

The Senate

Economics Legislation Committee

Provisions of the Intellectual Property Laws
Amendment Bill 2006

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CHAPTER 1

INTRODUCTION

Background

1.1 The Intellectual Property Laws Amendment Bill 2006 was introduced into the House of Representatives on 30 March 2006 by the Parliamentary Secretary to the Minister for Industry, Tourism and Resources, the Hon. Robert Baldwin MP.

1.2 On 22 June 2006, on the recommendation of the Senate Standing Committee for the Selection of Bills, the Senate referred the provisions of the Bill to the Economics Legislation Committee for inquiry and report by 9 August 2006.

Conduct of the inquiry

1.3 The Committee advertised the inquiry nationally and posted details on its internet site.

1.4 The Committee received 7 submissions to its inquiry. These are listed at Appendix 1. The Committee also received a number of papers that were tabled during the hearing, and supplementary correspondence sent after the hearing. These documents are tabled with this report and form part of the Committee's record. IP Australia's response to questions taken on notice is included at Appendix 3.

1.5 The Committee held a public hearing at Parliament House in Canberra on Thursday, 3 August 2006. Witnesses who presented evidence at the hearing are listed in Appendix 2.

1.6 The Hansard of the Committee's hearing and copies of all submissions are tabled with this report. These documents, plus the Committee's report, are also available on the Committee's website at:

http://www.aph.gov.au/Senate/committee/economics_ctte/intellectual_property/index.htm

1.7 The Committee thanks those who participated in this inquiry.

CHAPTER 2

THE BILL

2.1 This 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*¹.

2.2 Submissions received by the Committee, and evidence received at the hearing relate to Schedules 1, 4, 6, 7 and 8 of the Bill.

Schedule 1 – Revoking registration of trade marks

2.3 Schedule 1 will amend the *Trade Marks Act 1995* (TMA) to:

- allow the Registrar of Trade Marks to revoke the acceptance of a trade mark before it proceeds to registration, if satisfied that it is reasonable to do so taking into account all of the circumstances. It aims to broaden the current provision, which has been interpreted in a narrower manner that was originally intended, to clarify that the Registrar must take into account all of the circumstances of the case. The intention 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;² and
- allow the Registrar to revoke, in certain circumstances, a trade mark that has already been registered. Under current legislation, if an error is not realised until after the trade mark has been registered, the only recourse is to seek redress in the courts. This is intended to provide a quicker and less expensive means of addressing incorrectly registered trade marks.³ In order to revoke registration, the Registrar must notify the owner or approved user within 12 months of registration.⁴

2.4 The Institute of Patent and Trade Mark Attorneys of Australia (IPTA) has raised several issues in relation to Schedule 1. The IPTA expressed concern that allowing the Registrar to revoke a registered trade mark:

...creates uncertainty for the owner of a trade mark registration. It is conceivable that in a 12 month period, trade mark owners may have spent a considerable amount of money using the trade mark including establishing licences and authorising others to use the trade mark. If the trade mark

1 Explanatory Memorandum, p. 1.

2 Explanatory Memorandum, p. 26.

3 Explanatory Memorandum, p. 1.

4 Explanatory Memorandum, p. 29.

registration is then revoked, the trade mark owner goes from the situation of having once been entitled to rely on the defence of owning a registered trade mark to the situation where the trade mark owner is exposed to liabilities and accusations of infringement with the potential for very expensive lawsuits.⁵

2.5 The IPTA considers that there is a need for further public consultation on this issue, in particular, whether the 12 month period is too long. The IPTA also considers that the meaning of 'within 12 months of registering the trade mark' in subsection 84A(4) needs to be clarified in the Bill to specify whether it commences on the date of registration (the filing date) as defined in the TMA or the date the decision was taken to physically register the trade mark (the sealing date).⁶

2.6 Evidence from IP Australia confirmed that the date of registration is the relevant date, not the filing date:

In paragraphs 40 and 41 of the explanatory memorandum, it makes it quite clear that it is when the details are entered into the register under section 69 of the Trade Marks Act. So, if there was any doubt about the drafting of the text, the explanatory memorandum should clarify that. But we think that the wording in the drafting of the text encapsulates that it is the date that it is actually registered and not the date that it was filed.⁷

2.7 IP Australia advised that it consulted with interest groups on these provisions when they were first proposed in 2002. At that time, the IPTA generally favoured the revocation of registration provisions, but preferred a time limitation of three or six months for revocation. In April 2006, IP Australia conducted further discussions concerning the operation of the provisions with some interest groups. It was agreed to develop guidelines, in conjunction with stakeholders, to ensure the views of trademark owners would be taken into account. This work has commenced and consultations with stakeholders, including the IPTA, will be carried out before the new provisions come into effect.⁸

2.8 In relation to the IPTA's claim that the new provisions create uncertainty, IP Australia explained to the Committee that:

...the provisions set up a two-part test which would have to be met before the trademark could be revoked. The first part of the test protects the interests of the public; the second part protects the interests of the registered owner...

In the first part of the test the registrar has to be satisfied that the trademark should not have been registered because there was some error or something

5 IPTA, *Submission 1*, pp. 5–6.

6 IPTA, *Submission 1*, pp. 5–6.

7 Dr O'Rourke, *Proof Committee Hansard*, 3 August 2006, p. 16.

8 IP Australia, *Responses to questions on notice*, 7 August 2006, p. 11. See Appendix 3.

else that led to an incorrect registration. In the second part of the test the registrar has to be satisfied that it is reasonable to revoke the registration. The registrar has to take into account all the circumstances, and a number of them are listed in subsection 3 of that provision. The registered owner will get a chance to argue before the registrar that, even though a mistake was made, it is not reasonable in this case to revoke that registration. They will be able to rely on the grounds that are specifically mentioned in the act or on any other grounds that might apply. On the case that IPTA raises—if they have invested money in using the trademark, for instance—paragraph 84A(3)(a) specifically mentions use. So they will be able to argue, ‘I have invested this much money in it, therefore it is unreasonable for you to revoke the registration.’ The provisions of the act are set out to protect the interests of the trademark owner.⁹

2.9 IP Australia highlighted the fact that, at the moment, any registered trademark can be cancelled by the court on a variety of grounds so, in that sense, uncertainty is already there. However, under the new Bill there will be merits grounds as well as technical grounds for revocation.¹⁰

2.10 In relation to IPTA’s concern that trademark revocation might expose the trade mark owner to ‘liabilities and accusations of infringement with the potential for very expensive lawsuits’ (see para 2.4); IP Australia said that:

And if the trade mark owner would be exposed to liabilities and accusations of infringement...the registered owner would have a strong argument that revocation would be unreasonable.¹¹

2.11 IP Australia has examined these issues in greater detail in its *Responses to questions on notice* (see sections 2.2.1–2.2.3) which the Committee has included in this report at Appendix 3.

Schedule 4 – Availability of documents about trade marks

2.12 Schedule 4 amends the TMA to make documents relating to trade marks publicly available. It also gives the Registrar the power to specify that information contained in documents be held confidentially. The intention is to 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.¹²

2.13 Currently, there is no provision in the TMA for making these documents available for public inspection. Members of the public have to apply for access under

9 Dr O’Rourke, *Proof Committee Hansard*, 3 August 2006, pp. 16–17.

10 Dr O’Rourke, *Proof Committee Hansard*, 3 August 2006, p. 17.

11 IP Australia, *Responses to questions on notice*, 7 August 2006, p. 11.

12 Explanatory Memorandum, p. 1.

the *Freedom of Information Act 1982* (FOI Act). This will also bring the TMA in line with section 55 of the Patents Act and section 60 of the Designs Act, which provide for certain documents to be publicly available.¹³

2.14 The IPTA considers that several elements of this Schedule are unclear and require further consultation prior to implementation, including:

- the benchmark to be used by the Registrar to determine whether a document will be held confidentially;
- if the standard is unknown or below that applied under the FOI Act, applicants may be reluctant to lodge sensitive material, leading to difficulty in obtaining registration; and
- whether a person who claims confidentiality when lodging a document has any recourse if the Registrar does not agree for the material to be held confidentially.

