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THE PARLIAMENT OF THE COMMONWEALTH OF AUSTRALIA

SENATE

INTELLECTUAL PROPERTY LAWS AMENDMENT

(RAISING THE BAR)

BILL 2011

EXPLANATORY MEMORANDUM

(Circulated by authority of the Minister for Innovation, Industry, Science and Research, the Honourable Kim Carr)

INTELLECTUAL PROPERTY LAWS AMENDMENT (RAISING THE BAR) BILL 2011

OUTLINE

The objective of the intellectual property (IP) rights system is to support innovation by encouraging investment in research and technology in Australia and by helping Australian businesses benefit from their good ideas. The purpose of this Bill is to make improvements to IP rights legislation to better meet these objectives.

The Bill's amendments to the *Patents Act 1990*, the *Trade Marks Act 1995*, the *Copyright Act 1968*, the *Designs Act 2003* and the *Plant Breeder's Rights Act 1994* can be divided into six categories, corresponding to the following six schedules:

- Schedule 1 - Raising the quality of granted patents
- Schedule 2 – Free access to patented inventions for regulatory approvals and research
- Schedule 3 – Reducing delays in resolution of patent and trade mark applications
- Schedule 4 - Assisting the operations of the IP profession
- Schedule 5 - Improving mechanisms for trade mark and copyright enforcement
- Schedule 6 – Simplifying the IP system

Schedule 1: Raising the quality of granted patents

In order to meet its objective of supporting innovation, the patent system must strike a balance. It must provide sufficient protection to reward innovation, but not so much protection as to block future or follow-on innovation. Concerns have been raised that the thresholds set for the grant of a patent in Australia are too low, suppressing competition and discouraging follow-on innovation. Particular concerns have been raised that patents are granted for inventions that are not sufficiently inventive, and that the details of inventions are not sufficiently disclosed to the public.

These concerns were recognised in the 2008 review of the national innovation system '*Venturous Australia'* and the Government's response to this review: *Powering Ideas*: *the innovation agenda for the 21st century.*

The Bill amends the Patents Act to address four key areas of patentability.

First, the Bill amends the Patents Act to remove restrictions on the information and background knowledge taken into account when assessing whether an application is sufficiently inventive to justify a patent. This will raise the standard set for inventive step in Australia to a level that is more consistent with standards set in our major trading partners.

Secondly, the amendments bolster the requirement that a patented invention be useful: that is, that the invention works in the way that the patent says it does and that the specification explains how the invention works. The amendments strengthen this requirement to prevent the grant of patents for speculative inventions that require too much further work before they can be put into practice.

Thirdly, the Bill raises the standards set for disclosure of an invention. A patent is a compact between an inventor and the state: in exchange for a time-limited exclusive right to exploit an invention, a patentee must give the public sufficient information to make and use the invention. In this way the patentee is rewarded for what they have done and the public has access to the information necessary to conduct follow-on innovation and to make and use the invention once the patent has expired. The amendments address circumstances where the information disclosed in a patent specification, although sufficient to make one thing within the scope of each claim, is not sufficient to make the invention across the full scope of each claim. The changes ensure that granted patents are no broader than the invention which has been disclosed.

Fourthly, the Bill amends the Patents Act to increase certainty in the validity of granted patents. Currently, the Commissioner is limited in the grounds she can consider when deciding whether to grant a patent, or whether to revoke a patent after re-examination. In contrast the courts can consider a wider range of grounds. As a consequence, a patent correctly granted by the Commissioner may be subsequently found invalid by the courts. The change will expand the grounds that the Commissioner can consider, and apply a consistent standard of proof across all grounds, so that the Commissioner is not obliged to grant patents which would not pass scrutiny in a court challenge.

Schedule 2: Free access to patented inventions for regulatory approvals and research

The patent system grants exclusive rights to commercialise and exploit inventions free of competition. Research, as such, does not affect this. However, currently there is no statutory provision clarifying researchers' freedom to conduct experiments and there is uncertainty about the scope of any existing common law protection. This leads to inefficiencies in research. Researchers are discouraged from taking up new lines of research where there is uncertainty about their liability for patent infringement. Uncertainty also leads to researchers expending effort and expense on seeking advice, where they have concerns about how their experiments intersect with the patent system.

The Bill amends the Patents Act to draw a line between research and commercial activities, leaving researchers free to conduct their experiments without worrying about the patent system. The amendments are designed to clarify that research and experimental activities relating to patented inventions are exempt from infringement, whereas commercial activities are not. The intent is to give broad and clear protection to research and experimental activities in order to maximise the potential for research in Australia.

