Property Laws Amendment (Raising the Bar) Act 2012* clarifies the rights of those seeking access to genes for research purposes. The Act introduces a statutory research exemption applying to all technologies, making it clear that researchers will not infringe a patent when carrying out research on the patented invention.

The *Raising the Bar Act* was passed after extensive public consultations over a two year period and provides for a number of changes to raise the standards for grant of a patent. The various changes will in combination increase the quality of patents that are granted.

Meanwhile, there are important reasons why patent rights continue to be so important to knowledge-based economies such as ours.

Research, development and commercialisation (particularly in cutting edge technology areas such as biotechnology) are often tremendously expensive and financially risky. Without an incentive such as the patent system, many innovations would not be translated into new technologies that benefit Australian society.

Patent rights facilitate this vital innovation and technology transfer by providing an exclusive title to an invention for a limited period of time. This gives inventors an opportunity to recover their investment and profit from their work.

In turn, the patent system requires innovators to disclose the details of their inventions to the public, thus supporting follow-on research and innovation. Similarly, the potential availability of patent rights increases the likelihood of public sector research eventually being commercialised by industry and then put to use for the public good. This is how the patent system helps stimulate the fresh innovation which is essential for creating future diagnostics, medical treatments and research.

The three comprehensive reviews noted above have concluded that at this time the current legislation with the various changes in the *Raising the Bar Act* and initiatives such as review of the existing compulsory licence safeguard strike a balance between promoting the public interest and providing necessary patent incentives to promote innovation in Australia.

Thank you once again for your correspondence.

Yours sincerely

A handwritten signature in black ink, appearing to read 'F. Beattie', written in a cursive style.

F. Beattie  
Deputy Director General  
IP Australia

**C12/2056 - Copy of Departmental Reply [SEC=UNCLASSIFIED] - Notes Memo**

**From:** [Andrea.Blazsev@ipaaustralia.gov.au](mailto:Andrea.Blazsev@ipaaustralia.gov.au)  
**To:** mlocorro@innovation.gov.au, kaye.fisk@innovation.gov.au  
**Cc:** Matthew.Forno@ipaaustralia.gov.au, Frances.Roden@ipaaustralia.gov.au, Matthew.Ginn@ipaaustralia.gov.au  
**Sent:** 06-06-2012 09:29:37 AM

MLO

Please find attached a copy of IP Australia's departmental reply to s47F for C12/2056 - Gene Patent Legislation.  
Please upload to Slipstream.

Kind Regards,  
Andrea

<Attachment: 12-06-05 C12-2056 Reply To s47F.pdf>

## Ministerial Support Team

**Julie Baxter** P: + 61 2 6283 2540

**Andrea Blazsev** P: + 61 2 6222 3611

Strategy, Research and Ministerial Support  
IP Australia

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File C2012/12966 FOI 384  
Ministerial Coversheet

<b>Date Due in MLO:</b>	15/06/2012	<b>Ministerial Item:</b>	C12/2056
<b>Action Division:</b>	IP Aust	<b>Current Division:</b>	IP Aust
<b>Action:</b>	Reply by Department	<b>Minister Office:</b>	Dreyfus
<b>Signatories:</b>			
<b>Subject:</b>	Gene Patent Legislation		

<b>Ministerial Type:</b>	Correspondence	<b>Attachments:</b>	N
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<b>Corro Date:</b>	15/05/2012	<b>Interim Reply:</b>	N
<b>MO Received Date:</b>	17/05/2012		
<b>Complexity:</b>	NON-COMPLEX	<b>MP Rep Constituent:</b>	N
<b>Campaign:</b>			

**Instructions:**

C12/2056

Zygodlo, Amanda

From: stephen.madden@pmc.gov.au  
Sent: Wednesday, 16 May 2012 7:07 PM  
To: MLO Corro  
Subject: Ministerial Correspondence Referral from PM&C. C12/33484 [SEC=UNCLASSIFIED:NO CAVEATS]

The below correspondence addressed to the PM was received by PM&C and has been referred for your Minister's consideration. Thank you.

Reader: Madden, Stephen  
Date of letter: 15 May 12 11:12:03  
PMC ID: C12/33484

s47F

Parliamentary Secretary for Industry and Innovation

Division: *IPAus* DLO: *Actm*

Subject:

RECEIVED 17 MAY 2012

<input type="checkbox"/> Covering Brief	<input checked="" type="checkbox"/> Departmental Reply
<input type="checkbox"/> VIP Reply	<input type="checkbox"/> Appropriate Action
<input type="checkbox"/> Acknowledgement	<input type="checkbox"/> For Information (NFA)
<input type="checkbox"/> Parl Sec Reply	<input type="checkbox"/> Campaign
<input type="checkbox"/> CoS/Adviser	<input type="checkbox"/> Refer to:.....

Gene Patent

Subject - Gene Patent Message - Dear Prime Minister We are moved to write to you after seeing Lateline last night. MP for Fremantle Melissa Parke, while acknowledging the improvements made by your government, also highlighted important deficiencies that need to be corrected in the area of gene patent legislation. We won't rehash her coherent, well considered reasoning. We are deeply concerned and quite shocked at the implications of the issues raised by Melissa Parke. It is also significant that cross party support by Senator Heffernan exists at a time when there are few bipartisan issues - again this points to the serious nature of the issues raised on Lateline. We strongly urge you and your government to provided formal support for this important legislative initiative of the Member for Fremantle. We would be please to hear your response. Thanks for your consideration.

s47F

IMPORTANT: This message, and any attachments to it, contains information that is confidential and may also be the subject of legal professional or other privilege. If you are not the intended recipient of this message, you must not review, copy, disseminate or disclose its contents to any other party or take action in reliance of any material contained within it. If you have received this message in error, please notify the sender immediately by return email informing them of the mistake and delete all copies of the message from your computer system.

Att: s47F, re query about gene patents[SEC=UNCLASSIFIED] -  
Notes Memo

From: [Julie.Baxter@ipaaustralia.gov.au](mailto:Julie.Baxter@ipaaustralia.gov.au)

To: s47F

Sent: 04-07-2012 10:54:11 AM

Dear s47F,

Thank you for your recent correspondence to the Department of Health and Ageing. It has been passed to IP Australia for response. A letter to you is attached below.

<Attachment: Copy of C12-2304.pdf>

Kind Regards,

## Ministerial Support Team

**Julie Baxter** P: + 61 2 6283 2540

**Andrea Blazsev** P: + 61 2 6222 3611

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IP Australia

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3 July 2012

Our reference: C2012/2304

s47F

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Dear s47F

Thank you for your email of 15 May 2012 to the Australian Government Department of Health and Ageing. In that email, you expressed concerns about the legitimacy of gene patents, and asked whether new legislation is needed to address this issue. Your email has been referred to me at IP Australia, as this agency has responsibility for patent matters.

IP Australia is mindful of the debate in Australia about patenting genetic material, and I hope to reassure you about the current legislation and how we apply it to patent applications.

Every new patent must meet clear standards. By way of example, under the *Patents Act 1990*, if a given patent application lacks an inventive step (ie is 'obvious', or merely a discovery) then it is not patentable. Moreover, the new *Intellectual Property Laws Amendment (Raising the Bar) Act 2012*, passed after two years of extensive public consultations, now provides for a number of changes to raise patent standards. This will increase the quality of all patents granted by IP Australia.

Concerns specifically related to gene patents have been comprehensively investigated by the Australian Law Reform Commission (2004), the Advisory Council on Intellectual Property (2010), the Senate Community Affairs References Committee (2010) and the Senate Legal and Constitution Affairs Committee (2011). None of these reports recommended a ban on the patenting of isolated gene sequences.

In part, this is because there are already meaningful limits on the patenting of genetic material in Australia. Genetic material in its natural state cannot be patented in Australia. Likewise, Australia does not allow patents over human beings and biological processes for their generation.

Australia's patent system does allow the patenting of substances isolated from nature (for example, chemical compounds) so long as a new practical application for them has been identified. These are the circumstances under which isolated gene sequences can be patented. Even then, a patent over an isolated gene sequence does not equate to ownership of that gene, and in no way impinges on the freedom of individuals.

To ensure public access to medical care (including medical care or diagnostics based on patented genetic material), the *Patents Act 1990* contains powerful compulsory licensing and Crown use provisions. The Australian Government has recently committed to review the compulsory licence provisions to ensure that they can be invoked efficiently and operate effectively as a safeguard.

Meanwhile, there are important reasons why patent rights continue to be a feature of knowledge-based economies.

Research, development and commercialisation (particularly in cutting edge technology areas such as biotechnology) are often tremendously expensive and financially risky. Without an incentive such as the patent system, many innovations would not be translated into new technologies that benefit Australian society.

Patent rights facilitate this vital innovation by providing an exclusive title to an invention for a limited period of time. This gives inventors an opportunity to recover their investment, protect their innovation and profit from their work.

In turn, the patent system requires innovators to disclose the details of their inventions to the public, thus supporting follow-on research and innovation. Similarly, the potential availability of patent rights increases the likelihood of public sector research eventually being commercialised by industry and then put to use for the public good. This is how the patent system helps stimulate the innovation which is essential for creating future diagnostics and medical treatments.

Current legislation (including the legislative changes made in early 2012) takes account of these diverse issues, and consequently imposes proper limits on the patenting of genetic material patents while still allowing sufficient patent incentives to promote innovation in Australia.

Thank you once again for your correspondence.

Yours sincerely



Victor Portelli  
Acting Deputy Director General  
IP Australia

File C2012/12966 FOI 389  
Ministerial Coversheet

<b>Date Due in MLO:</b>	21/06/2012	<b>Ministerial Item:</b>	C12/2304
<b>Action Division:</b>	IP Aust	<b>Current Division:</b>	IP Aust
<b>Action:</b>	Reply by Parliamentary Sec	<b>Minister Office:</b>	Dreyfus
<b>Signatories:</b>	DREYFUS QC MP, MARK		
<b>Subject:</b>	Abuse of patent law in relation to Gene and DNA discovery		

<b>Ministerial Type:</b>	Correspondence	<b>Attachments:</b>	N
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<b>Corro Date:</b>	15/05/2012	<b>Interim Reply:</b>	N
<b>MO Received Date:</b>	5/06/2012		
<b>Complexity:</b>	NON-COMPLEX	<b>MP Rep Constituent:</b>	N
<b>Campaign:</b>			

**Instructions:**

C12/2304

**Zygadlo, Amanda**

---

**From:** Diane.McDevitt@health.gov.au on behalf of Referrals@health.gov.au  
**Sent:** Monday, 4 June 2012 12:18 PM  
**To:** MLO Corro  
**Subject:** Possible Referral from DoHA - D12008145 [SEC=UNCLASSIFIED]  
**Attachments:** opening a Tif document.doc; D12008145 - s47F

Good afternoon

Could you please review the attached referral and advise if the matter raised falls within the Innovation, Industry, Science, Research and Tertiary Education portfolio.

It would be appreciated if you review the attached file and advise by 12 June 2012 if you are able to accept the referral. However, if you have any problems meeting this deadline please let me know as soon as possible.

Should a response not be received by the requested date, we will take this as approval and consider the item as referred to your portfolio.

Please note that the **hard copy will not be sent** unless requested.

Many thanks

**Lorraine Walker**

Parliamentary Referrals Officer

Ministerial Liaison and Support Section | Ministerial and Parliamentary Support Branch | Department of Health and Ageing

Ph 02 6289 7985

*Please note: This document is saved as a tif file - Instruction on how to open a TIF document and also how to save it to a PDF are attached below.*

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ENQUIRIES  
Sent by: Joshua Bee  
15/05/2012 11:59 AM

To MinCorro/Health@Health\_gov\_au  
cc  
bcc

Subject Fw: New feedback received for OtherEnquiry - [REDACTED]  
[SEC=UNCLASSIFIED]

UNCLASSIFIED

Dear MinCorro,

Please see email below from [REDACTED] If you could please respond directly to the email address provided it would be much appreciated.

