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THE PARLIAMENT OF THE COMMONWEALTH OF AUSTRALIA

HOUSE OF REPRESENTATIVES

INTELLECTUAL PROPERTY LAWS AMENDMENT BILL 2006

EXPLANATORY MEMORANDUM

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

# INTELLECTUAL PROPERTY LAWS AMENDMENT BILL 2006

## Outline

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

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

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

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

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

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

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

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

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

## ***Financial Impact Statement***

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

## ***Regulation Impact Statements***

### **PRIOR USE**

#### **PROBLEM OR ISSUE IDENTIFICATION**

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

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

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

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

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

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

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

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

## OBJECTIVE

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

## IDENTIFICATION OF OPTIONS

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

### *Option 1*

Retain section 119 in its current form.

### *Option 2*

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

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

### *Option 3*

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

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

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

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

## IMPACT ANALYSIS:

### *Impact group identification*

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

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

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

### Option 1: Retain the current section 119

#### *Costs*

#### **Industry**

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

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

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

### **Consumers**

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

### **Government**

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

### *Benefits*

### **Industry**

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

## **Consumers**

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

## **Government**

- No legislative change will be needed.

Option 2: Adopt the recommendation of the IPCR Report

### *Costs*

## **Industry**

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

## **Consumers**

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

## **Government**

- Legislative change will be required.

### *Benefits*

## **Industry**

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

## **Consumers**

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

## **Government**

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



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

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

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

### *Costs*

#### **Industry**

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

#### **Consumers**

- There will be not net costs to consumers.

#### **Government**

- Legislative change will be required.

### *Benefits*

#### **Industry**

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

#### **Consumers**

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

#### **Government**

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

## CONSULTATIONS

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

## CONCLUSION AND RECOMMENDED OPTION

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

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

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

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

## IMPLEMENTATION AND REVIEW

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

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

## COMPULSORY LICENCES

### PROBLEM OR ISSUE IDENTIFICATION

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

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

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

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

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

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

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

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

## OBJECTIVE

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

## IDENTIFICATION OF OPTIONS

The government has the following three options:

### *Option 1*

Continue to apply the existing compulsory licensing provisions.

### *Option 2*

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

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

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

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

### *Option 3*

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

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

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

## IMPACT ANALYSIS:

### *Impact group identification*

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

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

### Option 1: Continue to apply existing compulsory licensing provisions

#### *Costs*

##### **Industry**

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

##### **Consumers**

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

##### **Government**

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

#### *Benefits*

##### **Industry**

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

##### **Consumers**

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

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

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

### **Government**

- No legislative change will be needed.

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

### *Costs*

### **Industry**

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

### **Consumers**

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

### **Government**

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

## *Benefits*

### **Industry**

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

### **Consumers**

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

### **Government**

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

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

## *Costs*

### **Industry**

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

### **Consumers**

- There should be no costs to consumers.

### **Government**

- There should be no costs to Government.

## *Benefits*

### **Industry**

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



## **Consumers**

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

## **Government**

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

## **CONSULTATIONS**

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

## **CONCLUSION AND RECOMMENDED OPTION**

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

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

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

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

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

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

## IMPLEMENTATION AND REVIEW

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

# SPRINGBOARDING ON PHARMACEUTICAL PATENTS

## BACKGROUND

### Pharmaceuticals Industry in Australia

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

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

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

### Generic Pharmaceuticals Industry in Australia

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

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

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

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

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

#### Current Springboarding Provision

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

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

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

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

## PROBLEM

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

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

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

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

## OBJECTIVES

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

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

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

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

## OPTIONS

### *Option 1 – Status Quo*

Maintain the status quo.