The Bill also introduces an exemption for activities undertaken solely for the purpose of gaining regulatory approval to market or manufacture a patented technology. This

expands the existing exemption for pharmaceutical inventions to all technologies; recognising that technologies other than pharmaceuticals may also suffer delays in bringing products to market as a consequence of lengthy pre-market and pre-manufacturing regulatory approval processes.

Schedule 3: Reducing delays in resolution of patent and trade mark applications

The patent and trade mark systems also need to strike a balance between giving sufficient time to get applications in order for grant or registration and minimising delays in giving certainty about whether a right will be granted, and what scope that right will have.

Two elements of the current patents and trade marks systems, in particular, lend themselves to lengthy delays in applications proceeding to grant or registration. These are patents and trade marks opposition proceedings and divisional patent applications (which occur when part of an application is divided out into a new application). Currently opportunities exist for a party, usually an applicant but sometimes also a competitor, to substantially delay finalisation of these elements. Delay may suit the party, but it is not in the interests of the public, or the party's competitors.

The Bill amends the Patents and Trade Marks Acts to refine opposition proceedings to better meet their intended purpose as a means for settling disputes quickly and inexpensively. The Bill also amends the Patents Act to tighten the timeframes within which divisional applications can be filed, reducing opportunities for abusive use of these types of application.

Schedule 4: Assisting the operations of the IP profession

Patent and trade mark attorneys play a valuable role in assisting businesses and innovators to negotiate the IP system and protect their good ideas. Currently, there are anomalies between the ways in which patent and trade mark attorneys can conduct their business and the ways in which other professionals can operate, specifically the legal profession. The Bill amends the Patents and Trade Marks Acts to allow attorneys to incorporate and to extend to client-attorney communications the same privilege as currently exists for communications between a lawyer and their client. The changes will help patent and trade mark attorneys deliver professional high quality services to their clients.

Schedule 5: Improving mechanisms for trade mark and copyright enforcement

Effective enforcement of trade marks and copyright is a significant issue for rights owners, who have worked to establish their brand in the marketplace and do not want to see others take unfair advantage of their hard work. Stakeholders have raised concerns that the penalties for trade mark counterfeiting are lower than those for copyright infringement and insufficient to deter infringers. Concerns have also been raised that the current system for confiscating imported counterfeit trade mark and copyright goods is inadequate. The Bill amends the Trade Marks and Copyright Acts to bolster the penalties for trade mark infringement and to improve the system for confiscating counterfeit goods.

Schedule 6: Simplifying the IP system

An ever present challenge for the IP rights system is to balance the level of complexity necessary to ensure a robust system with the need for the system to be accessible and cost effective to a wide range of users.

The Bill amends the Patents, Trade Marks, Designs and Plant Breeder's Rights Acts to implement a number of fixes to the system to remove procedural hurdles, streamline processes and make improvements to ensure that the system is fit for purpose in an increasingly electronic and globalised business environment.

FINANCIAL IMPACT STATEMENT

The Bill is expected to have no financial impact on the Commonwealth.

REGULATION IMPACT STATEMENT

The following Regulation Impact Statements apply only to the items in Schedule 2.

Exemptions to Patent Infringement: Experimental Use

PROBLEM

Background

1. The last 20 years has seen a shift in the Australian economy from a reliance on traditional resource and agricultural industries, to industries such as banks, financial services, telecommunications and retailers which rely heavily on intellectual property.[1] Even in traditional industries, the intellectual property underpinning Australian innovation has substantially contributed to increases in productivity and efficiency. Australia now ranks amongst the top innovative economies in the world[2], with the total value of Australia's intellectual property standing at about AU$30 billion.[3]

2. One of the keystones of an innovative economy is its intellectual property regime.[4] For a country such as Australia, which is a net importer of technology, a strong and well regulated IP regime encourages the flow of innovation, technology and knowledge into the country by giving importers confidence that their technology will be protected from copying. This gives Australians access to new technology and helps Australian businesses which rely on foreign technology to remain competitive. Intellectual property is also vital for companies to attract investment to fund research, generate returns on investment and continue the cycle of innovation. These activities support economic growth and competitiveness.[4]

3. The patent system is a key element in the intellectual property system. It encourages business to invest in innovation by providing innovators with exclusive rights to commercialise their inventions. The rights conferred by a patent are defined