Kind Regards,

Enquiries  
Australian Government Department of Health and Ageing

\*\*\*please bcc enquiries into your final response\*\*\*

D12008145  
19/06/12

----- Forwarded by Joshua Bee/BG/Health on 15/05/2012 11:58 AM -----



WCMPRD01/S  
VR/Health  
15/05/2012  
11:24 AM

To enquiries@health.gov.au  
cc

Subject New feedback received for OtherEnquiry

FEEDBACKTYPE: OtherEnquiry

NAMECONTACT: [REDACTED]

EMAIL: [REDACTED]

ENQUIRY: I am concerned about the abuse of patent law in relation to Gene and DNA discovery and wonder whether the Minister supports the introduction of legislation to address the issue of corporate holding of what is essentially our body's biology.

Excel formatted data (copy and paste this text into Column A, on a new row, in Excel)  
\*\*\*\*\*

OtherEnquiry [REDACTED] I am concerned about the abuse of patent law in relation to Gene and DNA discovery and wonder whether the Minister supports the introduction of legislation to address the issue of corporate holding of what is essentially our body's biology...

UNCLASSIFIED

Parliamentary Secretary for Industry and Innovation

Division: *IP Australia* DLO: *AW*

Subject:

RECEIVED 05 JUN 2012

<input type="checkbox"/> Covering Brief	<input type="checkbox"/> Departmental Reply
<input type="checkbox"/> VIP Reply	<input type="checkbox"/> Appropriate Action
<input type="checkbox"/> Acknowledgement	<input type="checkbox"/> For Information (NFA)
<input checked="" type="checkbox"/> Parl Sec Reply	<input type="checkbox"/> Campaign
<input type="checkbox"/> CoS/Adviser	<input type="checkbox"/> Refer to: .....

File C2012/12966 FOI 392  
**Ministerial Coversheet**

<b>Date Due in MLO:</b>	4/07/2012	<b>Ministerial Item:</b>	C12/2304
<b>Action Division:</b>	IP Aust	<b>Current Division:</b>	IP Aust
<b>Action:</b>	Reply by Department	<b>Minister Office:</b>	Dreyfus
<b>Signatories:</b>			
<b>Subject:</b>	Abuse of patent law in relation to Gene and DNA discovery		

<b>Ministerial Type:</b>	Correspondence	<b>Attachments:</b>	Y (1)
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<b>Corro Date:</b>	15/05/2012	<b>Interim Reply:</b>	N
<b>MO Received Date:</b>	5/06/2012		
<b>Complexity:</b>	NON-COMPLEX	<b>MP Rep Constituent:</b>	N
<b>Campaign:</b>			

**Instructions:**

C12/2304

all redactions s47F

Zygodlo, Amanda

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**Sent:** Monday, 4 June 2012 12:18 PM  
**To:** MLO Corro  
**Subject:** Possible Referral from DoHA - D12008145 [SEC=UNCLASSIFIED]  
**Attachments:** opening a Tif document.doc; D12008145 - [REDACTED]

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Should a response not be received by the requested date, we will take this as approval and consider the item as referred to your portfolio.

Please note that the **hard copy will not be sent** unless requested.

Many thanks

Lorraine Walker  
Parliamentary Referrals Officer  
Ministerial Liaison and Support Section | Ministerial and Parliamentary Support Branch | Department of Health and Ageing  
Ph 02 6289 7985

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4/06/2012

all redactions s47F

ENQUIRIES  
Sent by: Joshua Bee  
15/05/2012 11:59 AM

To MinCorro/Health@Health\_gov\_au  
cc  
bcc  
Subject Fw: New feedback received for OtherEnquiry [REDACTED]  
[SEC=UNCLASSIFIED]

UNCLASSIFIED

Dear MinCorro,

Please see email below from [REDACTED]. If you could please respond directly to the email address provided it would be much appreciated.

Kind Regards,

Enquiries  
Australian Government Department of Health and Ageing

\*\*\*please bcc enquiries into your final response\*\*\*

----- Forwarded by Joshua Bee/BG/Health on 15/05/2012 11:58 AM -----



WCMPRD01/S  
VR/Health  
15/05/2012  
11:24 AM

To enquiries@health.gov.au  
cc  
Subject New feedback received for OtherEnquiry

D12008145  
19/06/12

FEEDBACKTYPE: OtherEnquiry

NAMECONTACT: [REDACTED]

ENQUIRY: I am concerned about the abuse of patent law in relation to Gene and DNA discovery and wonder whether the Minister supports the introduction of legislation to address the issue of corporate holding of what is essentially our body's biology.

Excel formatted data (copy and paste this text into Column A, on a new row, in Excel)

\*\*\*\*\*  
OtherEnquiry [REDACTED] am concerned about the abuse of patent law in relation to Gene and DNA discovery and wonder whether the Minister supports the introduction of legislation to address the issue of corporate holding of what is essentially our body's biology..

UNCLASSIFIED

Parliamentary Secretary for  
Industry and Innovation

Division: *IP Australia* DLO: *AW*

Subject:

RECEIVED 05 JUN 2012

<input type="checkbox"/> Covering Brief	<input type="checkbox"/> Departmental Reply
<input type="checkbox"/> VIP Reply	<input type="checkbox"/> Appropriate Action
<input type="checkbox"/> Acknowledgement	<input type="checkbox"/> For Information (NFA)
<input checked="" type="checkbox"/> Parl Sec Reply	<input type="checkbox"/> Campaign
<input type="checkbox"/> CoS/Adviser	<input type="checkbox"/> Refer to:.....

To be released after review opportunities exhausted - third party objection s47F, s47G

To be released after review opportunities exhausted - third party objection s47F, s47G

To be released after review opportunities exhausted - third party objection s47F, s47G

To be released after review opportunities exhausted - third party objection s47F, s47G

To be released after review opportunities exhausted - third party objection s47F, s47G

Parliamentary Secretary Dreyfus for Information

Brief No: B12/1728

cc: Minister Combet  
Minister Evans

Agency: IP Australia

**PROGRESS OF THE US AND AUSTRALIAN MYRIAD COURT CASES**

Timing: Routine

Recommendation/s:	Noted
1. That you note information on the progress of the US and Australian Myriad court cases.	Yes / No
Parliamentary Secretary's signature:	Date: / /

**Key Points:**

- You requested additional information on both the US and Australian Myriad Court cases, in response to **B12/1051** regarding potential implications for gene patents in Australia in light of *Mayo Collaborative Services v Prometheus Laboratories, Inc.* (Mayo case).
- On 27 March 2012 the Supreme Court of the United States remitted the *Association for Molecular Pathology v Myriad Genetics* (US Myriad case) to the Court of Appeal for the Federal Circuit (CAFC) for further consideration in the light of the Mayo case (**B12/1051 refers**). CAFC's remand decision is yet to issue. The case relates to the patentability of isolated gene sequences and methods of using these sequences to detect certain cancers, including breast cancer.
- The CAFC had previously ruled that isolated gene sequences, and methods of identifying potential cancer therapeutic agents using these sequences, were eligible for patent protection. Isolated gene sequences were determined to be patentable because the isolation of the DNA from the chromosome involves breaking chemical bonds; creating a new and distinct molecule with a markedly different chemical nature to the parent chromosome. Claims to methods of identifying potential cancer therapeutics were found patentable because they included the transformative step of manipulating and growing cells.
- However, the CAFC ruled that claims to methods of comparison using the isolated gene sequences were not patentable. The court determined that comparing the information in two DNA sequences to identify similarities and differences was nothing more than an abstract mental process.
- The Mayo decision places a considerable emphasis on the fact that the body's response to a drug is just a "law of nature" and is therefore not patent eligible. If this leads to the CAFC (or the Supreme Court on further appeal) categorising a gene sequence in vitro as the embodiment of a law of nature, the question will be whether isolation of the gene sequence constitutes a sufficient addition to be a patent eligible "application" of the law of nature. If not, the claims to the isolated gene sequence may be struck down.

- Mayo seems to me to embody a clear disposition in the Supreme Court against the increasingly liberal approach to patent eligibility which has been pursued by CAFC in recent years. It is on that basis that I expressed the view in B12/1051 that it “seems very possible” that the case will result in isolated gene patents not being patentable in the US. Of course, we cannot be certain of that at this stage.
- On 20-24 February 2012, Nicholas J in the Federal Court of Australia heard *Cancer Voices Australia v Myriad Genetics Inc* (AU Myriad case), relating to the equivalent of the Myriad US patents. IP Australia is monitoring the case and we hope to have 24 hours notice of the decision.

**Background:** See **Attachment A**.

**Key Issues / Sensitivities:**

- If isolated genes are excluded from patentability this could lead to uncertainty about how any rule articulated by the court would be interpreted with respect to other biological materials. This could impact negatively on investment in biotechnology and other industries.

Philip Noonan  
Director General  
IP Australia  
(02) 6283 2000 /  
13 June 2012

Contact Officer:  
Frances Roden  
(02) 6283 2151

s47F

**Consultation:** Nil

**Attachments:**

Attachment A      Additional information

## Chronological discussion of the US and AU Myriad patents

### The original challenge to the US Myriad patents – US District Court

The US Myriad case was first heard in the United States District Court Southern District of New York before Justice Sweet. The decision issued on 29 March 2010. The case related to 15 claims across seven patents held jointly by Myriad Genetics and the University of Utah Research Foundation. The coalition of plaintiffs in the case was represented by the American Civil Liberties Union Foundation (ACLU).

The claims-in-suit were of two types:

1. product claims relating to isolated human Breast Cancer Susceptibility Genes 1 and 2 (BRCA genes); and
2. method claims relating to methods for comparing or analysing the BRCA genes to identify the presence of mutations correlating to a predisposition to breast or ovarian cancer and for identifying potential cancer therapeutics.

The key question posed in the case was “*Are isolated human genes and the comparison of their sequences patentable?*”

Under the US Patent Act, “*whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore*” (35 U.S.C. 101). The Supreme Court has consistently construed this broadly, but with three judicially created exceptions: laws of nature, physical phenomena, and abstract ideas. This draws a distinction between products of nature, which are not patentable subject matter, and material that is the result of human intervention, which is.

US patent office practice has, and continues to be, to treat genes no differently from any other chemical compound and to consider that isolation of the gene from the larger chemical entity (the chromosome) within which it normally exists in the body is sufficient to render the gene the product of human intervention. Thus an isolated gene is patent eligible subject matter. If the isolated gene meets all other substantive requirements for patentability, including that it has a practical use, is novel and is inventive, it can be the subject of a patent.

Opponents of patenting argue, however, that isolation alters neither the fundamental quality of the gene as it exists in the body or the information that it encodes, despite the fact that it may include cleavage of the gene from the chromosomal material with which it is normally associated.

Justice Sweet was sympathetic to this view. He considered DNA, such as chromosomal DNA, as comprised of multiple functional units of information, genes and functional parts of genes. He held that purification of a distinct functional unit, although altering the chemical structure of the DNA, did not alter the nature of the information provided in the functional unit or result in a product that had markedly different characteristics to the DNA as it exists in nature.

He consequently held that claims to isolated genes were not patentable. He also held that the method claims were not patentable, being nothing more than the application of mental steps to a law of nature.

## **Appeal of the District Court decision on the Myriad case to the Court of Appeal for the Federal Circuit (CAFC)**

Myriad and the University of Utah appealed the District Court decision to the CAFC. The case was decided on 29 July 2011, with the majority finding (two judges to one) in favour of the appellants with respect to the isolated gene sequences, but not the methods.

