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

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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 is 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 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…
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> 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

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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

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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]

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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]

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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]

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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]

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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]

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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

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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 Europern 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-evergreening[47] 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

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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

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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

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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:
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> (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]

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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.

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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 Court[67] 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]

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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.

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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

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