[1] Wilson T., 'Intellectual Property and the Australian Economy', Institute of Public Affairs, 2008, , http://www.ipa.org.au/library/publication/1219635913_document_080612_-_paper_-_ip_and_the_australian_economy_in.pdf>.
[2] Gans J. *et al*., 'Assessing Australia's Innovative Capacity: 2006 Update', Melbourne Business School and Intellectual Property Research Institute of Australia, 2006.
[3] Department of Foreign Affairs and Trade, 'Intellectual Property and International Trade', viewed 25 September 2009 at <http://www.dfat.gov.au/ip/>.
[4] Zink R., 'The role of IP in promoting economic growth through innovation', *Intellectual Asset Management*, pp. 23-29, May/June 2009.

in s 13(1) of the *Patents Act 1990*, which provides that the patentee has the exclusive rights during the term of the patent (generally 20 years) to 'exploit' the invention or authorise another person to exploit the invention. The term 'exploit' is defined in the Patents Act as follows:

> ***exploit***, in relation to an invention, includes:
>
> (a) where the invention is a product—make, hire, sell or otherwise dispose of the product, offer to make, sell, hire or otherwise dispose of it, use or import it, or keep it for the purpose of doing any of those things; or
>
> (b) where the invention is a method or process—use the method or process or do any act mentioned in paragraph (a) in respect of a product resulting from such use.

4. In exchange for patent protection inventors must disclose information about their inventions and how they work. The information is published, which helps subsequent innovators to build on previous innovations and enables the public to perform inventions once patents have ceased.

The problem

5. A second keystone of an innovative economy is a strong and active research community. The patent system supports research by encouraging investment in the research that underpins development of new technologies. However, this support is reduced where there is uncertainty about the overlap between patent rights and researchers' freedom to operate. Such uncertainty currently exists in Australia.

- It is widely assumed that a common law experimental use exemption exists alongside the patent system and it is likely that a court would find that, *in some circumstances*, use of a patented invention for experimental or research purposes would not constitute an infringement of a patent. However it is difficult to predict how broadly or narrowly an Australian court would interpret the scope of an experimental or research exception.[8]

- In countries where there is no statutory experimental use provision, courts have struggled to ascertain the scope of the exemption or have applied overly restrictive tests that are potentially detrimental to research. For example, a recent US case considered the existence and scope of the common law experimental use exemption in the United States.[5] Consistent with earlier court decisions this defence was interpreted narrowly, finding that it was dependent on the experiments involved being 'for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry'.[6] There have been suggestions that this decision has adversely impacted on research organisations that previously thought they were subject to a broader experimental use exemption.[7]

[5] *Madey v Duke University* 307 F 3d 1351, 1362 (Fed. Cir. 2002)
[6] *Roche Products Inc. v Bolar Pharmaceutical Co., Inc.,* 733 F.2d, 858, 863 (Fed. Cir. 1984)
[7] See for example, Donaldson R., 'An update on the proposed experimental use exemption to patent infringement', Australian Intellectual Property Law Bulletin, 19(9), pp. 147-148 (2007).

- Whilst there is no strong empirical evidence of patents preventing follow-on innovation in Australia[8], it has been cautioned that an absence of evidence in Australia is not an absence of a problem, and that 'it is risky to assume that the present lack of evidence is indicative of future trends'.[9] Anecdotal evidence from a survey of Australian researchers and research institutions[10] showed that there is considerable uncertainty among researchers in respect of where they have freedom to operate around patented technology. This study considered survey responses from 49 companies, 23 research institutions and 18 genetic testing laboratories. About 40 interviews were also held with respondents. The researchers concluded that a 'practice-based' research exemption had developed in Australia, under which companies were loathe to enforce their rights against researchers because it would have a negative effect on the company's image and because research institutions generally lack financial resources to make legal challenge worthwhile. However the study also cautioned that this attitude may not continue into the future.

6. The absence in Australia of both statute and case law provides researchers and business with little guidance as to whether or not experimental use of a patented invention constitutes an infringement. As a consequence the potential for litigation may deter businesses and researchers from researching in areas covered by patents. This could have significant impact on Australian business by inhibiting research, or driving it overseas to countries with more favourable experimental use provisions, leading to a loss of research investment in Australia.