The CAFC concluded that the markedly different chemical nature of the isolated BRCA genes claimed in the Myriad patents could not be ignored when considering whether they were patentable subject matter. Isolation of DNA from the chromosome involves severing chemical bonds; creating a new and distinct molecule with a markedly different chemical nature to the parent chromosome.

The CAFC found, however, that the claims to methods of comparison and analysis did not define patent eligible subject matter because they claimed nothing more than the abstract mental processes of comparing information. Such claims do not pass the ‘machine-or-transformation test’, which requires a physical process or transformative step to distinguish the method from a purely abstract thought process. In contrast, the claims to methods of identifying potential cancer therapeutics were patentable because they included the transformative step of manipulating and growing cells, which necessarily involve physical manipulation and transformation of cells.

Both the ACLU, and Myriad and the University of Utah sought to appeal the decision to the US Supreme Court.

## **Hearing of the *Mayo Collaborative Services v Prometheus Laboratories, Inc.* (Mayo case) in the Supreme Court**

On 20 March 2012 the US Supreme Court issued a decision in the Mayo case. The two patents in question claimed methods of optimising treatment of an immune-disorder by administering a drug and then monitoring the body’s levels of a metabolite of the drug. Too much of the metabolite signifies too high a dosage of the drug. Conversely, too little of the metabolite signifies too low a dosage.

The Supreme Court considered the body’s natural response in metabolising the drug to be a ‘law of nature’. Although the drug is administered through human action, the process of metabolising the drug is a purely natural process, or ability, that exists independent of any human intervention.

The Court held that such a process would only be patentable if additional features of the method were sufficient to transform the ‘law of nature’ into a patentable method. The test for such further steps was that they must be more than “*well understood, routine or conventional activities already engaged in by the scientific community*” and that “*when viewed as a whole add nothing significant beyond the sum of their parts taken separately*”. The Court held that the methods did not meet this threshold because the steps of administering, monitoring and determining the quantity of the drug were nothing more than routine and conventional activities.

## **The Supreme Court’s remittal of the US Myriad to the CAFC**

Following issue of the Supreme Court’s decision in the Mayo case the Court remitted the US Myriad case back to the CAFC, where a new decision is currently pending.

If the naturally occurring chromosome is considered to be a 'law of nature', the likely question before the CAFC is whether the steps of cleaving and isolating genetic material from the chromosome are sufficient to transform the genetic material from a 'law of nature' to a patentable invention. These steps are generally well understood, routine, conventional activities regularly undertaken by the scientific community. Based on the Mayo case decision, such steps are likely to not be sufficient to confer patentability.

If the CAFC considers that there is no distinction between a method based on a natural phenomenon (as in Mayo) and a product derived from nature (as in Myriad), then it is likely that the CAFC will reverse its original decision and declare the isolated BRCA genes not patentable subject matter.

This would also have implications for other naturally occurring chemical molecules, such as proteins, RNA and other cellular components and DNA fragments, such as those used as probes in diagnostic methods. If the methods of isolating these molecules were routine or well understood, then they would likely not be regarded as patentable subject matter.

Such a decision would be unlikely to impact on claims to synthetic molecules that have no naturally occurring equivalents as these would not be regarded as 'laws of nature'. Examples of such are complementary DNA (cDNA), recombinant DNA and genetically engineered vectors, such as recombinant viruses.

The key aspect of the Mayo case involved a method, while an isolated gene sequence is a product. CAFC may consider that this represents a significant distinction. If so, CAFC may affirm its earlier decision, and this could result in an appeal to the Supreme Court.

### **The Australian Myriad case**

On 20 to 24 February 2012, in Australia, the AU Myriad case was heard before Justice Nicholas in the Federal Court. Judgement was reserved.

The case arose because patient advocacy organisation Cancer Voices Australia has challenged the validity of the Australian patent (Patent 686004) owned by Myriad. The plaintiffs include Cancer Voices and an interested party as a breast cancer survivor, Ms Yvonne D'Arcy.

The Australian patent is equivalent to one of the patents in the US court decisions. However, in contrast to the US cases, the plaintiffs are only seeking revocation of the claims relating to isolated BRCA genes.

The requirement for patentable subject matter, as set out in paragraph 18(1)(b) of the *Patents Act 1990* is that a claimed invention is a "*manner of manufacture within the meaning of section 6 of the Statute of Monopolies*". The 'manner of manufacture' test, as it has been applied by IP Australia in the light of the NRDC<sup>1</sup> case, requires that the gene represents an artificially created state of affairs i.e. it has been isolated, purified or some way changed from its native configuration, and that it has a practical use, e.g. is useful for diagnosing cancer. In Australia, the key test would seem to be whether isolation of the gene sequence creates an artificially created state of affairs.

<sup>1</sup> National Research Development Corporation v Commissioner of Patents (1959) 102 CLR 252

# B12/1728 - Progress of the US and Australian Myriad Cases [SEC=IN-CONFIDENCE] - Notes Memo

**From:** [Andrea.Blazsev@ipaaustralia.gov.au](mailto:Andrea.Blazsev@ipaaustralia.gov.au)  
**To:** mlobriefs@innovation.gov.au, kaye.fisk@innovation.gov.au  
**Cc:** Matthew.Forno@ipaaustralia.gov.au,  
**Sent:** 13-06-2012 10:50:28 AM

MLO

Please find attached B12/1728 - Progress of the US and Australian Myriad Court Cases.  
It has been cleared by Director General Philip Noonan.

Kind Regards,  
Andrea

<Attachment: 12-06-13 B12-1728 IB Progress of the US and Australian Myriad Court Cases.doc>

## Ministerial Support Team

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IP Australia

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Australian Government

Department of Industry, Innovation  
Science, Research and Tertiary Education

**Parliamentary Secretary Dreyfus for Information**

**Brief No:** B12/1728

**cc:** Minister Combet  
Minister Evans

**Agency:** IP Australia

**PROGRESS OF THE US AND AUSTRALIAN MYRIAD COURT CASES**

**Timing:** Routine

Recommendation/s:	Noted
1. That you note information on the progress of the US and Australian Myriad court cases.	<input checked="" type="radio"/> Yes <input type="radio"/> No
<b>Parliamentary Secretary's signature:</b> 	<b>Date:</b> 9/6/12

**Key Points:**

- You requested additional information on both the US and Australian Myriad Court cases, in response to **B12/1051** regarding potential implications for gene patents in Australia in light of *Mayo Collaborative Services v Prometheus Laboratories, Inc.* (Mayo case).
- On 27 March 2012 the Supreme Court of the United States remitted the *Association for Molecular Pathology v Myriad Genetics* (US Myriad case) to the Court of Appeal for the Federal Circuit (CAFC) for further consideration in the light of the Mayo case (**B12/1051 refers**). CAFC's remand decision is yet to issue. The case relates to the patentability of isolated gene sequences and methods of using these sequences to detect certain cancers, including breast cancer.
- The CAFC had previously ruled that isolated gene sequences, and methods of identifying potential cancer therapeutic agents using these sequences, were eligible for patent protection. Isolated gene sequences were determined to be patentable because the isolation of the DNA from the chromosome involves breaking chemical bonds; creating a new and distinct molecule with a markedly different chemical nature to the parent chromosome. Claims to methods of identifying potential cancer therapeutics were found patentable because they included the transformative step of manipulating and growing cells.
- However, the CAFC ruled that claims to methods of comparison using the isolated gene sequences were not patentable. The court determined that comparing the information in two DNA sequences to identify similarities and differences was nothing more than an abstract mental process.
- The Mayo decision places a considerable emphasis on the fact that the body's response to a drug is just a "law of nature" and is therefore not patent eligible. If this leads to the CAFC (or the Supreme Court on further appeal) categorising a gene sequence in vitro as the embodiment of a law of nature, the question will be whether isolation of the gene sequence constitutes a sufficient addition to be a patent eligible "application" of the law of nature. If not, the claims to the isolated gene sequence may be struck down.

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- Mayo seems to me to embody a clear disposition in the Supreme Court against the increasingly liberal approach to patent eligibility which has been pursued by CAFC in recent years. It is on that basis that I expressed the view in B12/1051 that it “seems very possible” that the case will result in isolated gene patents not being patentable in the US. Of course, we cannot be certain of that at this stage.
- On 20-24 February 2012, Nicholas J in the Federal Court of Australia heard *Cancer Voices Australia v Myriad Genetics Inc* (AU Myriad case), relating to the equivalent of the Myriad US patents. IP Australia is monitoring the case and we hope to have 24 hours notice of the decision.

**Background:** See Attachment A.

**Key Issues / Sensitivities:**

- If isolated genes are excluded from patentability this could lead to uncertainty about how any rule articulated by the court would be interpreted with respect to other biological materials. This could impact negatively on investment in biotechnology and other industries.

***Slipstream Version 13 June 2012***

Philip Noonan  
Director General  
IP Australia  
(02) 6283 2000  
13 June 2012

Contact Officer:  
Frances Roden  
(02) 6283 2151

s47F

**Consultation:** Nil

**Attachments:**

Attachment A      Additional information

## Chronological discussion of the US and AU Myriad patents

### The original challenge to the US Myriad patents – US District Court

The US Myriad case was first heard in the United States District Court Southern District of New York before Justice Sweet. The decision issued on 29 March 2010. The case related to 15 claims across seven patents held jointly by Myriad Genetics and the University of Utah Research Foundation. The coalition of plaintiffs in the case was represented by the American Civil Liberties Union Foundation (ACLU).

The claims-in-suit were of two types:

1. product claims relating to isolated human Breast Cancer Susceptibility Genes 1 and 2 (BRCA genes); and
2. method claims relating to methods for comparing or analysing the BRCA genes to identify the presence of mutations correlating to a predisposition to breast or ovarian cancer and for identifying potential cancer therapeutics.

The key question posed in the case was “*Are isolated human genes and the comparison of their sequences patentable?*”

Under the US Patent Act, “*whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore*” (35 U.S.C. 101). The Supreme Court has consistently construed this broadly, but with three judicially created exceptions: laws of nature, physical phenomena, and abstract ideas. This draws a distinction between products of nature, which are not patentable subject matter, and material that is the result of human intervention, which is.

US patent office practice has, and continues to be, to treat genes no differently from any other chemical compound and to consider that isolation of the gene from the larger chemical entity (the chromosome) within which it normally exists in the body is sufficient to render the gene the product of human intervention. Thus an isolated gene is patent eligible subject matter. If the isolated gene meets all other substantive requirements for patentability, including that it has a practical use, is novel and is inventive, it can be the subject of a patent.

Opponents of patenting argue, however, that isolation alters neither the fundamental quality of the gene as it exists in the body or the information that it encodes, despite the fact that it may include cleavage of the gene from the chromosomal material with which it is normally associated.

Justice Sweet was sympathetic to this view. He considered DNA, such as chromosomal DNA, as comprised of multiple functional units of information, genes and functional parts of genes. He held that purification of a distinct functional unit, although altering the chemical structure of the DNA, did not alter the nature of the information provided in the functional unit or result in a product that had markedly different characteristics to the DNA as it exists in nature.

He consequently held that claims to isolated genes were not patentable. He also held that the method claims were not patentable, being nothing more than the application of mental steps to a law of nature.

## **Appeal of the District Court decision on the Myriad case to the Court of Appeal for the Federal Circuit (CAFC)**

Myriad and the University of Utah appealed the District Court decision to the CAFC. The case was decided on 29 July 2011, with the majority finding (two judges to one) in favour of the appellants with respect to the isolated gene sequences, but not the methods.

The CAFC concluded that the markedly different chemical nature of the isolated BRCA genes claimed in the Myriad patents could not be ignored when considering whether they were patentable subject matter. Isolation of DNA from the chromosome involves severing chemical bonds; creating a new and distinct molecule with a markedly different chemical nature to the parent chromosome.