2.15 In the IPTA's opinion, the benchmark should not be below that applied under the FOI Act. The IPTA is also concerned that granting easy access to documents allows anyone to gain information about a competitor, even if they have no interest in the matter before the Trade Marks Office.¹⁴

2.16 IP Australia informed the Committee that it is in the process of undertaking further consultation as to how this system will operate and the IPTA is one of the stakeholders who will be consulted as part of this process.¹⁵

Schedule 6 – Exemption of continued prior use from patent infringement

2.17 Schedule 6 amends the *Patents Act 1990* (PA) to implement the Government's response to recommendations of the Intellectual Property and Competition Review Committee's (IPCRC) *Review of the Intellectual Property Legislation under the Competition Principles Agreement*, regarding 'prior use' as a defence against patent infringement.¹⁶

2.18 The Bills Digest states:

Not everyone who duplicates a patented invention will infringe the patent. One exemption, known as 'prior use', permits someone to continue using a process or making a product, where they were doing so (or about to do so) at the time a patent application was lodged by someone else, but that prior use was not publicly known.¹⁷

13 Explanatory Memorandum, p. 37.

14 IPTA, *Submission 1*, pp. 6–7.

15 IP Australia, *Responses to questions on notice*, 7 August 2006, p. 12. See Appendix 3.

16 Explanatory Memorandum, p. 39.

17 Bills Digest, No. 159, 19 June 2006, p. 10.

2.19 The IPCRC recommended that section 119 of the PA be amended to clarify that:

- prior use be confined to use within the patent area (ie Australia); and
- this use includes experimental use.¹⁸

2.20 The IPCRC recommended against allowing a prior user to assign, licence or sell their right. A majority thought that 'extending the exemption might tilt the benefits too far toward a de facto right for the prior secret user'.¹⁹

2.21 The Government accepted the IPCRC's recommendations 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 should also encompass other acts such as selling, hiring or otherwise disposing of the product.²⁰

2.22 According to the Explanatory Memorandum:

Section 119 attempts to provide a balance between the rights to 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.²¹

2.23 This amendment clarifies 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.²²

2.24 The IPTA has expressed concern that the proposed amendments to section 119 of the PA go beyond the recommendations of the IPCRC and, as a result, they have not been available for public comment and their impact has not been properly assessed. The IPTA also considers that it goes beyond what was intended by the Government's response to the IPCRC's recommendations.²³

18 Explanatory Memorandum, p. 39.

19 Intellectual Property and Competition Review Committee (IPCRC), *Review of the Intellectual Property Legislation under the Competition Principles Agreement*, 30 September 2000, p. 158.

20 Explanatory Memorandum, p. 39.

21 Explanatory Memorandum, p. 3.

22 Explanatory Memorandum, p. 1.

23 IPTA, *Submission 1*, p. 7.

2.25 Further, the IPTA is concerned that the amendments to section 119 will not remove the current uncertainty in this area and may have the potential to undermine the value of an Australian patent. The IPTA considers that the use of the non-exclusive definition of 'exploit':

...broadens the scope of the infringement exception provided by the section...Rather than just being a simple defence to infringement for prior use, the new section 119 will create a new and potentially very valuable and broad non-infringement right.

Still further, the person will be entitled to assign this very broad non-infringement right to a third party.²⁴

2.26 According to the IPTA, the combination of both these factors has the potential to be damaging to Australian innovators and to the perception of the value of Australian patents here and overseas. For example, under the new legislation, large multinational competitors may seek to avoid infringement of their Australian patents by looking for and buying a prior use right.²⁵

2.27 The IPTA considers that the defence under section 119 should be limited to the actual prior use or acts and should specify that it includes experimental use, as recommended in the IPCRC report. Alternatively, the prior use right should be limited to the specific product, method or process prior used, which the IPTA suspects was the intention of the amendment. Otherwise, the IPTA considers that the right to assignment should be removed.²⁶

2.28 A submission from Dr Thomas Faunce, a senior Lecturer at the Australian National University Medical School and at the College of Law also considered that it was necessary to clarify that 'prior use' in the new section 119 included experimental use. Dr Faunce pointed out that following a recent decision in the US court of appeal, the experimental use defence was now 'practically ineffective' in that country. Dr Faunce gave examples of a number of countries where there were statutory provisions providing such exemptions to patent infringements, but in Australia, there is no case law nor statutory exemption for experimental use.²⁷

2.29 The IPTA also claims that the proposed amendment will result in Australia's position on prior user rights differing from our major trading partners, including the United Kingdom, where a business holding the prior user right can only dispose of the right if the business is also being assigned.²⁸

24 IPTA, *Submission 1*, p. 8.

25 IPTA, *Submission 1*, p. 8.

26 IPTA, *Submission 1*, pp. 8–9.

27 Dr Thomas Faunce, *Submission 7*, pp. 5-6.

28 IPTA, *Submission 1*, p. 9.

2.30 The Generic Medicines Industry Association Pty Ltd (GMiA) supports the proposed section 119, subject to the comment below. The GMiA is of the view that:

...the proposed amendment removes a number of the ambiguities that exist in the current provision which is very useful...

Further, the inclusion of a right to assign that prior use right is a realistic recognition of the fact that products are sold by one company to another, or perhaps transferred between companies as part of an acquisition. There is no good reason why this prior use right should not be able to pass with that transfer or sale.²⁹

2.31 The GMiA sees no reason why the provision should not be retrospective, arguing that Note 1 of sub-section (1) of the new section 119 should be removed and the provision should apply to all patents currently in force.³⁰

2.32 IP Australia has addressed the IPTA's concerns relating to Schedule 6 to the Committee's satisfaction in its *Responses to questions on notice* at Appendix 3, paragraphs 2.5.1–2.5.4.

Schedule 7 - Springboarding and patents

Background

2.33 This Bill implements a wider 'springboarding' scheme for generic pharmaceuticals than is currently provided under the *Patents Act 1990*. In his second reading speech, the Hon. Robert Baldwin MP describes springboarding as:

...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 a patented drug, when the patent is still in force. This allows generic pharmaceutical manufacturers to establish that their generic pharmaceutical product is bioequivalent to the original product before the patent expires and have it ready for the market upon patent expiry.³¹

2.34 In other words, it allows the necessary preliminary work that must be done before bringing a generic drug onto the market to be undertaken before the patent expires, speeding up the production and marketing of generics.

2.35 Springboarding of pharmaceutical patents was first introduced with the introduction of the *Intellectual Property Laws Amendments Act 1998*, which came into effect on 27 January 1999. This Act allowed for an extension of effective patent life of up to five years, and allowed springboarding for the manufacturers of generic or off-patent pharmaceuticals where an extension of patent life had been granted.³²

29 GMiA, *Submission 6*, pp. 3–4.

30 GMiA, *Submission 6*, p. 3.

31 Second Reading Speech, The Hon. Mr Robert Baldwin MP, 30 March 2006.

32 Bills Digest, No. 159, 19 June 2006, p. 6.

2.36 The Government introduced the five year extension in recognition of the lengthy regulatory approval process required before pharmaceuticals can be marketed.³³ The purpose of the introduction of the springboarding provision was:

...to allow earlier regulatory approval for generic pharmaceuticals, faster market entry upon patent expiry and prevent originator companies from receiving further de factor extension of patent term.³⁴

2.37 On 28 June 2002, the Prime Minister wrote to the Minister for Industry, Tourism and Resources, the Hon. Ian Macfarlane MP, requesting that an Interdepartmental Committee (IDC) be established to examine the impact of patent extensions and springboarding provisions on generic manufacturers. The IDC concluded that under the current springboarding provisions, Australian manufacturers were not able to compete on equal terms with overseas competitors.³⁵

2.38 The current springboarding provisions only allow springboarding on patents that have been extended after the extension has been granted. The proposed amendments seek to:

...allow springboarding on any pharmaceutical patent at any time for the 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.³⁶

Issues raised during the inquiry

2.39 Schedule 7 was discussed in the following submissions:

- the IPTA and Medicines Australia expressed concern about the transition provision introduced by Part 4 of Schedule 7, which sees the new provisions applying to all patents in force at the commencement of the schedule;³⁷
- Nufarm Limited (Nufarm) supported the proposed amendments, however it would like to see the amendments extended to include agricultural chemical products;³⁸

33 Bills Digest, No. 159, 19 June 2006, p. 6.

34 Explanatory Memorandum, p. 19.

35 Explanatory Memorandum, p. 19.

36 Explanatory Memorandum, p. 23.

37 IPTA, *Submission 1*, p. 9.

38 Nufarm, *Submission 2*, p. 1.

- Medicines Australia is concerned about the proposed broadening of the springboarding exemptions, in particular the proposed new section 119A,³⁹
- the Generic Medicines Industry Association Pty Ltd (GMiA) supported the Bill in its current form.⁴⁰

Application of springboarding to all existing patents

2.40 The IPTA and Medicines Australia expressed concern about the application of Schedule 7. Part 4 of the Schedule states:

The amendments of the *Patents Act 1990* made by this Schedule apply in relation to the exploitation, at or after the time this Schedule commences, of inventions claimed in patents in force at or after that time.⁴¹

2.41 The IPTA claims that the result of Part 4 will be that current patentees of pharmaceutical patents will have a sudden reduction in the patent rights they presently enjoy without any compensation. The IPTA argues that the new springboarding provisions should be restricted to patents granted on applications filed on or after the commencement of the new provisions.