7. It was in view of such concerns that the Advisory Council on Intellectual Property (ACIP) was asked by the then Minister for Industry, Tourism and Resources to examine whether patents are inhibiting research and development and determine whether Australian research and business would benefit from introducing an experimental use provision. ACIP recommended that the Patents Act be amended to incorporate an experimental use exemption, and after consideration of a number of options arrived at a preferred form of exemption. Around the same time, the Australian Law Reform Commission (ALRC) considered similar issues as part of a review of the impact of gene patents, and they also recommended introduction of an experimental use exemption. Strong support for the introduction of an experimental use provision was also voiced by research and academic institutions in a recent Senate enquiry into gene patents.[11]

8. The research and academic communities have repeatedly expressed concerns that uncertainty about where there is freedom to operate is negatively impacting on research activities. The current reforms seek to introduce such an experimental use exemption.

[8] Advisory Council on Intellectual Property, 'Patents and Experimental Use, October 2005 at page 22.
[9] McBratney A. *et al.,* 'Australia Experiments with Experimental Use', *Nature Biotechnology* p22, 2004.
[10] D Nicol and J Nielsen, Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry (2003) Centre for Law and Genetics Occasional Paper No 6.
[11] Senate Standing Committee on Community Affairs Inquiry into Gene Patents, 2009

Government regulation

9. There is no existing government regulation in Australia to deal with this problem.

OBJECTIVE OF GOVERNMENT ACTION

10. The key objectives are to ensure that patent rights do not inhibit follow-on or cumulative research, and to provide researchers and users of the patent system with greater certainty about where there is freedom to operate.

OPTIONS THAT MAY ACHIEVE THE OBJECTIVE

11. Options may be broadly grouped as follows:

- Option 1: No change.

  Under this option, no action would be taken and the existence and application of an experimental use exemption would be left to the courts to determine.

- Option 2: Introduce an express provision allowing for experimental use.

  Under this option, the Act would be amended to introduce an exemption from infringement for use of the patented invention for experimental purposes. Further guidance on the scope and application of the exemption would be provided by an inclusive list of experimental acts. The specific list of experimental acts would be developed taking into account recommendations from ALRC and ACIP, as well as overseas law and practice and international norms.

- Option 3: Modify the definition of exploit to not include experimental use.

  Under this option the Act would be amended so that the definition of exploit would not include experimental use. This could be achieved by adding the phrase 'other than experimental uses' or 'other than for experimental purposes' to the current definition.

12. In developing their recommended experimental use exemption, ACIP also considered options that expressly preclude experimental use as an allowable activity. These have not been considered here as they would not meet the Government objective of ensuring that patents do not inhibit follow-on research. Moreover, ACIP concluded that such options did *'not address the main concerns of many researchers, particularly with regard to cumulative innovation, and that it would broaden patent rights to a point where total innovation levels may become sub-optimal'*.[12]

13. Introducing an exemption for fair experimentation using an analogous concept in copyright was also considered and disregarded by ACIP because it provided insufficient guidance for courts and ran the risk of Australian law breaching the

[12] ACIP, *'Patents and Experimental Use, Options Paper'*, December 2004.

TRIPS agreement. For these reasons this option was not considered here as it would not meet the Government's objective.

14. These three options are considered in more detail below.

IMPACT ASSESSMENT

Who would be affected by each option?

15. The groups which would be impacted by each of these options are, broadly speaking:

- Patent holders (This group will be taken to include applicants for patent rights whose applications have not yet been determined.)
- Researchers
- Consumers
- Government. (This group will be taken to include all arms of government which are involved in the administration of the patent system: the executive arm of government, the Parliament, and the courts.)

Impacts of each option

16. The anticipated impacts of the options are outlined below.

Option 1: No change

17. This option maintains the *status quo*, and relies only on the courts to develop case law as and when required.

18. If the courts were to consider the question, there is a good chance that the courts would interpret any existing common law exemption narrowly, as has been the case in the US. In the past in patents cases the courts have recommended looking to US law as a guide.[13]

19. As noted in one submission to ACIP consultation: 'while this uncertainty does not in itself appear to be hampering Australia's research effort, if the Australian courts were to adopt the approach that has been applied in the United States, the impact on our public sector research institutions is likely to be significant'.[14] For example a 2005 US survey of industry and academic researchers found that patents had caused 58% of respondents to delay their research, 50% to change their research and 28% to abandon a research program.[15]

[13] *Lockwood v Doric* [2004] HCA 58
[14] ACIP report at page 35.
[15] American Association for the Advancement of Science survey, 'The Effects of Patenting in the AAAS Scientific Community', viewed on 11 November 2009 at <http://sippi.aaas.org/survey/AAAS_IP_Survey_Report.pdf>

20. In the absence of the courts considering the question the current uncertainty and disincentives to the research and academic community will remain.