The CAFC found, however, that the claims to methods of comparison and analysis did not define patent eligible subject matter because they claimed nothing more than the abstract mental processes of comparing information. Such claims do not pass the 'machine-or-transformation test', which requires a physical process or transformative step to distinguish the method from a purely abstract thought process. In contrast, the claims to methods of identifying potential cancer therapeutics were patentable because they included the transformative step of manipulating and growing cells, which necessarily involve physical manipulation and transformation of cells.

Both the ACLU, and Myriad and the University of Utah sought to appeal the decision to the US Supreme Court.

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This would also have implications for other naturally occurring chemical molecules, such as proteins, RNA and other cellular components and DNA fragments, such as those used as probes in diagnostic methods. If the methods of isolating these molecules were routine or well understood, then they would likely not be regarded as patentable subject matter.

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<sup>1</sup> National Research Development Corporation v Commissioner of Patents (1959) 102 CLR 252



Australian Government  
Department of Industry, Innovation, Science,  
Research and Tertiary Education

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BRIEF

1. Please provide further information on the progress of the US *Mayo* case, including the rationale the suggestion below that is "very possible" that the C will find that genes are not patentable

Brief No: B12/1051

Division/Agency: IP Australia

Parliamentary Secretary: Information  
cc: Minister Combet  
Minister Evans

POTENTIAL IMPLICATIONS FOR GENE PATENTS IN AUSTRALIA OF THE  
UNITED STATES SUPREME COURT PATENT DECISION MAYO  
COLLABORATIVE SERVICES V PROMETHEUS LABORATORIES, INC.

2. Please provide further information on the Australian case.

Timing: 27 April 2012

Recommendation/s:

1. That you note possible implications arising from the United States Supreme Court decision in *Mayo Collaborative Services v Prometheus Laboratories, Inc.* for the patenting of genes and the biotechnology sector in Australia.

Approved/Noted

(Yes) No

Parliamentary Secretary's signature

Date: 22/5/12

Key Points

- On 20 March 2012 the Supreme Court of the United States issued a decision in *Mayo Collaborative Services v Prometheus Laboratories, Inc.* (*Mayo* case). The decision was that two patents relating to optimising the dosage of a drug for treatment of autoimmune diseases were invalid. The patents sought to use information about the body's reaction to a certain drug to indicate whether the dosage of a drug should be increased or decreased, in accordance with the current concentration of the drug in the bloodstream. The Supreme Court held that information about the body's reaction to the drug was a "law of nature" and therefore not eligible to be patented under US law. The additional information about dosage alterations was insufficient to allow the overall patent to constitute an "application of a law of nature", which would be eligible to be patented.
- This case has potential implications for the treatment in the US of patents relating to isolated gene sequences. The court may take the view that the gene sequence is a law of nature and that isolating the sequence is insufficient to make the isolated gene sequence eligible for a patent.
- To date, the position in the US on gene patents has been unclear. The *Association for Molecular Pathology v Myriad Genetics* case (US *Myriad* case) has been heard in two lower courts, the decisions on which have been divided. On 27 March 2012, the US Supreme Court remitted the US *Myriad* case to the Court of Appeal for the Federal Circuit for further consideration 'in light of the *Mayo* decision'.
- It seems very possible that the Federal Circuit's decision on the US *Myriad* case will result in isolated gene patents not being patentable in the US.
- While this decision would not be binding in Australia, Australian courts may well take guidance from the decision in applying Australia's test for patent eligibility, which is not quite the same as the US test, but which often leads to similar results. This may be

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File C2012/12966 FOI 412  
**Ministerial Coversheet**

<b>Date Due in MLO:</b>	13/06/2012	<b>Ministerial Item:</b>	B12/1728
<b>Action Division:</b>	IP Aust	<b>Current Division:</b>	IP Aust
<b>Action:</b>	Information - Request MO	<b>Minister Office:</b>	Dreyfus
<b>Signatories:</b>	DREYFUS QC MP, MARK		
<b>Subject:</b>	Gene Patents - The Australian and US 'Myriad' cases		

<b>Ministerial Type:</b>	Brief	<b>Attachments:</b>	N
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<b>Critical Date:</b>		<b>Talking Points:</b>	N
<b>Critical Date Reason:</b>		<b>Sensitivities Involved:</b>	N

**Summary:**

**Instructions:**

**Officer:** Wright, Adam  
**Date:** 30 May 2012 10:56  
**Text:** Matters to be addressed in Brief. Further information on these cases as requested by the Parl Sec (see annotated B12/1051). Suggested Action Officer: Baxter, Julie Requesting Adviser: Round, Jim (Dreyfus)

**Officer:**

## Gene patents and IP reform

### Issue

Addressing concerns over gene patents and reforming the IP system.

### Headline Statement

- Reforming the IP system to address concerns over gene patents, while ensuring there is sufficient incentive to develop new medicines and tests.

### Key Points

- The patentability of isolated gene sequences is the subject of legal action in the Federal Court of Australia. Cancer Voices Australia, as a consumer organisation representing Australians affected by cancer, instigated legal action against Myriad Genetics Inc in respect of the validity of Myriad's patent claims relating to breast cancer gene sequences. As the matter is currently before the courts I am unable to comment further.
- The *Intellectual Property Laws Amendment (Raising the Bar) Act 2012* (the 'Raising the Bar Act') received Royal Assent on 15 April 2012. The Act implements key IP reforms. It does not ban gene patents. Instead the Act includes technology-neutral measures to raise patent thresholds, increase certainty in the validity of granted patents and introduce a statutory exemption from patent infringement for research activities.
- Most of the changes in the Act commence on 15 April 2013. An exception is the research exemption, which commenced immediately after Assent on 16 April 2012. This gives researchers certainty about where they have freedom to operate as soon as possible.
- The issue of gene patents has been investigated by the Australian Law Reform Commission (ALRC) (2004), the Advisory Council on Intellectual Property (ACIP) (2010), and the Senate Community Affairs References Committee (2010). None of these reports recommended a ban on the patenting of isolated gene sequences.
- The Government has accepted the majority of the recommendations of the Senate, ACIP and ALRC reports, including reviewing the existing compulsory licensing safeguards and rewording the legislative test for subject matter that is eligible for patent protection.

## Background

### Media interest

Articles in *The Age* (*Genetic inheritance belongs to all humanity* 22 Feb 2012) and letters to the editor from the Sydney Morning Herald (*Drug companies need to have an incentive* 22 February 2012) represent the polarising nature of this debate. Public concerns centre around intergenerational access to diagnostic testing and treatment.

Public concerns about gene technology and the patenting of isolated gene sequences, and the potential impacts on health access and costs, have been periodically raised over the last fifteen years. The debate centres on whether Australia should allow the patenting of isolated gene sequences, particularly in the context of private ownership and control of inventions that have human health implications.

The current patent law allows medical and other industrial inventions derived from nature to be patented. This is a long standing aspect of the Australian law, which has enabled the development and access to important drugs, diagnostics and medical treatments, and other industrial products and processes. The law in Australia on this issue is consistent with that of our major trading partners.

### Current court cases

The patentability of isolated gene sequences is the subject of court action in Australia, in a current case heard by the NSW Federal Court before Justice Nicholas on 20-24 February 2012. Cancer Voices Australia (CVA) is a consumer organisation representing Australians affected by cancer. CVA and others are challenging Myriad Genetics Inc in respect of the validity of Myriad's patents relating to breast cancer antigen (BRCA1 and BRCA2) gene sequences.

CVA is challenging Myriad's patent for lack of patent eligible subject matter (manner of manufacture) within the meaning of s18(1)(a) *Patents Act 1990* (Cth). CVA argues that the gene sequence mutations are the product of nature and their isolation is a discovery of a naturally occurring phenomenon, rather than a patentable invention. In the alternative CVA asserts these are claims for biological processes for the generation of human beings and therefore not a patentable invention.

The BRCA patents have also been the subject of legal proceedings in the United States. The *Association for Molecular Pathology v Myriad Genetics* case (US *Myriad* case) has been heard in two lower courts, the decisions on which have been divided. On 27 March 2012, the US Supreme Court remitted the US *Myriad* case to the Court of Appeal for the Federal Circuit for further consideration.

### Government response to the gene patent reports and IP reforms

On 11 November 2008, the Senate referred matters relating to the impact of gene patents on the provision of healthcare in Australia to the Community Affairs Committee. The Senate Report was tabled on 26 November 2010 and contained 16 recommendations. On

23 November 2011, the Government provided a combined response addressing the Senate Report, the Australian Law Reform Commission's 2004 report- *Genes and Ingenuity: Gene Patenting and Human Health*, and the Advisory Council on Intellectual Property's report on patentable subject matter. The key recommendations agreed to by the Government are:

- a review of the existing compulsory licensing safeguards to address concerns that gene patents may hinder public access to patented diagnostic tests and treatments;
- in principle agreement to reword, using contemporary language, the legislative test for subject matter that is eligible for patent protection, subject to public consultation on the draft legislative provisions; and
- to introduce a research exemption from patent infringement and raise patent standards. The research exemption will ensure researchers have the freedom to conduct research in patented technologies, including genes.

On 3 April 2012, the Assistant Treasurer approved the Productivity Commission to undertake a review of the compulsory licensing provisions in the *Patents Act 1990*. Draft terms of Reference (ToR) have been developed in consultation with other relevant departments and agencies. Pending approval of the ToR by the Parliamentary Secretary for Industry and Innovation, the Assistant Treasurer and the Prime Minister, it is anticipated the review will commence in mid-2012 and take nine months to complete.

The research exemption and amendments to raise patent standards will be implemented by the Raising the Bar Act, which received Royal Assent on 15 April 2012. Most of the changes in the Act will commence on 15 April 2013, 12 months after Assent. An exception is the research exemption, which commenced on 16 April 2012. This gives researchers certainty about where they have freedom to operate as soon as possible.

#### Private Member's Bills

On 24 November 2010, Senators Heffernan, Coonan, Xenophon and Siewert introduced the *Patent Amendment (Human Genes & Biological Materials) Bill 2010* into the Senate (with a corresponding Bill introduced into the House of Representatives on 21 February 2011). The Private Member's Bill is broad ranging in effect and would amend the *Patents Act 1990* to prevent patents being granted over biological materials which are identical or substantially identical to that existing in nature. It would have significant impact on the biotechnology, pharmaceutical, veterinary, agricultural and other industrial chemical sectors, as innovations in these areas would not be able to be protected, discouraging investment and research.

The Senate referred the Bill to the Senate Legal and Constitutional Affairs Committee for inquiry and report. On 21 September 2011, the Committee released its report recommending that the Bill not be passed.

On 13 March 2012, Ms Melissa Parkes MP wrote to a number of Ministers seeking support for a Private Members Bill, the *Patents Amendment (Genetic Materials) Bill 2012*. This Bill is similar to the previous Private Member's Bills.

## GENE PATENTS AND IP REFORM

### Issue

Addressing concerns over gene patents and reforming the IP system.

### Headline Statement

- Reforming the IP system to address concerns over gene patents, while ensuring there is sufficient incentive to develop new medicines and tests.

### Key Points

- The patentability of isolated gene sequences is the subject of legal action in the Federal Court of Australia, *Cancer Voices Australia v Myriad Genetics Inc.* As the matter is currently before the courts I am unable to comment further.
- The *Intellectual Property Laws Amendment (Raising the Bar) Act 2012* (the 'Raising the Bar Act') received Royal Assent on 15 April 2012. The Act implements key IP reforms. It does not ban gene patents. Instead the Act includes technology-neutral measures to raise patent thresholds, increase certainty in the validity of granted patents and introduce a statutory exemption from patent infringement for research activities.
- Most of the changes in the Act commence on 15 April 2013. An exception is the research exemption, which commenced immediately after Assent on 16 April 2012. This exemption allows researchers to conduct experiments even when the subject of the research has been patented.
- There has been a suggestion that another private member's Bill seeking the banning of gene patents may be introduced. The issue of gene patents has been investigated by the Australian Law Reform Commission (ALRC) (2004), the Advisory Council on Intellectual Property (ACIP) (2010), and the Senate Community Affairs References Committee (2010). None of these reports recommended a ban on the patenting of isolated gene sequences.
- The Government has accepted the majority of the recommendations of the Senate, ACIP and ALRC reports, including reviewing the existing compulsory licensing safeguards and rewording the legislative test for subject matter that is eligible for patent protection.