2.42 Further, the IPTA told the Committee that patentees will seek redress on the basis that the proposed provisions contravene Section 51(xxxi) of the Australian Constitution as there is no compensation to the patent owner who suddenly loses its rights to enforce a patent against those who make use of his invention for the purpose of obtaining regulatory approval for a drug.⁴²

2.43 Medicines Australia also argued against the proposed springboarding provisions. Medicines Australia submitted that the exclusive rights conferred by the granting of a patent provide the necessary incentive for patentees to undertake research and development, by providing certainty of return for those who undertake the risks associated with such research. Further, it claims that biotech and innovator pharmaceutical companies play a crucial role in providing innovative new products to society and rely on intellectual property protection to give the necessary return to justify the risks.

2.44 Medicines Australia argues that the patent term generally regarded as providing a suitable basis for a reward for risk and innovation is a minimum of 20 years under the Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement). However, in the case of pharmaceuticals, there may be substantial lags in gaining regulatory approval, eroding the effective life of the patent. Medicines

39 Medicines Australia, *Submission 4*, p. 2.

40 GMiA, *Submission 6*, p. 1.

41 Bill, p. 23.

42 IPTA, *Submission 1*, p. 9.

Australia said that this lag was recognised by the Australian Government in 1999 with patent term restoration, which enabled a five year patent extension in recognition of the time lost in the regulatory process.⁴³ (This is confirmed in the Explanatory memorandum – see paragraph 2.36 above).

2.45 Medicines Australia argued that the original springboarding provisions as currently exist in the Act were introduced to maintain the balance between competition and preserving innovation incentives. However, Medicines Australia sees the proposals in this Bill as:

...likely to undermine Australia's reputation for encouraging, supporting and rewarding innovation.⁴⁴

and have:

...the potential in their current form to further weaken Australia's intellectual property framework relative to competitor countries (eg: the United States and European Union) and are contrary to the Government's stated aim of these amendments bringing Australia's practices in line with other countries.⁴⁵

2.46 Medicines Australia is of the opinion that the proposed new section 119A, which will extend springboarding to any pharmaceutical patent at any time, and will apply to all patents in force at the commencement of the Schedule, will result in a reduction in patent rights for pharmaceutical patentees, but with no *quid pro quo*, for example in the case of the current springboarding legislation this is patent term extension.⁴⁶

2.47 In addition to its objection to the general thrust of the extended springboarding provisions, Medicines Australia also submitted that there were a number of definitional issues that require attention. Finally, the organisation put forward a series of detailed recommendations for changes to the Bill. These issues and recommendations are described in its submission, and amongst others, seek the removal of the anti-evergreening⁴⁷ amendments inserted during the passage of the legislation implementing the Australia-United States Free Trade Agreement (AUSFTA).

2.48 In contrast to the Medicines Australia position, the GMiA supports the amendments to Schedule 7, and argued that the proposed section 119A should be

43 *Submission 4*, p. 3.

44 *Submission 4*, p. 5.

45 *Submission 4*, p. 5.

46 *Submission 4*, p. 3.

47 Evergreening – a description used by critics of the major drug companies of a strategy allegedly employed by brand-name drug companies to extend patent protection on their medicines and keep generic versions off the market. Derived from http://en.wikipedia.org/wiki/Generic_drug

applicable to all patents currently in force. The GMiA claims that this would be consistent with the equivalent provisions around the world.⁴⁸

2.49 A detailed submission made by Dr Tom Faunce, senior lecturer, ANU Medical School and College of Law, objected strongly to the proposals put forward by Medicines Australia. Dr Faunce said that:

They represent an unbalanced perspective that solely favours the interests of multinational pharmaceutical manufacturers over that of the Australian public.⁴⁹

2.50 Dr Faunce also disagreed with Medicines Australia's recommendations in relation to the anti-evergreening amendments. He said that the changes advocated by Medicines Australia would facilitate evergreening, to the detriment of medicines prices and public health. He supported the s119 amendments.⁵⁰

Agricultural chemical products

2.51 Nufarm supports the proposed extension of the springboarding provisions of the *Patents Act 1990*, but argues that the provisions should be extended to include agricultural chemical products. Nufarm argues that, as agricultural chemical products are subject to similar regulatory regimes in Australia and overseas as pharmaceutical products, they should enjoy the same extended springboarding provisions.⁵¹

2.52 Due to the restrictions on the importation and use of materials subject to patent in Australia, many of Nufarm's research projects are undertaken in countries outside of Australia, which allow the use of patented materials for the purposes of generating information for regulatory approval. Nufarm state that as an Australian company, it would like to undertake its research and development in Australia.⁵²

2.53 The Committee heard evidence from Nufarm at the hearing that, at present, much of their research and development is undertaken in India and New Zealand:

That process is problematic, because we as a company do not have big operations in those places. We hire independent contractors to do the work and that sort of thing. There is a lot of effort in actually controlling or managing that process.

If we were able to do it in Australia, one thing is that we could manage it in Australia with our Australian resource, which is where we have most resources globally....Obviously, we would be using Australian researchers

48 *Submission 6*, p. 2.

49 Dr Tom Faunce, *Submission 7*, p. 3.

50 Dr Tom Faunce, *Submission 7*, p. 3. Dr Faunce's submission includes a useful and detailed discussion about evergreening.

51 *Submission 2*, p. 1.

52 *Submission 2*, p. 1

and developers or academics to assist us—or we would hire the staff to do it—and we would conduct the fieldwork and other things in Australian rural and regional areas. From our point of view, this is our home. This is where we are based. This is where we have got the most resource and our business expertise in terms of trying to grow the business, so it would be much better to be able to do it here.⁵³

2.54 The Committee also heard evidence from Nufarm that it would continue to be at a competitive disadvantage if the springboarding provisions were not extended to the agricultural chemical industry:

Our largest competitor in the generic postpatent field in the world is an Israeli company. They have this exact legislation there and they use it. They do all their work in Israel for their product launches in various parts of the world. That puts us at a definite disadvantage because we cannot do a lot of it here at home, being an Australian company.⁵⁴

2.55 The Committee heard evidence from representatives from the Department of Industry, Tourism and Resources that there has been no investigation during the development of the Bill into the net benefit to Australia of applying the springboarding provisions to other industries. The reason for this was because the mandate given to the IDC from the Prime Minister was to examine the impact of patent extensions and springboarding provisions on generic manufacturers. As a result, the investigation by the IDC and the subsequent processes that were undertaken related specifically to the pharmaceuticals industry.⁵⁵

2.56 Nonetheless, the Committee considers that the proposal put forward by Nufarm warrants closer investigation. The Committee recommends that the Government consider initiating an IDC to examine whether the springboarding provisions should be extended to other industries, and in particular, the agricultural chemicals sector.