Option 2: Introduce an express provision allowing for experimental use

21. Under this option the Patents Act would be amended to clarify that research and experimental activities are exempt from patent infringement. This option is consistent with the recommendations made by ACIP and the ALRC in their respective reviews of aspects of the patent system.

22. It is also consistent with the approaches taken in a number of other countries that either currently have experimental use exemptions or are seeking to implement such a provision. Countries include Japan, the United Kingdom, Germany, Switzerland and Belgium. New Zealand is currently seeking to introduce an exemption based on ACIP's recommendation into the patents legislation.

23. ACIP's preferred exemption was based on a corresponding European provision, as follows:

> The rights of a patentee are not infringed by acts done for experimental purposes relating to the subject matter of the invention that do not unreasonably conflict with the normal exploitation of a patent.
>
> Acts done for experimental purposes relating to the subject matter of the invention include:
>
> - determining how the invention works;
>
> - determining the scope of the invention;
>
> - determining the validity of the claims;
>
> - seeking an improvement to the invention.[16]

24. Similarly, the ALRC recommended that[17]:

> The Commonwealth should amend the Patents Act 1990 (Cth) (Patents Act) to establish an exemption from patent infringement for acts done to study or experiment on the subject matter of a patented invention; for example, to investigate its properties or improve upon it.
>
> The amendment should also make it clear that:
>
> (a) the exemption is available only if study or experimentation is the sole or dominant purpose of the act;
>
> (b) the existence of a commercial purpose or objective does not preclude the application of the exemption; and

[16] The ACIP report, Recommendation 1 at page 5.
[17] The ALRC report, Recommendation 13-1.

(c) the exemption does not derogate from any study or experimentation that may otherwise be permitted under the Patents Act.

Costs

25. The key cost to patent holders and researchers would be acquiring familiarity with the new legislative arrangements. As with all new legislation there would be some uncertainty initially about the boundaries of the exemption. This could only be fully resolved if and when the courts considered the scope of the exemption.

26. The cost to government under this option would be the cost of amending and administering the new legislative provision and resolving any legal disputes which might arise.

Benefits

27. The key benefits to researchers would be that the limits to patent rights would be clarified, thus reducing uncertainty and resulting inefficiencies and underperformance in the research industry. Increased certainty would also benefit patent holders who would have greater clarity around when to, and when not to enforce their patent rights.

28. Removal of the uncertainty that is widely regarded as a disincentive to research would benefit consumers by improving research performance and activity, leading to increased follow-on innovation and access to new technologies.

29. The option would not have any direct benefits to Government.

Option 3: Modify the definition of exploit to not include experimental use

30. ACIP considered that since a patent provides the owner with the exclusive rights to 'exploit' the invention, one of the ways of limiting these rights would be to modify the definition of exploit. This could limit the definition to those exploitative activities which have a direct commercial outcome. Other activities such as those experimentations which do not directly infringe the commercial interests of the patent holder might then be excluded from the definition.

31. To achieve this, the definition of exploit in the Act would be amended to add the phrase 'other than experimental uses' or 'other than for experimental purposes'. There would not be any further explanation of the meaning of the term.

32. This would involve minimal changes to an existing provision in the Act and clarify that there is an inherent limit on the scope of patent rights. It would also allow the law to evolve over time.

33. However ACIP concluded that such evolution of law could be slow leaving users of the system with too little guidance. Further, courts could have too much flexibility, which could result in law which breaches international patent law treaties such as the Agreement on Trade Related Aspects of Intellectual Property Rights

(TRIPS Agreement). Stakeholders also believed that this option would provide insufficient clarity for users and not significantly improve the current situation.

34. These factors therefore suggest that overall levels of innovation in Australia would not be optimised which would run counter to the Government's objective.

CONSULTATION

The consultation process

35. There has been extensive consultation on the issue of experimental use through the ACIP and ALRC reports, as well as subsequent consultations by IP Australia.

36. In February 2003 ACIP was asked by the former Government to examine whether certain patents were inhibiting research and development in Australia, and whether an experimental use exemption would help researchers more effectively use the patent system to commercialise their research and development.