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

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

## IMPACT ANALYSIS

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

### **Business**

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

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

### Government

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

### Consumers

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

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

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

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

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

Table 1: Option 1

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

Table 2: Option 2

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

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

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

## CONSULTATION

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

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

Table 3: Summary of consultation

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

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

**CONCLUSION AND RECOMMENDED OPTION**

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

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



## Notes on Clauses

### **Clause 1—Short title**

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

### **Clause 2—Commencement**

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

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

### **Clause 3—Schedule**

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

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

#### *Trade Marks Act 1995*

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

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

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

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

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

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

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

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

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

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

## Item 1

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

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

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

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

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

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

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

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

## Item 2

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

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

### **Item 3**

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

### **Item 4**

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

### **Item 5**

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

### **Item 6**

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

### **Item 7**

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

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

## **Section 84A**

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

## **Section 84B**

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

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

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

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

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

## **Section 84C**

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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



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

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

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

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

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

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

### **Section 84D**

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

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

### **Item 8**

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

### **Item 9**

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

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

*Trade Marks Act 1995*

### **Items 1 and 2**

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

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

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

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

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

*Trade Marks Act 1995*

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

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

80. In order to obtain a CTM:

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

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

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

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

#### **Item 1**

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

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

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

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

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

## **Item 2**

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

## **Item 3**

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

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

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

## **Item 4**

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

## **Item 5**

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

## **Item 6**

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

## **Item 7**

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

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

### **Item 8**

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

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

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

### **Item 9**

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

### **Item 10**

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

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

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

### **Item 11**

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

### **Item 12**

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

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

### **Item 13**

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

### **Item 14**

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

### **Item 15**

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

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

### **Item 16**

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

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

### *Trade Marks Act 1995*

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

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

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

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

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

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

### **Item 1**

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

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

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

### **Item 2**

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

### **Item 3**

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

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

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

#### **Item 4**

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

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

*Patents Act 1990*

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

#### **Item 1**

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

#### **Item 2**

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

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

*Patents Act 1990*

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

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

#### **Item 1**

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



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

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

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

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

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

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

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

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

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

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

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

## **Item 2**

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

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

### *Patents Act 1990*

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

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

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

## **Items 1 and 2**

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

## **Item 3**

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

#### **Item 4**

161. Item 4 is an application provision.

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

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

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

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

*Patents Act 1990*

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

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

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

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

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

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

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

### **Item 1**

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

### **Item 2**

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

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

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

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

### **Item 3**

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

### **Item 4**

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

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

## **Item 5**

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

## **Item 6**

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

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

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

## **Item 7**

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

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

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

## **Item 8**

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

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

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

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

## **Item 9**

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

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

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

*Patents Act 1990*

### **Item 1**

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

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

### **Item 2**

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

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

*Patents Act 1990*

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

### **Item 1**

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

### **Item 2**

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

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



### **Item 3**

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

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

*Trade Marks Act 1995*

*Plant Breeder's Rights Act 1994*

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

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

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

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

### **Items 1 and 3**

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

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

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

### **Items 2 and 4**

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

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

*Designs Act 2003*

*Olympic Insignia Protection Act 1987*

*Patents Act 1990*

*Plant Breeder's Rights Act 1994*

*Trade Marks Act 1995*

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

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

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

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

### **Item 1**

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

### **Items 2–4, 7-8**

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

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

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

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

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

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

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

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

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

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

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

## **Item 5 and 6**

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

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

## **Schedule 13—Extension of time**

### *Trade Marks Act 1995*

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

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

### **Item 1**

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

### **Item 2**

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

## **Schedule 14—Approving forms**

### *Plant Breeder’s Rights Act 1994*

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

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

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

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

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

### **Item 1**

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

### **Item 2**

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

### **Item 3**

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

## **Schedule 15—Delegation**

*Designs Act 2003*

*Plant Breeder's Rights Act 1994*

### **Item 1**

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

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

### **Item 2**

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

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

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

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

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

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

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

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

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

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

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

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

### **Item 3**

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

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

*Patents Act 1990*

*Trade Marks Act 1995*

### **Item 1**

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

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

## **Item 2**

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

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

## **Item 3**

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

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