Schedule 8 - Compulsory licensing of patents

2.57 The Bills Digest explains:

A patent grant is, in essence, a right to stop others from doing certain things and a patentee may decide not to work the patent. The decision may be due to lack of resources, unavailability of raw materials or similar reasons. However it is also possible that the patentee's failure to work the patent is due to a desire to exploit a different patent, or promote a different product or simply to stifle the inventions. The Patents Act recognises that failure to work an invention may be contrary to the interests of the public and

53 Mr Lee, *Senate Hansard Committee*, p. 3.

54 Mr Gallagher, *Senate Hansard Committee*, p. 3.

55 Mr Pennifold, *Senate Hansard Committee*, pp. 10-11.

provides for the granting of compulsory license and for the revocation of a patent on the grounds of non working.⁵⁶

2.58 Subsection 133(2) of the current legislation 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.

2.59 The IPCRC considered the conditions currently prescribed for the grant of a compulsory license 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.⁵⁷

2.60 The Bills Digest explains:

The Government in response to the IPCR Committee report supported in principle the recommendation to make the compulsory licensing of patents subject to a competition test, but argued that a competition test alone is not sufficient as:

(a) the recommended test may be more stringent in some circumstances than the existing tests and may result in the compulsory licensing provisions ceasing to act as an incentive to negotiate a voluntary licence; and

(b) a competition test will not cover some situations where the non-working of the invention, or other effective denial of reasonable access to it, has some negative effect on the public interest which is not dependent on competition in the market.⁵⁸

2.61 Accordingly, the Government decided that the existing tests should be retained and a competition test be added as an additional ground on which a compulsory licence can be obtained. Schedule 8 implements this decision, adding the competition test to the pre-existing grounds for granting compulsory licences. Applications for such compulsory licences may only be made in the Federal Court.⁵⁹

Compulsory licences and international obligations

2.62 Under the competition test, if the patentee contravenes Part IV of the Trade Practices Act (TPA) or an application law in connection with a patent, then a compulsory licence is available as a remedy for that contravention.⁶⁰

56 Bills Digest, No. 159, 19 June 2006, p. 11.

57 Explanatory Memorandum, p. 11.

58 Bill Digest, No. 159, 19 June 2006, pp. 11-12.

59 Bill Digest, No. 159, 19 June 2006, p. 12.

60 Bills Digest, No. 159, 19 June 2006, p. 12.

2.63 The IPTA claims that there is an inconsistency in Chapter 12 of the *Patents Act 1990* which can be addressed in Schedule 8 of the Bill. Section 136 of the PA provides that an order must not be made under section 133 or 134 that is inconsistent with a treaty between the Commonwealth and a foreign country.⁶¹

2.64 Schedule 8 of the Bill proposes to amend section 133(b) of the *Patents Act 1990* by adding as a ground for obtaining a compulsory license the fact that the patentee is contravening a restrictive trade practices provision of the TPA.

2.65 Under the Australia/USA Free Trade Agreement, a compulsory license may only be granted for the purpose of remedying anti-competitive practices or in cases of public non-commercial use, or national emergency or other circumstances of extreme urgency.⁶²

2.66 The IPTA believe that it is unclear whether the "reasonable requirements of the public" test set out in proposed subparagraph 133(2)(a)(ii) survives section 136 or whether that section means that the test will not apply against US persons.

2.67 IP Australia has comprehensively addressed the IPTA's concerns relating to Schedule 8 in its *Responses to questions on notice* at paragraph 2.7 (page 14) of Appendix 3.

Queensland University of Technology submission and evidence

2.68 A submission lodged by Professor Stephen Corones and Mr Dale Clapperton of the Queensland University of Technology (QUT) expresses support for inclusion of a competition test as an alternative basis upon which a compulsory licence of a patent may be sought under the PA, in situations where a licence of the patent is required for competition in a market.⁶³

2.69 The QUT submission provides a useful discussion of how patents, while generally pro-competitive, can be used for anti-competitive purposes. The authors illustrated their case with examples including engineering by one company of laser printer cartridges to prevent refilling, forcing consumers to buy the more expensive genuine article; and efforts on the part of the Apple computer company in relation to digital rights management (DRM) systems intended to prevent interoperability with other competing products. Prof Corones and Mr Clapperton submitted that companies were increasingly using software patents in relation to DRM systems, posing a risk to interoperability and competition.

61 IPTA, *Submission 1*, p. 10.

62 Australia-United States Free Trade Agreement, Article 17.9 Patents, paragraph 7A http://www.dfat.gov.au/trade/negotiations/us_fta/final-text/chapter_17.html [accessed 1 August 2006]

63 Queensland University of Technology, *Submission 3*.

2.70 The QUT submission considered the interaction between the Trade Practices Act (TPA) and patent licensing, noting that while the licensing of intellectual property rights is partially exempt from some prohibitions in Part IV of the TPA, there are circumstances where conduct falls outside of this exemption and may contravene provisions of Part IV. These include:

- unilateral refusal to license, combined with other exceptional circumstances so as to constitute a misuse of market power;
- granting of an exclusive licence to the patent, thereby preventing the patented technology from being licensed to anyone else;
- 'patent pooling', or refusing to license an essential patent unless other non-essential (and unwanted) patents are also licensed.⁶⁴

2.71 Professor Corones and Mr Clapperton said that where access to a patent is required for competition in a particular market, the patent can take on the nature of an 'essential facility' for competition law purposes. They pointed out that Part IIIA of the TPA regulates access to services provided by essential facilities, but intellectual property including patents are specifically excluded from the definition of services covered by Part IIIA. They went on to say that in the few cases that had been considered, courts had sought to bridge this gap by using s46 of the TPA to create an access regime. However, the submitters consider that there are unresolved issues associated with this.⁶⁵

2.72 The major unresolved issue identified by the QUT submission was:

...whether s 133 of the *Patents Act 1990* is intended to operate as a complete code for the compulsory licensing of patents, to the exclusion of the courts' general power under other Acts.⁶⁶

2.73 Professor Corones elaborated on this issue at the public hearing, telling the committee that there had been some indication from the High Court⁶⁷ that s46 of the TPA could have a role:

There was a recent obiter ... of the High Court majority in the *NT Power* case. In that case the majority said that section 46 could be used as a basis for ordering compulsory licensing of intellectual property rights. We have no clearer guidance than that, but it is fairly high authority that section 46 is meant to operate in conjunction with section 133 of the *Patents Act*. We see that that might result in some confusion so that, if a party seeks a

64 QUT, *Submission 3*, p. 5.

65 QUT, *Submission 3*, p. 6.

66 QUT, *Submission 3*, p. 6.

67 *NT Power Generation Pty Ltd v Power and Water Authority* (2004) 219 CLR 90 at 122 per McHugh ACJ, Gummow, Callinan and Heydon JJ.

compulsory licensing order under section 133, when the amendment is made section 133(2)(b) will require the licence seeker first to show that there is a breach of part IV of the Trade Practices Act.⁶⁸

2.74 Professor Corones said that this may offer the licence seeker a choice of seeking a compulsory licence under the remedy provisions of part VI of the Trade Practices Act or under section 133 of the Patents Act.

2.75 Evidence provided in response by IP Australia argues that this is not the case, because specific provisions prevail over general legislative provisions. Accordingly, an application for a licence could only be made under the Patents Act:

...the new provisions of the Patents Act are specific provisions allowing for a person to apply to the Federal Court of Australia for the grant of a compulsory licence for a patent. The Patents Act provisions specify the grounds on which a compulsory licence may be ... In contrast, the Trade Practices Act provisions are expressed very generally, and do not make a specific reference to grant of a compulsory licence.

There is a general principle of statutory interpretation under which, in the case of a conflict or inconsistency between a specific and a general legislative provision, the specific provision will prevail. Therefore in the case of any conflict or inconsistency between the proposed compulsory licence provisions of the Patents Act and the provisions of the Trade Practices Act, the former would be expected to prevail.

As a result of the application of this interpretive principle, an application for a compulsory licence could only be made under the Patents Act, and a person seeking an order for a compulsory licence for a patent would not be faced with a choice of legislative provisions under which the licence could be granted.⁶⁹

2.76 The QUT submission also raised the issue of pricing principles, stating that clear legislative guidance would be of assistance to the courts dealing with the pricing of compulsory licences of patents. Professor Corones raised this issue during the public hearing in the following terms:

First of all, is it intended that section 133 of the Patents Act will operate to the exclusion of the Trade Practices Act in relation to compulsory licensing? If not, then it seems to us that perhaps the Trade Practices Act needs to be amended to incorporate pricing principles which are the same as those under the Patents Act to avoid any conflict.⁷⁰

2.77 IP Australia responded that because of the principles outlined (in paragraph 2.75 above) these issues would not be expected to arise.⁷¹

68 *Proof Committee Hansard*, 3 August 2006, p. 6.

69 IP Australia, *Responses to questions on notice*, 7 August 2006, p. 7. (see Appendix 3)

70 *Proof Committee Hansard*, 3 August 2006, p. 6.

71 IP Australia, *Responses to questions on notice*, 7 August 2006, p. 8. (see Appendix 3)

2.78 The final issue raised by Professor Corones was whether there was a need for an additional requirement in the competition test:

The committee may wish to consider whether there ought to be an additional requirement—namely, that the licence seeker demonstrate that the grant of a compulsory licence is necessary to promote competition in a market. The reason for saying this is that in some cases, perhaps many cases, the patented product is unlikely to constitute a discrete market: the patented product is likely to be part of a broader market containing substitutes for the patented product. Is it appropriate, then, to only grant a compulsory licence where it is necessary to cure some lessening of competition in a market, or is it simply sufficient for the licence seeker to prove a breach of part IV?⁷²

2.79 Professor Corones observed that this was probably an unnecessary additional requirement, but that it would probably make clear what the mischief is that requires the compulsory licence.