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The research exemption and amendments to raise patent standards will be implemented by the Raising the Bar Act, which received Royal Assent on 15 April 2012. Most of the changes in the Act will commence on 15 April 2013, 12 months after Assent. An exception is the research exemption, which commenced on 16 April 2012. This gives researchers certainty about where they have freedom to operate as soon as possible.

#### Private Member's Bills

On 24 November 2010, Senators Heffernan, Coonan, Xenophon and Siewert introduced the *Patent Amendment (Human Genes & Biological Materials) Bill 2010* into the Senate (with a corresponding Bill introduced into the House of Representatives on 21 February 2011). The Private Member's Bill is broad ranging in effect and would amend the *Patents Act 1990* to prevent patents being granted over biological materials which are identical or substantially identical to that existing in nature. It would have significant impact on the biotechnology, pharmaceutical, veterinary, agricultural and other industrial chemical sectors, as innovations in these areas would not be able to be protected, discouraging investment and research.

The Senate referred the Bill to the Senate Legal and Constitutional Affairs Committee for inquiry and report. On 21 September 2011, the Committee released its report recommending that the Bill not be passed.

On 13 March 2012, Ms Melissa Parkes MP wrote to a number of Ministers seeking support for a Private Members Bill, the *Patents Amendment (Genetic Materials) Bill 2012*. This Bill is similar to the previous Private Member's Bills.

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C12/ 2685



Thank you for your email of 6 July 2012 to the Prime Minister, the Hon Julia Gillard MP, concerning gene patents. Your correspondence has been forwarded to me for reply as I have responsibility for this matter.

In your email, you referred to a private member's bill from Ms Melissa Parke MP. There has been some publicity about a prospective bill, but until Ms Parke tables draft legislation in Parliament I will be unable to comment on specific details. Nevertheless, I am mindful of the debate in Australia about patents for genetic material, and I hope to reassure you about the issues you have raised.

Concerns about gene patents have been investigated by the Australian Law Reform Commission (2004); the Advisory Council on Intellectual Property (2010); the Senate Community Affairs References Committee (2010); and the Senate Legal and Constitutional Affairs Committee (2011). In our response, the Australian Government accepted the majority of those reports' recommendations, including that there be no ban on gene patents at this time. The recommendation was made based on a lack of evidence that systemic problems are caused by gene patents, and in recognition of the important role that patent protection plays in securing the investment funding necessary to bring new medical and biological technologies to market.

Research, development and commercialisation, particularly in cutting edge technology areas such as biotechnology, are often tremendously expensive and financially risky. Without an incentive such as the patent system, many innovations would not be translated into new technologies that benefit Australian society.

Among the recommendations accepted by Government was to review compulsory licensing to ensure Australians have reasonable and affordable access to vital new technologies and treatments. The Government has now commissioned the Productivity Commission to review the compulsory licensing provisions in the *Patents Act 1990*, with specific regard to concerns that gene patents may hinder access to patented diagnostic tests and therapeutic treatments.

You also raised concerns that genes are inherently unpatentable, being discoveries not inventions. At present most countries, including Australia and its major trading partners, regard isolated gene sequences as patent eligible subject matter. The basic requirements for patent eligibility are that an invention represents an artificial state of affairs with a practical

use. To actually qualify for a patent, other patentability criteria such as novelty and inventive step need to also be satisfied.

Thank you for bringing your concerns to the Government's attention.

Yours sincerely

**MARK DREYFUS QC MP**



**Cabinet Secretary**  
**Parliamentary Secretary for Climate Change and Energy Efficiency**  
**Parliamentary Secretary for Industry and Innovation**

s47F

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use. To actually qualify for a patent, other patentability criteria such as novelty and inventive step need to also be satisfied.

Thank you for bringing your concerns to the Government's attention.

Yours sincerely

A handwritten signature in black ink, appearing to read "Mark Dreyfus". The signature is fluid and cursive, with a large initial "M" and "D".

**MARK DREYFUS QC MP**

7/8/12

File C2012/12966 FOI 423  
**Ministerial Coversheet**

<b>Date Due in MLO:</b>	26/07/2012	<b>Ministerial Item:</b>	C12/2685
<b>Action Division:</b>	IP Aust	<b>Current Division:</b>	IP Aust
<b>Action:</b>	Reply by Parliamentary Sec	<b>Minister Office:</b>	Dreyfus
<b>Signatories:</b>	DREYFUS QC MP, MARK		
<b>Subject:</b>	Gene patent Private Members Bill		

<b>Ministerial Type:</b>	Correspondence	<b>Attachments:</b>	Y (1)
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<b>Corro Date:</b>	6/07/2012	<b>Interim Reply:</b>	N
<b>MO Received Date:</b>	10/07/2012	<b>MP Rep Constituent:</b>	N
<b>Complexity:</b>	NON-COMPLEX		
<b>Campaign:</b>			

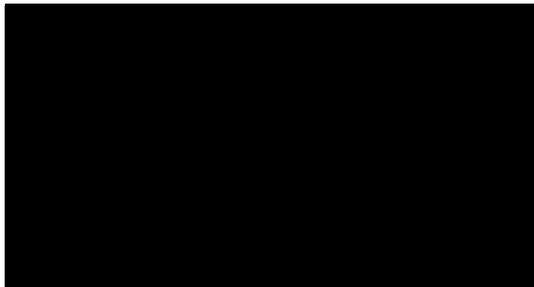
**Instructions:**

all redactions s47F

**Zygodlo, Amanda****From:** stephen.madden@pmc.gov.au**Sent:** Friday, 6 July 2012 7:16 PM**To:** MLO Corro**Subject:** Ministerial Correspondence Referral from PM&C. C12/45860 [SEC=UNCLASSIFIED:NO CAVEATS]

The below correspondence addressed to the PM was received by PM&C and has been referred for your Minister's consideration. Thank you.

Reader: Madden, Stephen  
Date of letter: 06 Jul 12 11:37:58  
PMC ID: C12/45860



<b>Parliamentary Secretary for Industry and Innovation</b>	
Division: <i>PAustralia</i>	DLO: <i>AW</i>
Subject: .	
RECEIVED 10 JUL 2012	
<input type="checkbox"/> Covering Brief	<input type="checkbox"/> Departmental Reply
<input type="checkbox"/> VIP Reply	<input type="checkbox"/> Appropriate Action
<input type="checkbox"/> Acknowledgement	<input type="checkbox"/> For Information (NFA)
<input checked="" type="checkbox"/> Parl Sec Reply	<input type="checkbox"/> Campaign
<input type="checkbox"/> CoS/Adviser	<input type="checkbox"/> Refer to.....

Gene Patent Private Members Bill

Subject - Gene Patent Private Members Bill Message - Dear Prime Minister,

I am writing to express my support for the private members bill banning the patenting of the human genome that Melissa Parke is planning to introduce into parliament later this year.

I believe this is an urgent matter of public interest. The human (or any naturally occurring life's) gene code is not information that should be exclusively in the hands of private corporations. I find the very concept of patenting human genes absurd, even offensive. The gene code is not an invention but a discovery. It is like patenting the street layout of Canberra, anyone is free to create a map based on the publicly available data.

The gene code belongs to all of us and should remain public property. By all means, protect IP based on that code, but not the code itself.

I trust that both sides of parliament will stand strong against blatant and unjustified commercial interest in this matter and act in the public interest.

Yours sincerely,




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**IMPORTANT:** This message, and any attachments to it, contains information that is confidential and may also be the subject of legal professional or other privilege. If you are not the intended recipient of this message, you must not review, copy, disseminate or disclose its contents to any other party or take action in reliance of any material contained within it. If you have received this message in error, please notify the sender immediately by return email informing them of the mistake and delete all copies of the message from your computer system.

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9/07/2012

Minister Combet for Information

Brief No: B12/2458

cc: Parliamentary Secretary Dreyfus  
Minister Evans

Division: Innovation

**Further Update on gene patents debate**

Timing: Routine

<b>Recommendation:</b>	<b>Noted</b>
1. That you note the information provided	Yes / No
<b>Minister's signature:</b>	<b>Date:</b> / /

**Key Points:**

- The gene patent debate centres on whether Australia should allow patenting of isolated gene sequences, particularly in the context of private ownership and control of inventions that have human health implications. driver of the gene patents debate since 2008 has been the ability of patentees to unreasonably restrict or deny access to healthcare.
- The major power of a patentee is to exploit the invention or authorise others to do so. A patent gives the patent owner the exclusive right to commercially exploit the invention for a limited term. This effectively means that they, or those authorised, can allow or refuse the making, use or importation of an invention, often for a fee. Importantly it allows the patentee or assignee to prevent others from making, using or importing an invention or to set conditions on this.
- In 2008 the Australian exclusive licensee of certain gene-based patents used for a diagnostic test for some breast cancers briefly sought to enforce their licence rights, many years after they had publicly gifted those rights to the Australian people. Most labs that had been making the test were told to cease and desist the practice. The large potential cost increase for the test could have denied access to healthcare for many Australian women. The fear that that the licensee's testing services might be more expensive fuelled the debate about human gene patents.
- Ms Melissa Parke, MP (Ms Parke) may introduce a private member's Bill, the draft Patents Amendment (Genetic Materials) Bill 2012 (at Attachment A). While the draft Bill is more detailed than previous similar Bills, it has primarily the same effect - a prospective ban on gene patents.
- The resulting gene patents debate has concerned patent issues including, access to gene-related inventions, the patentability of isolated DNA and the appropriateness of, and the placing of, a 'line' drawn to restrict (or ban) patenting on isolated genetic material to enhance health access without adverse consequences.
- On 9 August a gene patents roundtable co-chaired by Parliamentary Secretary Dreyfus and Minister Plibersek discussed these issues (summary record and list of attendees is at **Attachment AB**).
- No clear legislative option arose from the roundtable and it was apparent that there were strong and diverse views on the patenting of isolated genetic material from participants. There was, however, significant support for the current patentability of isolated genetic material. Some stakeholders did have strong contrary views.

**Background:**

- Your Office has asked for a further brief regarding the 'update gene patents debate' brief (**B12/2336**). This further briefing in a relatively short document is to: summarise gene patent issues, stakeholder views, include analysis of Melissa Parke MP's (Ms Parke's) draft Bill (**Attachment B**) and its possible impact and refer to the gene patents roundtable.