2.80 In response, IP Australia said:

...the mischief that the provision is addressing is set out in the Explanatory Memorandum to the Bill (see paragraphs 165 ff) and in the IPCR Committee's final report (see pages 162-3). It is also noted that both of these documents are extrinsic material that are able to be used in the interpretation of the Patents Act according to section 15AB of the *Acts Interpretation Act 1901*. Therefore the mischief this provision is addressing is already apparent from these sources. The provisions are drafted so that the legislative provisions contain the substantive legal test that must be applied. The description of the mischief sought to be cured is contained in the extrinsic material.

2.81 IP Australia also noted that under the AUSFTA, compulsory licences can only be granted to remedy anti-competitive practices, not promote competition, and that it was therefore not an option to insert an additional requirement along the lines suggested by Professor Corones.⁷³

Other issues

2.82 Two further issues which were not dealt with in the Bill were raised in a submission by Ms Catherine Macneil (appearing in a private capacity). Ms Macneil argued that:

- the term 'pharmaceutical substance' is being construed by the Australian Patent Office and the Federal Court of Australia in a much broader view

72 *Proof Committee Hansard*, 3 August 2006, p. 7.

73 IP Australia, *Responses to questions on notice*, 7 August 2006, pp. 8-9. (see Appendix 3)

than intended by Parliament, so as to allow for, or uphold, the extension of patents that claim new formulations of old drugs; and

- sub-regulation 10.7(7) of the Patents Regulations is an inadequate measure for rectification of the Patents Register when an applicant provides the Commissioner of Patents with false, misleading, or otherwise incorrect information relating to the first regulatory approval date for a pharmaceutical substance.⁷⁴

2.83 Schedule 1 of the *Patents Act 1990*, defines a pharmaceutical substance as:

...a substance (including a mixture or compound of substances) for therapeutic use whose application (or one of whose applications) involves:

- (a) a chemical interaction, or physico-chemical interaction, with a human physiological system; or
- (b) action on an infectious agent, or on a toxin or other poison, in a human body;

but does not include a substance that is solely for use in in vitro diagnosis or in vitro testing.

2.84 The Committee notes that the definition of pharmaceutical substance has not been amended by the Bill and further, that the regulations discussed above are also not referred to in the Bill, however draws these matters to the attention of the government for consideration in the future.

Committee comments

Schedules 1, 4 and - Consultation process

2.85 The Committee has some reservations about the consultation process relating to the new provisions. The IPTA's concerns relating to Schedules 1, 4 and 6 and the response from IP Australia raise questions about the adequacy of consultations conducted and the timing of the process.

2.86 The Committee notes that IP Australia is still in the process of consulting with stakeholders in relation to Schedules 1 and 4. The Committee considers that it would have been preferable to finalise these matters with stakeholders before the new Bill was brought before parliament.

2.87 In relation to Schedule 6, the Committee notes IP Australia's comment that the Government's response to the IPCRC report was publicly released in August 2001, allowing ample time for interest groups to assess the impact of the proposed changes and to provide comments to the Government. However, there is no indication that any formal consultation process with stakeholders has been conducted in relation to this issue.

74 Ms Catherine Macneil, *Submission 5*.

Schedule 7 - Springboarding

2.88 The Committee considers that the broadening of the springboarding provisions, while opposed by some parties and in particular Medicines Australia, are consistent with the Government's intentions and policy position, as stated in the Explanatory Memorandum. The intention is to improve the ability of Australian manufacturers to compete internationally, and maintain Australia's competitiveness as an investment location for generics research and development.

2.89 As to whether the provisions contravene Section 51(xxxi), the Government clearly considers that this is not the case. In its *Responses to questions on notice*,⁷⁵ IP Australia has said that the Government believes that the provisions do not fall within the operation of section 51(xxxi) of the Constitution. The Committee has no reason to question the Government's view on this matter.

Schedule 8 - Compulsory licensing of patents

2.90 In the light of the views of Professor Corones and Mr Clapperton, the Committee has some concerns about whether the Bill provides sufficient clarity about whether the Patents Act will be the sole avenue for seeking a compulsory licence, as suggested by IP Australia's evidence. The observation of four Justices of the High Court, while an *obiter dictum*, suggests that the courts are unlikely to take the view propounded by IP Australia. If this is the case, then the issues raised by Professor Corones and Mr Clapperton will become more pressing. The Committee draws this possible uncertainty to the Government's attention.

Recommendation

2.91 The Committee recommends that the Government consider initiating an Interdepartmental Committee to examine whether the springboarding provisions should be extended to other industries, and in particular, the agricultural chemicals sector.

2.92 The Committee recommends that the Government reconsider Schedule 8 of the Bill in the light of the concerns raised by Professor Corones and Mr Clapperton, in order to clarify the relationship between the patent licensing provisions of the Bill and the Trade Practices Act.

2.93 Subject to paragraph 2.92, the Committee recommends that the Senate pass the Intellectual Property Laws Amendment Bill 2006.

Senator George Brandis

Chair

75 IP Australia, *Responses to questions on notice*, 7 August 2006, p. 14 (see Appendix 3)

Appendix 1

Submissions & Additional Information

**Submission
Number**

Submitter

- | | |
|---|--|
| 1 | The Institute of Patent and Trade Mark Attorneys of Australia (IPTA) |
| 2 | Nufarm Limited |
| 3 | Queensland University of Technology (QUT) |
| 4 | Medicines Australia |
| 5 | Ms Catherine Macneil |
| 6 | Generic Medicines Industry Association Pty Ltd (GMiA) |
| 7 | Dr Thomas Faunce |

Additional Information

1. Department of Industry, Tourism and Resources – Correction to advice provided at public hearing.
2. IP Australia Responses to Questions on Notice taken at public hearing.
3. IP Australia Responses to Additional Issue Raised by the Generics Medicine Industry Association. (Included at Appendix 3)

Appendix 2

Public hearing and witnesses

Thursday, 3 August 2006 - Canberra

CLAPPERTON, Mr Dale, Senior Research Assistant
Queensland University of Technology

CORONES, Professor Stephen, Professor of Law
Queensland University of Technology

GALLAGHER, Mr Matthew Joseph
Global Product Manager, Insecticides and Fungicides, Nufarm Ltd

LEE, Mr Bernard Daniel, Manager, Industry and Government Affairs, Nufarm Ltd

MACNEIL, Ms Catherine, Private capacity

O'ROURKE, Dr Michael, Assistant Director, Domestic Policy Section
IP Australia

PENNIFOLD, Mr Craig, Head, Innovation Division
Department of Industry, Tourism and Resources

PETERS, Dr Kirrily, Assistant Manager
Pharmaceuticals and Biotechnology Branch, Innovation Division
Department of Industry, Tourism and Resources

WERNER, Ms Janet, Director, Domestic Policy Section, IP Australia

*SENATE ECONOMICS LEGISLATION COMMITTEE INQUIRY
INTO THE
INTELLECTUAL PROPERTY LAWS AMENDMENT BILL 2006*

IP AUSTRALIA RESPONSES TO QUESTIONS ON NOTICE

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1. Responses to Professor Corones' submissions

1.2 Background

1.2.1 Introduction

In September 2000, the Intellectual Property and Competition Review (IPCR) Committee released its report *Review of Intellectual Property Legislation under the Competition Principles Agreement*. This review considered the balance between competition law and intellectual property law. The Government responded to this report in 2001.

This report considered insertion of a competition ground for the grant of compulsory licenses for patents. Schedule 8 to the Intellectual Property Laws Amendment Bill 2006 (the Bill) implements the Government's response to this recommendation.

1.2.2 Compulsory licences for patents

A patent represents the grant of an exclusive right to exploit an invention. Under the current provisions of the *Patents Act 1990*, a person may obtain a compulsory licence for the use of a patent if the "reasonable requirements of the public" with respect to that patent have not been met. Section 135 of the Patents Act sets out what is meant by the "reasonable requirements of the public". For example, the reasonable requirements of the public will not have been satisfied if an existing trade or industry in Australia is unfairly prejudiced because of the patentee's failure to manufacture the patented product to a reasonable extent and to supply it on reasonable terms.

Given that the grant of a patent gives the grantee exclusive rights, the IPCR Committee pointed out that the grant of a compulsory licence to another party "is *prima facie* inconsistent with the policy purpose underpinning that grant".

In its 1984 report *Patents, Innovation and Competition in Australia*, the Industrial Property Advisory Committee, described the justification for the present compulsory licence provision in the following terms:

"... compulsory licensing and forfeiture should have the purpose in Australia of providing a mechanism by which a patentee can be prevented from misusing a patent to preclude local working which is economically desirable, in circumstances where, but for the patent, it could and would occur."

For detailed background to patent compulsory licences, see Chapter 27 of the Australian Law Reform Commission's report *ALRC 99 – Genes and Ingenuity: Gene Patenting and Human Health*: <http://www.austlii.edu.au/au/other/alrc/publications/reports/99/27.html>

Although a compulsory license has been sought in a small number of court cases, as far as is known, no compulsory licences for patented inventions have been granted in Australia to date.

Instead, the evidence indicates that the present compulsory licence provisions serve to encourage the licensing and working of inventions sooner, with the compulsory licence provisions serving as an effective incentive for patent holders to grant a licence voluntarily and on their own terms.

1.2.3 The IPCR Report

The IPCR Committee considered the compulsory licence provisions of the Patents Act, and recommended amendments to the provisions.

The Committee recognised that compulsory access to patented invention through compulsory licence provisions can affect the terms on which parties negotiate licences for the use of patents, and was informed that the existing compulsory licence provisions of the Patents Act have an impact on licence negotiations, notably between foreign rights owners and potential users of patents in Australia.

The Committee accepted that compulsory licences were warranted in some situations, such as:

- When bargaining between parties is not able to achieve an outcome; or
- When the access right acts as a pro-competitive remedy that tempers the exclusivity that the patent right primarily provides.

The Committee noted that, in other jurisdictions with compulsory licences, most notably the United States and Canada, this can lead to more efficient and immediate outcomes without harming long-term incentives to innovate, and that the threat of compulsory licensing may lead to innovations being worked sooner and more widely than they would otherwise have been.

However, the Committee noted that the current compulsory licence provisions in the Patents Act seem poorly aligned to securing these goals, but that, instead, they hark back to a period where the primary concern was the promotion of domestic industry, rather than securing the best use of resources and achieving high levels of productivity. In addition, the Committee was of the opinion that the provisions lacked an explicit competition test, and did not seem to allow for the legitimate interests of the rights owner to be adequately protected.

The IPCR Committee then 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.

In its *Interim Report*, released in April 2000, the IPCR Committee gave its rationalisation for this form for the competition-based compulsory licence test (which reflects the test set out in Part IIIA of the Trade Practices Act):

“Overall, the Committee considers that there is merit in having provisions that can provide for third party access to IP rights along the lines provided in respect of other services by Part IIIA and Part XIC. However, the Committee is not convinced that this objective is well met by simply repealing the exception that IP rights currently have from these sections of the Trade Practices Act. Rather, it is the Committee’s view that this goal is best served by reviewing, and where appropriate amending, the relevant provisions in the intellectual property statutes themselves.”

The IPCR Committee also recommended that such orders should be obtainable on application first to the Australian Competition Tribunal, with rights of appeal to the full Federal Court.

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.

The IPCR Committee acknowledged that it did not seek to draft the conditions that would need to be met for the grant of a compulsory licence.

1.2.4 The Government response to the IPCR Report

The Government’s response to the IPCR Committee’s recommendation is as follows:

“Accept in part.

Compulsory licensing is one of the more contentious and politically sensitive TRIPS issues and therefore in considering this recommendation the Government has taken into account the need for consistency with international standards.

In principle, the Government supports the Committee's recommendation to make the compulsory licensing of patents subject to a competition test. However, as it stands, this recommendation would limit the grounds on which to obtain a compulsory licence to the situation where access to patented technology is required to ensure competition in the (relevant) market, rather than the broader grounds based on the 'reasonable requirements of the public.' Depending on its interpretation, this could preclude situations where compulsory licensing could be argued to be valuable from a public policy perspective.

For this reason, a competition test alone is not sufficient as:

- (a) the recommended test may be more stringent in some circumstances than the existing tests and may result in the compulsory licensing provisions ceasing to act as an incentive to negotiate a voluntary licence; and
- (b) a competition test will not cover some situations where the non-working of the invention, or other effective denial of reasonable access to it, has some negative effect on the public interest which is not dependant on competition in the market.

Accordingly, the Government believes that the existing tests should be retained and a competition test be added as an additional ground on which a compulsory licence can be obtained.

It is inappropriate that applications for compulsory licences be considered by the Australian Competition Tribunal in the first instance because the Tribunal is essentially a review body. In addition, it is not the appropriate body to hear applications for compulsory licences under the ‘reasonable requirements of the public’ test and, in view of the likely difficulties if applications under different grounds were to be heard by more than one body, the Government considers that all applications for compulsory licences should be considered by the Federal Court in the first instance.”

It is noted that the Government, in its response, did not accept the particular competition test proffered by the IPCR Committee. It is also noted that this response emphasised “consistency with international standards”.

1.2.5 The ALRC Report

In its report *ALRC 99 – Genes and Ingenuity: Gene Patenting and Human Health*, the Australian Law Reform Commission further considered the interaction between competition law and patent law – see Chapter 24 of that report. The ALRC also considered the issue of the grant of patent compulsory licences on the basis of a competition test, and reiterated the IPCR Committee’s recommendation to implement a competition based test for patent compulsory licences. See Chapter 27 of that report.

The report can be found at the following link:

<http://www.austlii.edu.au/au/other/alrc/publications/reports/99/>

The Government has not as yet finalised its response to this report.

1.2.6 International obligations and standards

1.2.6.1 International obligations

Under Article 30 of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), Australia can only provide limited exceptions to the exclusive rights provided by a patent, and only if these exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.

Under Article 31 of the TRIPS Agreement, compulsory licences may be granted, and that Article sets out procedural requirements that must be observed.

Under Article 17.9.7 of the Australia-United States Free Trade Agreement (AUSFTA), Australia is further limited as to its ability to grant compulsory licences. This Article is as follows:

“A Party shall not permit the use^{17-[22]} of the subject matter of a patent without the authorisation of the right holder except in the following circumstances:

- (a) to remedy a practice determined after judicial or administrative process to be anti-competitive under the Party's laws relating to prevention of anti-competitive practices;^{17-[23]} or
- (b) ... ”

The footnotes are as follows:

^{17-[22]} “Use” in this paragraph refers to use other than that allowed under paragraph 3 and Article 30 of the TRIPS Agreement.

^{17-[23]} With respect to sub-paragraph (a), the Parties recognize that a patent does not necessarily confer market power.”

In order to comply with our AUSFTA obligations, a compulsory licence cannot be granted in order to promote competition against a patentee – it must be confined to remedying anti-competitive practices.

1.2.6.2 International standards

In other jurisdictions in which compulsory licenses are granted on competition grounds, it is generally done so as a remedy to address anti-competitive conduct of the patent holder. Compulsory licenses are not granted in order to promote competition in the market. See Chapter 27 of the ALRC *Genes and Ingenuity* report for a comparative international summary.

1.3 The provisions of Schedule 8 to the Bill

Schedule 8 to the Bill implements the Government's response to the recommendation of the IPCR Committee's final report.

The proposed amendments to the Patents Act maintain the existing test for grant of a compulsory licence for a patent, on the ground that the “reasonable requirements of the public” with respect to the patented invention have not been satisfied. In addition to this, the amendments insert a competition-based test for the grant of a compulsory licence.

As per the IPCR Committee's recommendation, this provision has been inserted into the Patents Act rather than in the Trade Practices Act.

It is noted that the specific test proposed by the IPCR Committee, and also recommended by the ALRC, is not aimed at addressing anti-competitive practices on the part of a patentee. Rather, it is aimed at promoting competition. Indeed, the IPCR Committee considered that a compulsory licence would only be granted if the enhancement of competition in the relevant market that would be secured by grant of the compulsory licence was material and substantial. A test aimed at promoting competition would not be consistent with Australia's international obligations under the AUSFTA.