**Key Issues / Sensitivities:**

- Stakeholders primary arguments for a ban or restriction on gene patenting has been that patent monopolies should not be granted for isolated genes as they are discoveries not inventions. Private Member's Bills would ban patents on isolated genes of all biologic materials, for example, bacteria that had been genetically modified for waste treatment or crops modified for drought tolerance, but the debate has focussed on human genes.
- Many stakeholders seeking to ban gene patents have ethical issues with gene patenting – that humans should not be subject to property rights. Also, many stakeholders claim that method patents would sufficiently protect investment while competition would be increased on the underlying molecule.
- Stakeholders primary argument against a ban on gene patents is that it would prevent investment in the research and development of gene-based medicines (along with jobs that are associated with this) and would breach our international obligations. Also, that method patents are nowhere near as significant for investment as patents on underlying molecules and that there is no evidence of a problem to be addressed.
- The key issue for the Government is the adverse impact on investment and potential adverse impact on health treatment availability if a ban or restriction on gene patenting were to be put in place - yet this has not been a focus of debate or Private Member Bills.
- As a net importer of medicines and diagnostics there is a substantial risk of non-supply, and a dramatic reduction in R&D of medicines, in, and imported to, Australia if a gene patent ban were introduced. A ban could undermine global business models by reducing protection for investment which is undertaken on a global basis.
- Global head offices responsible for decision-making are likely not to examine the detail of a restriction or ban on gene based medicines, and may well act on a perception that Australia's patent system provides weak protection, even if the restrictions are reversed.
- Other issues include the likely impact on collaboration, the availability of health treatments and the impact on climate change. Any reduction in collaboration may not be restricted to gene-based medicines, as global offices may perceive a risk that other changes will be made to Australia's patent system. One page case studies illustrating the impact of the initial Private Member's Bill are at **Attachment C**.
- ~~Ms Parke's may introduce a private member's Bill, the draft Patents Amendment (Genetic Materials) Bill 2012 (at Attachment B). While the draft Bill is more detailed than previous similar Bills, it has primarily the same effect – a prospective ban on gene patents.~~
- The considerable adverse impact of ~~the Melissa Parke's~~ proposed Bill and previous similar Bills (Sen Heffernan's Bill and Mr Dutton's Bill) would primarily be on pharmaceutical and biotechnology sectors, including on industrial biotechnology sectors.
- These are sectors of the future that have high paid, high skilled, high value-added jobs that leverage from the quality research capacity that exists in Australian universities, public research bodies and medical research institutes. The growth potential of these sectors is enormous, and industrial biotechnology in particular can increase the productivity of existing industries. Analysis and history of Private Member's Bills is at **Attachment D**.
- Mechanisms that are already underway to address gene patents issues include: raising patent standards and the introduction of a statutory research exemption as part of the Raising the Bar Act 2012; ~~the introduction of an explicit patent objective where the patent system 'should not lead to patients being denied reasonable access to healthcare'~~; a the Productivity Commission's review of the compulsory licensing provisions, which is effectively a 'pressure valve' to remedy actual, or prevent potential, are a safe-guard to ensure the reasonable requirements of the public are being met-unreasonable conduct of patentees; and, ~~the introduction of a legal requirement that an invention must be useful to a higher standard before it is patentable.~~ economic study of the impact of human gene patents in relation to healthcare and medical research in Australia.
- The Pproductivity Commissions review is underway and future activities that will be informed by the review are awareness raising of the Crown use provisions, codifying

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Comment [C11]: Added this for clarity - necessary?

common law manner of manufacture provisions into s18 *Patents Act*, and introducing objectives into the *Patents Act 1990*.

- The economic study of human gene patents will commence in October 2012, with a planned completion date of early 201~~2~~3.

~~• The first and last mechanisms above may be able to be prioritised to address concerns in the gene patents debate more rapidly, but the processes and regulations underpinning examination of the higher standard of usefulness in patent grant may not be feasible if accelerated.~~

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Peter Chesworth  
General Manager  
Pharma, Health Ind & ET  
02 6213 6058 / [REDACTED]  
September 2012

Contact Officer:  
Peter Lunn  
02 6276 1221

**Consultation:** IP Australia

**Attachments:**

~~Attachment A – Melissa Parke MP's draft Bill (7 March 2012 version)~~

Attachment ~~A-B~~ – Gene Patent round table summary and attendees

~~Attachment B – Melissa Parke MP's draft Bill (7 March 2012 version)~~

Attachment C – Case studies illustrating the impact of Private Member's Bills

Attachment D – Brief history and analysis of Private Member's Bills and Questions regarding a ban on gene patents

**Attachment A**

Melissa Parke MP's draft Bill (7 March 2012 version) separately attached to go here

Attachment B

**Gene Patent round table summary**

The roundtable was convened by the Minister for Health, Minister Plibersek and the Parliamentary Secretary for Industry and Innovation, Mr Dreyfus to canvass views on gene patents. Attendees at the roundtable were selected from across consumer, healthcare and research, industry ~~government~~ and government ~~groups~~ groups. A list of attendees and themes that emerged from discussions ~~are~~ is provided below.

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**Themes:**

The following themes emerged from the roundtable discussions:

- Strong support for the current technology neutral approach in the patent system and recognition of the dangers inherent in legislating against the patenting of specific technologies. Some stakeholders stated that the health system should not dictate patenting generally;

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- Some stakeholders strongly supported the current ability to patent genes. However some stakeholders were particularly concerned regarding access to patented genetic material for the development of multi-gene technologies and sought further safeguards against restrictive practices by patentees;
- Recognition that, and support for the, amendments in the *Intellectual Property Laws Amendment (Raising the Bar) Act 2012* and further changes agreed to by the Government in its response to the Senate Community Affairs Committee's Gene Patents report. It was viewed that these will go some way to addressing issues raised in the gene patents debate;
- Agreement that further work needs to be done to develop objective measures for assessing the social and economic costs of the patent system;
- Conflicting views on whether genes should be considered discoveries or inventions;
- Recognition of the importance of patents to investment in gene-related technologies and of the possibility that gene patent numbers will reduce as more gene sequences are published;
- Recognition of the importance of data generated from genetic testing and concerns regarding access to this data where tests are conducted by commercial entities;
- Safeguards against restrictive licensing practices (or potential practices) emerged as an important area of concern, with strong support for the Productivity Commission's review of compulsory licensing;
- Improving the clarity of the patentable subject matter provisions in the *Patents Act 1990* was seen as priority;
- There was concern that the significant costs of litigation meant most patents were not independently scrutinised and more should be; and
- Suggestions were made for creation of an oversight body to advise on new technologies or oversight the quality of patents granted by IP Australia.

Further detail below.

***The technology neutral approach of the patent system should be maintained***

- Many attendees considered that technology neutrality is an important feature of the patent system and that this has been central to the system being able to deal with new technologies [REDACTED]
- It was argued that it is very difficult to predict what technologies will emerge in the coming years and prescriptively legislating against technologies runs the risk of blocking future innovation. This is particularly relevant in an environment of accelerating technological change where at the time of patenting it is not clear what will be valuable in the future and what will be routine.
- There was general agreement that, if a ban were to be introduced, it would be very difficult to work out where to draw the line, due to the rapid development of technology.
- [REDACTED] cautioned that decisions made because of concerns about possible, but as yet unrealised problems in the human health area because of the patenting of genes, could have huge implications for agriculture, where genes are frequently used to manipulate plant traits such as yield, nutrition content and disease resistance.

***The changes in Raising the Bar and further legislative changes proposed by Government (the morality exclusion, statement of objectives, clarifying patentable subject matter) will address many of the issues raised in the gene patents debate***

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- A number of attendees considered that the changes in Raising the Bar and the further changes proposed by Government (morality exclusion, statement of objectives, clarifying patentable subject matter) will address many of the issues raised in the gene patents debate [REDACTED].
- [REDACTED] suggested that introducing the utility requirement will take the requirements for patentability to a new level.
- [REDACTED] suggested that the combination of the current system and the changes proposed in Raising the Bar and subsequent amendments will provide a good framework for distinguishing between discovery and invention.

***Further work needs to be done to develop objective measures for assessing the social and economic costs and benefits of the patent system***

- It was generally acknowledged that there is a lack of empirical evidence about the impact of gene patents on access to healthcare and there ~~was~~ ~~was~~ a need to develop objective measures to assess this [REDACTED].

***Conflicting views on the patentability of genes***

- Some attendees argued that isolated genes are inherently unpatentable because they are discoveries rather than inventions [REDACTED].
- [REDACTED] noted that the United States government policy position, as stated in its *amicus curiae* brief in the Myriad BRCA patent proceedings, was that genes are not patentable.
- [REDACTED] argued that uncertainty regarding whether or not genes are patentable should be resolved by legislating against the patenting of genes, rather than waiting for the courts to decide on the matter.
- Other attendees argued that the current system provides a sufficient distinction between discovery and invention [REDACTED].
- [REDACTED] argued that the patenting of all biological materials should be banned because patenting forecloses access to any uses of these materials until the patent expires.

***Patents are important for investment in genetic technologies***

- A number of attendees argued that there would likely be a reduction in the amount of research done, and new products may not be brought to market if genetic material could not be patented [REDACTED].
- [REDACTED] stating that no one would have been prepared to invest in such a risky and expensive technology if not for the patent system [REDACTED].

***Problems with gene patents will reduce as more gene sequences are published***

- [REDACTED] suggested that the inevitable result of increasing publication of gene sequences is reduced numbers of gene patents, as fewer gene sequences meet the requirements for novelty and inventive step.
- He gave the example of the International Cancer Consortium, which is comprised of 20 countries and where everything that is publicly funded must be placed in the public domain once the research has been published.

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- The importance of patents to disclosure of information was raised by a number of attendees, who argued that without patents there is the risk that information is locked up as trade secrets (██████████).

#### *What more needs to be done*

- **Licensing**

- Licensing was seen as a significant area of concern for gene patents, with many attendees arguing that there are insufficient mechanisms to deal with circumstances where access to technology is restricted or where there is abuse of monopolies by patent owners. ██████████ made the point that it should not be necessary to rely on a public relations campaign, as was the case with BRCA [and [Genetic Technologies Limited](#),] patents to stop abusive patenting practices.
- There was some agreement the cost and complexity of seeking multiple licenses when testing panels of genes could be prohibitive and that restrictive licensing of genetic inventions may adversely impact on access to new forms of diagnosis (██████████).
- ██████████ argued that the power that the government has to intervene about licensing is necessary to ensure the balance between risks and benefits of the patent system.
- There was widespread support for reviewing compulsory licensing provisions (and some support for reviewing Crown Use provisions) to ensure that they provide safeguards to ensure public access to technologies on reasonable terms.
- A number of attendees suggested that further consideration should be given to how inventions and IP developed with public funding are to be managed and licensed (██████████).
- However, ██████████ cautioned that industry collaborations often rely on proprietary licensing agreements with industry partners.

- **Manner of manufacture**

- ██████████ suggested that the principle in manner of manufacture that patents should not be granted for things that are generally inconvenient might provide some protection against the patenting of inventions that impacted on public access to healthcare.
- ██████████ suggested the need to increase clarity around the distinction between invention and discovery and around the level of intervention required to qualify for a patent.

- **Oversight body**

- ██████████ raised the need for an independent arbiter to intervene when things aren't working. This would provide an alternative to litigation, which is too expensive and yields uncertain results.
- ██████████ suggested that it would be helpful to have an expert panel or arbiter to assist with new technologies.

#### *Access to data generated from testing*

- A number of attendees stressed the importance of access to data generated from genetic testing. This data is an important source of information concerns linkages between genes and disease and there are significant public benefits to ensuring that researchers have access to this data (██████████).

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- Where testing is conducted by private companies there is no guarantee that this data will be made available to the wider research community. This problem exists independent of patenting.
- [REDACTED] also raised concerns about how information gathered from testing was used and how privacy issues were managed.
- [REDACTED] also raised the question of how IP generated from public data was managed.

Attachment C

**Case studies illustrating the impact of the initial Private Member's Bill**

**1. Restricting biologic patents is likely to impair R&D on climate change**

**Patenting and biotech**

In the future and presently, a significant use of biotechnology will be outside food and pharmaceuticals, in the industrial and agricultural sectors. The research in these areas has the potential to mitigate against climate change, by reducing greenhouse gas emissions, or to help agriculture adapt to changed conditions. However, these biotechnology developments depend on the patentability of biological material, particularly genes.

**Biotechnology can replace petrochemicals as industrial feedstocks**

Oil and gas were originally formed from organic material, mostly of plant origin. In many cases plant material (biomass) can replace petrochemicals as feedstock for manufacture of commodities such as fuels or plastics. This can significantly mitigate climate change, through reduction in industrial greenhouse gas emissions and promoting clean manufacturing practices.