Instead, proposed amendments to the Patents Act introduce a further ground for grant of a compulsory licence, that is, that a compulsory licence is obtainable as a remedy for anti-competitive practices under Australia's law governing anti-competitive practices. This has been implemented by making a compulsory licence for a patent available as a remedy if the

patent holder has contravened or is contravening Part IV of the *Trade Practices Act 1974* or an application law. Such conduct is considered to be anti-competitive under Australia's law relating to prevention of anti-competitive practices. For example, as explained by the ALRC in its report (Chapter 24):

“24.8 Certain conduct is prohibited if it has the purpose or effect of ‘substantially lessening competition’ in a market, while other conduct is prohibited on a per se basis. Per se breaches do not involve an analysis of the impact of the conduct on competition because the conduct is presumed, by its nature, to substantially lessen competition.”

The new ground for grant of a compulsory licence for a patent relies on a breach of the competition code, and provides that, if the breach is related to a patent, then a compulsory licence is available as a remedy for that breach. The provisions therefore make it clear what the contravening conduct must be – a breach of Part IV of the Trade Practices Act or an application law.

In line with the Government response to the IPCR Committee's report, these provisions are also drafted so as to be in line with international standards, in so far as compulsory licenses are available as a remedy for anti-competitive conduct, rather than to aid in promoting competition against the patentee. The provisions are also consistent with Australia's international obligations, in particular, those under TRIPS and the AUSFTA.

1.4 The issues raised by Professor Corones

In his submission and evidence to the Senate Economics Legislation Committee, Professor Corones raises several issues with Schedule 8 to the Bill.

1.4.1 Whether section 133 of the Patents Act is intended to be a code

Professor Corones queries whether the new provisions are intended to be a code in relation to compulsory licensing, or whether the corresponding remedy under the Trade Practices Act remains available.

As explained at the hearing, the new provisions of the Patents Act are specific provisions allowing for a person to apply to the Federal Court of Australia for the grant of a compulsory licence for a patent. The Patents Act provisions specify the grounds on which a compulsory licence may be sought (paragraph 133(2)(b)), the payment that must be made to the patentee in respect of the licence (subsection 133(5)), provisions governing revocation of the licence (subsection 133(6)), and for the revocation of a patent after a compulsory licence has been granted (section 134). In contrast, the Trade Practices Act provisions are expressed very generally, and do not make a specific reference to grant of a compulsory licence.

There is a general principle of statutory interpretation under which, in the case of a conflict or inconsistency between a specific and a general legislative provision, the specific provision will prevail. Therefore in the case of any conflict or inconsistency between the proposed compulsory licence provisions of the Patents Act and the provisions of the Trade Practices Act, the former would be expected to prevail.

As a result of the application of this interpretive principle, an application for a compulsory licence could only be made under the Patents Act, and a person seeking an order for a compulsory licence for a patent would not be faced with a choice of legislative provisions under which the licence could be granted.

1.4.2 Remuneration under the Trade Practices Act

Professor Corones observes that under the remedial provisions of the Trade Practices Act, there are no pricing guidelines if a compulsory licence is granted under that Act, whereas under the Patents Act provisions, such pricing guidelines are included (subsection 133(5)). Professor Corones then observes that, if a pricing order is made under the Trade Practices Act, a court could order the grant of a licence on a completely different basis that allows the patentee to charge or to include a monopoly profit element in their royalty. Professor Corones then states that the Trade Practices Act may need to be amended to incorporate pricing principles which are the same as those under the Patents Act to avoid any conflict.

Based on the discussion in 1.4.1 above, these issues would not be expected to arise, as applications for compulsory licences would be dealt with under the Patents Act rather than under the Trade Practices Act.

It is emphasised that the amendments proposed to be made by the Bill to the Patents Act do not alter the operation of the Trade Practices Act with regard to pricing principles for remuneration for intellectual property licences.

The amendment to the Patents Act relating to the insertion of a competition test for compulsory licences has arisen as a result of extensive consultation and analysis by the IPCR Committee. The ALRC subsequently considered this issue, and made similar recommendations to those made by the IPCR Committee. Prior to these considerations, the issues have been considered in earlier reports, such as the 1984 report *Patents, Innovation and Competition in Australia* by the Industrial Property Advisory Committee.

It is noted that the issues raised by Professor Corones have not identified in any of these earlier studies, and to IP Australia's knowledge have not been raised in any other forums.

1.4.3 Whether an additional requirement is needed in the competition test

1.4.3.1 Mischief

Professor Corones raised the issue of whether there should be an additional requirement in the test for the grant of a compulsory licence – namely, that the licence seeker demonstrate that the grant of a compulsory licence is necessary to promote competition in the market. Professor Corones acknowledges in his oral evidence that this:

“is probably an unnecessary additional requirement, but if it were included it would probably make clear what the mischief is that requires the compulsory licence”.

It is noted that the mischief that the provision is addressing is set out in the Explanatory Memorandum to the Bill (see paragraphs 165 ff) and in the IPCR Committee's final report (see pages 162-3). It is also noted that both of these documents are extrinsic material that are able to be used in the interpretation of the Patents Act according to section 15AB of the *Acts Interpretation Act 1901*. Therefore the mischief this provision is addressing is already apparent from these sources. The provisions are drafted so that the legislative provisions contain the substantive legal test that must be applied. The description of the mischief sought to be cured is contained in the extrinsic material.

1.4.3.2 Promotion of competition

As explained above, it would be inconsistent with Australia's obligations under the AUSFTA for a compulsory licence to be granted for the purpose of *promoting* competition in the market. Under the AUSFTA, a compulsory licence can only be granted to remedy anti-competitive practices, and not for the purpose of promoting competition.

It is therefore not an option to insert an additional requirement along the lines suggested by Professor Corones.

In any event, in practice, it is to be expected that the grant of a compulsory licence would result in the entrance of a competitor into the marketplace, and that that would be likely to result in promoting competition in the market.

If, after grant of a compulsory licence, the patentee continues to act in breach of Part IV of the Trade Practices Act, then the patent may be revoked – paragraph 134(2)(b) as proposed to be amended. This is expected to result in the promotion of competition in the market, as continued breaches of the Trade Practices Act could lead to revocation of the patent and the patented invention subsequently being freely available to all competitors.

2. Responses to IPTA's submissions

2.2 *Schedule 1 – Revoking registration of trade marks etc.*

2.2.1 **Clarity of subsection 84A(4)**

IPTA raises concerns that new subsection 84A(4) is unclear as to when the twelve month period in which the trade mark owner can be notified of the proposed revocation of registration commences.

The wording proposed to be inserted into the Act, “within 12 months of registering the trade mark”, refers to a 12 month period commencing from when the particulars of the trade mark are entered onto the Register under the provisions of section 69 of the Trade Marks Act. This is the date that the trade mark is actually registered and becomes a registered trade mark.

Paragraphs 40 and 41 of the Explanatory Memorandum reinforce this, and remove any doubt as to when the 12 month period commences.

“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.”

2.2.2 **Uncertainty for owners of registered trade marks**

IPTA's submission asserts that the new provision gives “open slather” to the Registrar to revoke a trade mark registration, and therefore creates uncertainty for owners of registered trade marks.

A trade mark that has been registered incorrectly can affect owners of other competing trade marks, and can affect the public as a whole, as explained in the EM. The provisions are intended to balance these interests with those of the trade mark owner.

The new provisions set up a two-part test that must be satisfied before the Registrar is able to revoke the registration of a trade mark. The first part of the test requires the Registrar to be satisfied that the trade mark should not have been registered. This protects the public interest factor that invalid trade marks should not be on the Register of Trade Marks.

The second part of the test requires that, before revoking a registration, the Registrar must be satisfied that it is *reasonable* to revoke the registration, taking account of all the circumstances that existed when the trade mark became registered. The provisions provide a non-exclusive list of circumstances that must be taken into account in determining this. Paragraph 35 of the EM emphasises that the Registrar is to take account of *all* of the circumstances, and not only of the circumstances listed in this subsection.

This part of the test provides protection for the registered owner of the trade mark. It requires the Registrar to balance the inconvenience to the trade mark owner of having his or her registration revoked against the inconvenience to the public and to other affected parties of the incorrectly registered mark remaining on the Register.

The registered owner will, in each case, have an opportunity to convince the Registrar that revocation would be unreasonable in the particular circumstances. Under the provisions, the Registrar must give the registered owner an opportunity to be heard before the Registrar can revoke the registration.

One of the factors that must be taken into account includes any use that has been made of the trade mark. If, in light of such usage, the registered owner can convince the Registrar that it would be unreasonable to revoke the registration of the trade mark, then the registration would not be revoked.

In the scenario described in IPTA's submission that the trade mark owner has spent a considerable amount of money using the trade mark, including establishing licenses and authorising others to use the trade mark, the registered owner would have a strong argument that it is unreasonable for the Registrar to revoke the registration.

And if the trade mark owner would be exposed to liabilities and accusations of infringement with the potential for very expensive law suits if the trade mark was revoked, they would have a strong argument that revocation would be unreasonable.

The consequence of revocation of registration of a trade mark is *not* that the owner loses all rights to the trade mark – instead, the registered trade mark reverts to being a pending application for registration of a trade mark, as it was immediately prior to its being registered. The trade mark owner then has a further opportunity to have the trade mark examined, and once again accepted and registered.

2.2.3 Consultation on the twelve month period

IPTA raises concerns that further public consultation should be undertaken and more consideration given to whether the twelve month period is too long.

IP Australia consulted with interest groups on these provisions when they were first proposed in 2002. The response that IPTA provided at that time generally favoured the revocation of registration provisions, but IPTA preferred a time limitation of three or six months for the revocation to occur.

The trade mark system seeks to balance all of the interests that are affected by the system. The time period has been set at 12 months in order to balance the interests of the public and the owners of competing trade mark registrations with those of the trade mark owner.

In April 2006, IP Australia discussed the operation of the provisions with some interest groups, and it was agreed that practice documents would be developed, in conjunction with stakeholders, to ensure that the perspective of owners of trade marks who were likely to be affected by the provisions would be taken into account. Work on these guidelines has commenced, and it is intended that it will be progressed in consultation with stakeholders, including IPTA, before the new provisions commence.

2.3 Schedule 4 – Availability of documents about trade marks

IPTA questions the benchmark that IP Australia will apply in determining what documents are to be held confidentially within the Trade Marks Office, and believes that further

consultation on this issue is necessary. IPTA is also concerned about some operational details of the proposed new system.

IP Australia is in the process of undertaking further consultation as to how this system for availability of documents about trade marks will operate, and IPTA will be consulted in this process. This should address IPTA's concerns.

2.4 Schedule 5 – Relief from infringement of patents

IPTA notes that the option of obtaining exemplary damages appears to be only available where the plaintiff has sought an award of damages, and does not appear to be applicable where an order for an account of profits has been sought.

The Patents Act is to be amended to insert provisions for exemplary damages along the lines of subsection 115(4) of the Copyright Act. IPTA's comments apply equally to the corresponding provisions of the Copyright Act.

2.5 Schedule 6 – Exemption of continued prior use from patent infringement

2.5.1 The Government response to the IPCR report

IPTA states that, since the amendments to section 119 of the Patents Act go beyond the recommendations in the IPCRC final report, these amendments should have been available for public comment to allow the impact of them to be properly assessed.

The amendments implement the Government's response to the IPCRC report. That response went beyond the recommendations of the IPCRC report. The response was publicly released in August 2001. There has been ample time for interest groups to assess the impact of the proposed changes and to provide comments to the Government.

2.5.2 Interpretation of section 119 as proposed to be amended

IPTA considers that the amendments will create a new and broad non-infringement right that has the potential to significantly undermine the value of an Australian patent. This is based on their interpretation of how section 119 permits a prior user to do any of the actions included by the term "exploit". IPTA is also concerned that the amendments will not remove the uncertainty in section 119.

To remedy this situation, IPTA suggests that the prior use defence should be limited to the actual prior use or acts, or the uses or acts for which definite steps had been taken. Alternatively it should be made explicit that section 119 does not entitle a person to exploit an infringing product, method or process other than the specific product, method or process that was prior used.

The aim of section 119 is to provide that a person (the prior user) may do *any* act that exploits a product, method or process if, immediately before the priority date of the relevant claim, the prior user was exploiting the product, method or process (or had taken definite steps to do so).

This means that, if a person was making a product before the priority date, they may continue to make that product without infringing the patent. However, they may also do any other act that exploits *that product*, such as hiring or selling the product, without infringing the patent. This provides greater certainty for the prior user.

However, the drafting of the provision limits the prior use exemption to acts that exploit the particular product, method or process that the prior user had been exploiting previously. In other words, the prior user is *not* able to exploit other forms of the product, method or process that may be covered by the patent. The EM reinforces the limitation to the prior user's ability to exploit that particular product in paragraph 132.

Adopting the alternative approach suggested by IPTA would not remove the uncertainty in the provisions, and would be of little value to the prior user. For example, if the prior use act had been to *make* a particular product, and someone subsequently patents that product, the prior user would not be able to, for example, sell that product, as selling would be an infringement of the patent. This situation creates uncertainty for the prior user, as it is not clear what a prior user is able to do with a product he or she has made.

2.5.3 Assignment of the prior user's entitlement

IPTA is also concerned that section 119 will permit the assignment of the prior use right. In particular IPTA raises concerns that large multinational competitors will now look for and buy prior use rights, and that Australian innovators will be disadvantaged by this provision.

The Government's reason for enabling the prior use entitlement to be assignable was primarily to benefit Australian research-based organisations that do not commercialise their own inventions. It is intended to provide an incentive for further R&D to take place in Australia by allowing such organisations to profit from their work, and is expected to have the effect of stimulating innovation. It is expected to benefit consumers by providing increased choice in the market.

Australian companies will be treated in exactly the same manner as foreign companies when it comes to having a prior use exemption assigned to them – both will benefit equally. However, as only prior use within Australia is covered by the provisions, Australian innovators will benefit in this respect over foreign innovators.

Overall, the patent owner is still in a significantly better position than is the prior user. The patentee may enforce their proprietary patent rights against others, whereas the prior user will not have any such enforceable rights. In addition, the prior user will not be able to exploit any other form of the invention that is covered by the patent – their prior use right is limited to exploiting the particular product, method or process that was being exploited before the relevant priority date.

2.5.4 The corresponding UK provisions

IPTA indicates that the proposed amendments will result in the Australian legislation differing from that of our major trading partners, and cites the UK provisions which require assignment of the business when the prior user assigns their right.

Under the UK legislation, the assignment provision does not require assignment of the *entire* business. It merely requires assignment of “that part of the business in the course of which the act was done or the preparations were made”.

It would be inappropriate if a prior user exemption were only to be assignable with the *entire* business of the prior user. For example, a business may be involved in other activities in addition to the activities relating to the prior use. It should not be forced to assign its *entire* business simply in order to assign the part of the business that relates to the prior use.

If a business *does* assign its prior use entitlement under the proposed provisions, then it is no longer able to conduct that part of its business relating to that prior use. Therefore it is effectively assigning that part of its business relating to the prior use when it assigns the prior use entitlement. Therefore the proposed provision is not substantially different in this respect from the corresponding UK provisions.

Unlike the UK provisions, the prior use defence will not be limited to acts done in the course of a business, in order to allow for research institutions to benefit from the prior use defence. Therefore the Australian provisions will be quite deliberately different from the UK provisions in this respect.

2.6 Schedule 7 – Springboarding and Patents

IPTA considers that the new springboarding provisions should be restricted to patents granted on applications filed on or after commencement of the new provisions. Also IPTA believes that the proposed provisions contravene Section 51(xxxi) of the Constitution.

The application of these amendments to current patents is necessary to capture the benefits to the Australian generic industry of the current period of drug patent expiries. The Government believes that the provisions do not fall within the operation of Section 51(xxxi) of the Constitution. This issue ultimately remains for the courts to decide.

2.7 Schedule 8 – Compulsory licensing of patents

IPTA has no comments on the proposed amendment but suggests a possible clarification to the compulsory licence provisions in relation to a conflict between the “reasonable requirements of the public” test and section 136. IPTA’s submission does not relate to any provision of the Bill.

Article 17.9.7 of AUSFTA provides for the use of patents without authorisation by the right holder in the following circumstances:

- 17.9.7(a) – to remedy anti-competitive practices; and
- 17.9.7(b) – in cases of public non-commercial use, national emergency or other circumstances of extreme emergency.

In the AUSFTA, the term "anti-competitive practices" is interpreted broadly and covers the present compulsory licence provisions under the Patents Act. These provisions provide for the grant of a compulsory licence if, among other conditions, "the reasonable requirements of the public" have not been met.

As such, there is no conflict with section 136 of the Patents Act nor is there any issue of preferential or different treatment for US persons.