Currently, the most common example of biomass based industries is the production of biofuels from corn or wheat. In the future, other goods such as plastics will be also manufactured from biological feedstocks. Genetic modification technology is central for this research and development.

CSIRO researchers are identifying new enzymes that can convert Australian biomass into biofuels. Importantly, this will enable the production of biofuel from non-food biomass such as wood, leaves or straw. CSIRO is also developing genetically modified oilseed crops that can produce new industrial compounds in their seeds.

**Biotechnology can produce crops for changed climate conditions.**

In the future, the Australian climate will be hotter, and much of the land area will be drier. New, more stress tolerant crops will be needed to ensure adequate food production. Modern biotechnology is applied to agricultural research to speed up traditional plant breeding with molecular markers, and to develop genetically modified varieties.

The Australian Centre for Plant Functional Genomics is using the molecular marker technology to speed up breeding of drought tolerant wheat. In addition, the Centre has recently successfully used genetic modification to improve the salt tolerance of rice.

**Impact of patent restrictions**

Patenting is essential for investments into the biotechnology industry. Biotechnology inventions are expensive to produce, with a high risk of failure and a long time to market.

Restricting patenting can prevent biotechnology from contributing to Australia's climate change responses by discouraging both commercial investments into R&D and the often necessary international collaboration required to secure those investments.

## **2. Restricting patenting impedes collaboration as with the Hendra Vaccine**

### **Patenting and collaboration**

CSIRO is involved in a broad livestock-based collaboration with a US partner. Patenting plays an important part in this collaboration. CSIRO's involvement in this livestock collaboration has provided it with a further collaboration opportunity. That is, to be involved in the development of the Hendra vaccine (which is produced by its US partner) at an early stage.

Although the evaluation of the Hendra vaccine is separate to the broader livestock-based collaborative project, without the existence of similar patenting criteria in Australia to global patenting criteria it is unlikely that the livestock collaboration would have proceeded.

Biological materials isolated from natural sources are a significant source of medicines (47% of human medicines approved between 1981 and 2006 were derived from natural sources). If the Australian patent system has restrictions on gene or biological patents it may not provide protection for the result of collaboration.

This demonstrates the importance of Australia having internationally aligned patent eligibility. Restricting gene patents thereby restricts Australian access to a broad range of projects and developments that can be of benefit to Australia, such as the Hendra vaccine.

### **Hendra vaccine**

Since 1994 a deadly new virus, now known as the Hendra virus, has killed four people in Australia and at least 69 horses<sup>1</sup>. It also threatened to stop the 1994 Melbourne Cup.

Scientists believe fruit bats are the natural 'hosts' of Hendra, meaning the virus is carried by bats but it has little effect on them. The Hendra virus is not highly contagious, but if it is transmitted to horses, other animals and humans it can be lethal.

CSIRO scientists at the Australian Animal Health Laboratory have actively researched the Hendra virus since they first isolated and identified it in 1994. The research was conducted in collaboration with scientists from the Uniformed Services University of the Health Sciences, National Cancer Institute and the National Institutes of Health in the US. In 2009, the research team demonstrated that administering human monoclonal antibodies after exposure to the Nipah virus, which is closely related to Hendra virus, protected animals from serious disease in an infection model.

In May 2011, CSIRO announced that a prototype vaccine for horses successfully prevented infection with the virus. This is important as it could break the cycle of the virus' transmission from flying foxes to horses and then to people, as it prevents both the horse developing the disease as well as passing it on to people.

The rapid development of this vaccine for horses, in less than one year, would not have been possible without a corporate partner's involvement, which would never have occurred without patent protection.

### **Impact of patent restrictions**

Patent restrictions reduce the amount of protection for the outcome of collaboration. This can directly affect collaboration, particularly in areas of international research. However, it can also affect whether further collaboration takes place and whether Australian health issues are addressed. Patent restrictions can affect whether Australia is part of international collaboration and preclude direct Australian health benefits, such as in the case of the Hendra vaccine.

<sup>1</sup> Figure includes infected horses that were euthanised.

### 3. Restricting patenting impedes drug and vaccine development as with Gardasil

#### Patenting and pharmaceutical development

Having internationally aligned patent eligibility criteria is important to investment in R&D, commercialisation and manufacture of drugs and vaccines in Australia. Patents, as a component of a business's value, can be a deciding factor in whether to invest in a particular business, particularly for international investors who have little incentive to examine all the issues in detail.

Biological materials isolated from natural sources are a significant source of medicines (47% of human medicines approved between 1981 and 2006 were derived from natural sources). Current estimates of the full cost of bringing a new medicine to market are around US\$1.2 to \$1.3 billion.<sup>2</sup> Given the high cost of conducting R&D before commercialisation, patents are vital for businesses, particularly start-ups, seeking capital.

#### Gardasil vaccine

Gardasil is a human papillomavirus (HPV) vaccine. Virtually all cases of cervical cancer are caused by HPV.

According to former Australian of the Year (2006) and one of the inventors of the Gardasil vaccine, Professor Ian Frazer, "the papillomavirus vaccines currently in use are based on a material, virus like particles, which might easily be construed to be "substantially identical" to something that exists in nature, defective HPV virions. In consequence, the patents relating to method of manufacture held with me as named inventor would, so far as I can determine, not be grantable under the [Patent Amendment (Human Genes and Biological Materials) Bill 2010]."<sup>3</sup>

Australian-based pharmaceuticals company CSL and Professor Ian Frazer's group at the University of Queensland (UQ) collaborated on developing a vaccine for HPV since 1989. In 1991, they had a breakthrough with recombinant HPV virus-like particles. CSL supported and then licensed a virus-like particle patent application from UQ. In 1995, a licence agreement was signed with global pharmaceuticals company Merck & Co. Merck received worldwide exclusive commercial rights in return for royalties and milestone payments to CSL. CSL retained the exclusive rights to market and sell the vaccine in Australia. The US Food and Drug Administration approved the vaccine in June 2006.

The criteria for patent eligibility are also important for the realisation of the benefits of an invention. For example, in 2011-2012, it was reported that \$107 million in Gardasil intellectual property revenue flowed to CSL under a licensing arrangement.<sup>4</sup>

In addition, Gardasil is an important tool for improving health outcomes. The vaccine has been shown to be highly effective and is used worldwide. Australia has recognised the vaccine's benefits as demonstrated by the Australian Government's funding of a HPV vaccination program since 2007.

<sup>2</sup> IBISWorld Industry Report, *Global Pharmaceuticals and Medicine Manufacturing: C1933-GL*, April 2010, p. 21.

<sup>3</sup> Submission 92 to the Senate Legal and Constitutional Affairs Committee, 28 February 2011.

<sup>4</sup> CSL Limited Full Year Results 2011-2012.

#### **4. The patent system is not a barrier, it is neutral or promotes inventions for greater philanthropy – iron fortified rice & developing country distribution of low cost medicines**

##### **Patenting and philanthropy**

The patent system does not act as a barrier to socially beneficial R&D, nor prevent access to medicines and healthcare. Development of beneficial technologies takes place alongside the patent system and the use of patents often facilitates medicine development for philanthropy.

##### **Not all inventions are patented**

Some inventions are not patented if the investment is not commercially based. According to the World Health Organization (WHO)<sup>5</sup>:

Iron deficiency is the most common and widespread nutritional disorder in the world. ... Iron deficiency affects more people than any other condition, constituting a public health condition of epidemic proportions. ... Overall, it is the most vulnerable, the poorest and the least educated who are disproportionately affected by iron deficiency, and it is they who stand to gain the most by its reduction.

Researchers at the University of Melbourne, University of Adelaide, Flinders University and University of South Australia have collaborated to develop rice with iron concentrations of up to four times more than in current varieties—the highest ever reported. The team has done this by increasing the activity of the gene in rice that develops iron. This breakthrough could have a big impact on reducing iron deficiency in millions of poor people who eat rice daily.<sup>6</sup>

The project has received funding from the Australian Research Council and Harvest Plus, which is partially funded by the Bill and Melinda Gates Foundation. One of the conditions of Harvest Plus' funding is that the project is not patented.<sup>7</sup>

##### **Some patented inventions are used for social good**

The patent system does not prevent access to healthcare in developing countries: the patent system can provide more inventions for greater philanthropy (patents underlie development investment).

Several pharmaceutical companies in Australia have programs and partnerships for the supply of medicines to developing countries. For example, GlaxoSmithKline Australia (GSK) reports that it is a primary vaccine supplier for the GAVI Alliance and the United Nations Children's Fund (UNICEF). GSK supplies approximately 1.1 billion vaccine doses for prevention of serious diseases to nearly 80 per cent of the developing world. On 7 June 2011, *The Australian* reported GSK's offer to supply 125 million doses of its rotavirus vaccine over five years to the GAVI Alliance at about five per cent of its Western price. Many of these technologies are the subject of patents<sup>iv</sup>.

Sanofi Pasteur Australia also supplies vaccines on a tiered pricing basis through organisations such as WHO, the GAVI Alliance, UNICEF and the Red Cross. On 20 May 2011, CSL announced its pledge to supply at least 10 per cent of its pandemic influenza vaccine output to WHO.

On 6 June 2011, the media reported that several large pharmaceutical companies, including Merck & Co, have pledged to reduce prices of vaccines for developing countries.

##### **Patenting on gene-based treatments provides investment certainty if and when it's needed**

Patents on gene-based treatments provide a mechanism for return on investment if and when it is needed. As the examples illustrate, this is not always the case. If unreasonable restrictions on health treatments do occur, compulsory licences can be used to meet the needs of the public by requiring a patent owner to license its rights on reasonable terms and conditions<sup>v</sup>.

<sup>5</sup> <http://www.who.int/nutrition/topics/ida/en/index.html> (accessed 19 September 2011).

<sup>6</sup> <http://www.harvestplus.org/content/root-rice-grain-iron-climbs-top> (accessed 16 September 2011).

<sup>7</sup> <http://www.abc.net.au/rn/breakfast/stories/2011/3318134.htm> (accessed 15 September 2011).

<sup>iv</sup> Merck & Co Human papillomavirus vaccine (HPV) (patent AU 714533) and GSK pneumococcal vaccine (patent US 7115271).

<sup>v</sup> [http://www.austlii.edu.au/au/legis/cth/consol\\_act/pa1990109/s133.html](http://www.austlii.edu.au/au/legis/cth/consol_act/pa1990109/s133.html) (accessed 20 September 2011).

<sup>vi</sup> The Gavi Alliance delivered 801 million doses of Hepatitis B vaccine between 2000-2010 and provides immunization and vaccines for other diseases such as diphtheria, tetanus, pertussis, yellow fever, pneumonia and diarrhoea.

## 5. Banning gene patents is likely to reduce access to new medical treatments

Gene-based technologies are an important and growing area for promising new medical treatments<sup>8</sup>. However, banning gene patents is likely to prevent Australian participation in the development of gene-based and other novel treatments in Australia and subsequent access to these treatments by Australian patients.

If there is uncertainty whether research in, or distribution of, treatments has a reasonable return on investment there is a strong disincentive to including Australia in development or distribution. Access to new technologies can lead to new medicines and cleaner industrial processes, and these can have widespread effects on productivity such as a healthier workforce.

### New cancer treatments

US Researchers have successfully used gene therapy to treat a patient with advanced leukaemia. After chemotherapy had stopped working, doctors removed a billion of his T-cells (blood cells that fight viruses and tumours) and gave them new genes that program the cells to attack his cancer.

These altered cells were re-inserted into the patient's body. This patient subsequently went into full remission and has been for a year so far<sup>ii</sup>. This experimental treatment was published in *The New England Journal of Medicine*<sup>iii</sup> and *Science Translational Medicine*.<sup>iv</sup>

The treatment may have potential to be used against other types of cancers. However, to be considered valid, the results must be repeated in more patients and by other research teams.

Patents granted on such technologies provide certainty to investors that they will be able to obtain a return on their investments in costly and risky technologies.

### New blood pressure research

An Australian researcher has been involved in international genetic research on blood pressure recently published in *Nature*<sup>v</sup>. 'Over one billion people worldwide have hypertension... Even small increments in blood pressure are associated with an increased risk of cardiovascular events. ... Our findings provide new insights into the genetics and biology of blood pressure, and suggest potential novel therapeutic pathways for cardiovascular disease prevention.'<sup>vi</sup>

### Likely restriction of treatment benefits: Australian development and patient access

Without the ability to patent promising treatments such as these, it is likely that there will be a disincentive to invest the millions of dollars needed to fund R&D and clinical trials in Australia or include Australia in global activities of this nature. This may cause such activity to be driven offshore and harm the Australian economy.

Further, it is likely that these treatments will be unavailable to Australian patients if gene patents are banned. If there is uncertainty around full patent protection for the treatment in Australia, Australian use could undermine a global return on investment in the treatment distribution, making Australia too risky to include in the distribution of such treatments.

This could have a devastating effect on the economy and patients who suffer, or will suffer from, serious medical conditions such as those above, Alzheimer's disease<sup>vii</sup>, schizophrenia, bipolar disorder and other genetically linked conditions.<sup>viii</sup> Companies such as Genzyme Australasia have already raised concerns about their ability to develop treatments for rare disorders, such as Lysosomal Storage Disorders, for Australian patients if a gene patents ban is passed.<sup>ix</sup>

<sup>8</sup> [Some predict 'that biology will be the foremost science of the 21st century.'](#) (accessed 20 September 2011).

<sup>ii</sup> [http://www.nytimes.com/2011/09/13/health/13gene.html?\\_r=1&pagewanted=all](http://www.nytimes.com/2011/09/13/health/13gene.html?_r=1&pagewanted=all) (accessed 19 September 2011).

<sup>iii</sup> See <http://www.nejm.org/doi/full/10.1056/NEJMoa1103849> (accessed 19 September 2011).

<sup>iv</sup> See <http://stm.sciencemag.org/content/3/95/95ra73.short> (accessed 19 September 2011).

<sup>v</sup> <http://www.ballarat.edu.au/media-releases/ub-researcher-in-blood-pressure-find> (accessed on 20 September 2011).

<sup>vi</sup> <http://www.nature.com/nature/journal/vaop/ncurrent/full/nature10405.html> (accessed on 20 September 2011).

<sup>vii</sup> Researchers predict that 'End of Alzheimer's curse 'a decade away'', *The Australian*, 19 September 2011, p5.

<sup>viii</sup> Australian research suggests : 'Mental illness [schizophrenia and bipolar disorder] may be in genes', *SMH*, 19 Sept 2011, p3.

<sup>ix</sup> [Submission 114 by Genzyme Australasia to Private Member's Bill](#) (accessed on 20 September 2011).

Attachment D

**Brief history and analysis and of Private Member's Bills**

**History of Private Member's Bills**

A previous private member's Bill, the *Patent Amendment (Human Genes & Biological Materials) Bill 2010* (Sen Heffernan's Bill) was introduced into the Senate on 24 November [2010](#) by Senators Heffernan, Coonan, Xenophon and Siewart.

An identical Bill (Mr Dutton's Bill) was introduced into the House of Representatives on 21 February 2011 by the Hon Peter Dutton MP, the Hon Rob Oakeshott MP, Mr John Forrest MP and the Hon Malcolm Turnbull MP.

[On 13 March 2012, Ms Melissa Parke MP wrote to a number of Ministers seeking support for a Private Members Bill, the Patents Amendment \(Genetic Materials\) Bill 2012. This Bill is more detailed than the previous Bills however it is similar in nature.](#)

**Analysis of Private Member's Bills**

The Sen Heffernan/Mr Dutton Bills were narrower in the subject matter of the exclusion, namely products, while the proposed exclusion in Ms Parke's Bill extends to products and diagnostic methods.

The product exclusion in Ms Parke's Bill could potentially be narrower, being directed to 'genetic' rather than 'biological' products. However, this in itself introduces definitional uncertainties as to what falls within 'genetic' in addition to uncertainty around what constitutes 'markedly different'.

Ms Parke's Bill seeks to exclude an area of technology of itself which may not be compliant with the Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement obligations.

[text re valuable patents on base molecules v much less valuable patents on methods, refer to evidence in submissions on Heffernan Bill]

An issue with all Private Member's Bills is that it is difficult to objectively distinguish an invention and [mere](#) discovery. For instance, a 1959 High Court case stated that 'the distinction between discovery and invention is not precise enough to be other than misleading' (NRDC reference).

Comment [C16]: I think Peter may have made this note.

Patents Act 1990 – Summary of Private Member’s Bills - Proposed amendments to 18(2) and 18(4)

<u>Bill</u>	<u>Proposed amendments</u>	<u>Outcome</u>
<p><u>Patent Amendment (Human Genes and Biological Materials) Bill 2010</u></p> <p><u>Person/s proposing amendments</u></p> <p><u>Senator the Hon Helen Coonan, Senator the Hon Bill Heffernan, Senator Rachel Siewert and Senator Nick Xenophon</u></p>	<p><u>ss. 18(2) - Repeal the subsection, substitute</u></p> <p><u>(2) The following are not patentable inventions:</u></p> <p><u>(a) human beings, and the biological processes for their generation; and</u></p> <p><u>(b) <i>biological materials</i> including their components and derivatives, whether isolated or purified or not and however made, which are identical or substantially identical to such materials as they exist in nature.</u></p> <p><u>After ss. 18(4) - Insert</u></p> <p><u>(5) In this section: <i>biological materials</i> includes DNA, RNA, proteins, cells and fluids.</u></p>	<p><u>In September 2011, the Senate Legal and Constitutional Affairs Committee recommended the Bill not be passed.</u></p>
<p><u>Patent Amendment (Human Genes and Biological Materials) Bill 2010</u></p> <p><u>Person/s proposing amendments</u></p> <p><u>Mr Dutton, Mr Oakeshott, Mr Forrest and Mr Turnbull</u></p>	<p><u>Identical Bill to the above private member’s Bill.</u></p>	<p><u>Not proceeding.</u></p>

<p><u>Patents Amendment (Genetic Materials) Bill 2012</u></p> <p><u>Person proposing amendments – in letter of 13 March 2012 to Minister Combet</u></p> <p><u>Ms Parke</u></p>	<p><u>ss. 18(2) – Repeal the subsection, substitute</u></p> <p><u>(2) The following are not patentable inventions:</u></p> <p><u>(a) human beings, and the biological processes for their generation;</u></p> <p><u>(b) <i>genetic materials that exist in nature, or are the same as or not markedly different from those existing in nature</i>, whether such materials are in situ, isolated or purified;</u></p> <p><u>(c) any <i>method that involves the mere comparison of genetic materials or genetic sequences in the provision of a diagnosis for a human being.</i></u></p> <p><u>(2A) A reference in subsection (2) to genetic materials includes, but is not limited to, DNA or RNA whether in whole or in part or in fragments, however made.</u></p>	<p><u>Bill has not yet been introduced into parliament.</u></p>
<p><u>Note that Ms Parke also proposed amendments in the course of debate: Intellectual Property Laws Amendment (Raising the Bar Bill) 2011</u></p> <p><u>Person/s proposing amendments</u></p> <p><u>Ms Parke</u></p>	<p><u>ss.18(2) - Repeal the subsection, substitute</u></p> <p><u>(2) The following are not patentable inventions:</u></p> <p><u>(a) human beings, and the biological processes for their generation; and</u></p> <p><u>(b) any <i>natural phenomena</i> whether isolated or purified or not and howsoever made.</u></p> <p><u>Schedule 1 (Dictionary) – Insert</u></p> <p><u><i>natural phenomena</i> for the purposes of ss. 18(2) include a composition of matter not markedly different to anything found in nature.</u></p>	<p><u>Issues analogous to Ms Parke’s proposal were considered as part of the Senate Legal and Constitutional Affairs Committee’s deliberations.</u></p>

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**Questions regarding a ban on gene patents**

1. Why unnecessarily risk jobs, new industries, access to future improved health treatments and impair climate change mitigation by a gene patents ban?
2. What evidence is there of a problem of access to gene-based tests or medicines caused by patents?
3. Why should health policy disproportionately dictate broader policy (e.g. innovation and economic)?
4. Why would a business make available new gene-based products in Australia if a gene patent ban undermines their global business and investment models?
5. Why would businesses invest in the development or commercialisation of gene-based products in Australia if there is less patent value for return on investment than in other countries?
6. Is an objective distinction between invention and discovery possible without adverse consequences (it has not appeared possible to date)? If so, how would it comply with our international obligations?
7. Why would an investor risk a large investment on a method patent rather than on a patent molecule?
8. How does the patent system make humans subject to property rights?
9. Why have all the gene patent reviews over the last 20 years not recommended a gene patent ban?
10. Why don't the three government initiatives address gene patenting issues?
  - a. Raising patent grant standards through the Raising the Bar Act (to address the granting of overly broad and speculative patents).
  - b. research and regulatory approval exemption from patent infringement through the Raising the Bar Act ( to address certainty for researchers and facilitate early entry into the market of generics).
  - c. A compulsory licence review (to address unreasonable restrictions by patentees).
11. How is it beneficial to treat inventions differently than developed countries and our major trading partners, including the European Union, US, UK, Japan, South Korea and China, especially when patents allow access to 98% of knowledge being developed internationally?

**Comment [BB7]:** Not clear who these questions are directed to or why they are included. Suggest they be deleted or, in the alternative, some explanation of the purpose of including them.

# Further Update on Gene Patents Debate - IPA comments[SEC=PROTECTED] - Notes Memo

**From:** [Brendan.Bourke@ipaaustralia.gov.au](mailto:Brendan.Bourke@ipaaustralia.gov.au)  
**To:** peter.lunn@innovation.gov.au  
**Cc:** Terry.Moore@ipaaustralia.gov.au, Charlotte.Iggulden@ipaaustralia.gov.au  
**Sent:** 03-09-2012 10:53:37 AM

Hi Peter

Thanks for consulting us on this brief.

We have made some suggestions shown as marked up changes in the attached document, in addition to the following comments:

From the email chain you provided, it appears the primary reason for the brief is to provide the Minister an analysis of the proposed Parke Bill and an update on the round-table.

Ms Parke's Bill

- We have suggested elevating one of your points on the Private Members Bill to the Key Points, given this is one of the primary reasons for the brief. We have suggested a consequential change to the order of attachments.
- It is not altogether clear what version of the Parke Bill is being referred to. (The copy we have is dated 6 March 2012 which is attached to C12-911). This may be resolved when it is added as an attachment, but it should also be made clear in attachment D if there are several versions. (If there is a more recent version, we would appreciate if you could provide us a copy).
- We have suggested including the table from C12/911 in Attachment D. This will need to be updated if the brief is referring to a new version of the proposed Bill
- It is not clear what the purpose of the questions in Attachment D is, or who the questions are directed to.
- Round Table
- Attachment - we have added the purpose of the round table and a list of the attendees to the attachment in the attached marked up copy, as it wasn't clear from the brief what the purpose was or who attended.
- While we haven't made a change to the marked-up copy, we suggest restricting the attachment to the Themes, to keep the brief tight. The further detail seems an unnecessary level of detail for a brief of this nature.
- Finally, on one minor point, we are not sure what the protocol is when referring to draft briefs - ( B12/2336 is referred to in the background). This is possibly something you could clarify with the MLO.
- Please call me if you want to discuss further.

<Attachment: B12-2458 BD 1 220338-1 further update briefv3 IPA comments.doc>

Regards

Brendan

**Brendan Bourke**  
Director  
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Business Development & Strategy Group  
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File C2012/12966 FOI 444



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