37. The ACIP review commenced in November 2003 with the circulation of a questionnaire to several hundred recipients, including tertiary research institutes and universities, IP professionals and businesses. The questionnaire sought to gather data on current views and practices regarding the experimental use of patented inventions. Forty four responses were received. Using information from the questionnaire, an issues paper was subsequently released in February 2004 which sought responses to a number of questions on the existing law and policy issues. Forty two submissions were received.

38. ACIP then released an options paper in December 2004. This discussed various actions that could be taken, and set out four specific options for comment that were considered to meet the terms of reference. Thirty five responses were received. The final ACIP report was released in November 2005. This made a number of recommendations around experimental use and set out a preferred statutory experimental use exemption.

39. In December 2002, the ALRC was asked by the then Attorney-General to undertake a review of intellectual property rights over genes and genetic material, with a particular focus on human health issues. An issues paper was released in July 2003 that set out 62 targeted questions that were designed to identify the main issues of relevance to the Inquiry. A subsequent discussion paper provided a more detailed discussion of issues and identified 49 proposals for reform. A total of 119 written submissions were received by the Inquiry. The Inquiry also held 73 meetings involving several hundred individuals. The final report, released in June 2004, included a recommendation for the incorporation of an experimental use exemption in the Patents Act.

40. In September 2006, IP Australia released a consultation paper seeking comment on each of the ACIP and ALRC recommendations for an experimental use exemption. The paper sought views as to which of the recommendations would be most effective. Twenty submissions were received in response.

41. A further consultation was undertaken in March 2009 by IP Australia. This paper took into account the ACIP and ALRC recommendations, as well as corresponding overseas provisions, and proposed some wording for an experimental use provision.

42. Thirty five responses to the paper were received, with 34 providing strong in-principle support for introduction of a research exemption. A second round of consultation on proposals for reform, including an experimental use exemption, commenced in November 2009.

43. The proposal put forward in the March 2009 consultation paper comprised an exclusive list of purposes with the experimental acts being solely for such purposes. A key issue raised in consultations was that this did not reflect the nature of research, which was seldom solely for a single purpose. The use of an exclusive list was also seen as being less favourable than the inclusive style of exemption developed by ACIP. IP Australia has responded to such concerns in the latest consultation by proposing an inclusive style of exemption and removing the term 'solely'. Consultations in relation to this proposal were completed in February 2010.

Views expressed during the consultation process

44. As noted above, the views expressed during consultation strongly supported introduction of a research exemption. The main debate was around the specific detail of the wording of the exemption, rather than about whether or not an exemption was appropriate.

45. The submission made by the Intellectual Property Research Institute of Australia in their submission to IP Australia's March 2009 consultation paper neatly summarise two of the key arguments put forward during consultation:

- The current system is uncertain and warrants a statutory change to provide certainty to industry and research organisations.
- Confusion and uncertainty in the boundaries around permissible behaviour leads to economic loss.

How stakeholders' views have been taken into account

46. Stakeholder views on the specific details of the proposed exemption have been taken into account in preparation of the drafting instructions. As noted above, IP Australia has modified its original proposal by removing the term 'solely' and proposing an inclusive, rather than exclusive list of activities that are exempt from infringement.

47. Issues such as compliance with treaty provisions have been taken into account through standard governmental processes.

CONCLUSION AND PREFERRED OPTION

48. Option 2, which proposes introducing a statutory research exemption, is the preferred option. This option reduces uncertainties for both researchers and patent holders by explicitly clarifying the limits to patent rights.

49. In contrast option 1 and option 3 do not provide the desired certainty and clarity for researchers and patent holders. Therefore neither option would meet the Government's objective and provide these benefits.

50. The proposed statutory exemption would not result in any additional costs for patentees, business and researchers, and indeed will reduce the need for parties to obtain legal advice on whether their activities constitute an infringement of a patent. Accordingly the benefits of this option are considered to exceed the costs. It also takes into account the recommendations made by ACIP and ALRC.

51. It is therefore recommended that option 2 be endorsed.

IMPLEMENTATION AND REVIEW

52. Amendments to the Act would be required to implement the preferred option for experimental use.

53. However, the operation of a provision in the Act 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. The exemption is intended to apply to all non-expired patents whether granted before or after date of commencement. The exemption will apply to all acts done on or after the date of commencement. The exemption will not apply to acts done prior to the date of commencement.

54. Review of the provision is anticipated to be in accordance with the Government's five-yearly review requirements.[18] No specific requirements or arrangements would be required.

[18] See the Office of Best Practice Regulation's *Best Practice Regulation Handbook*, August 2007, Chapter 2. See <http://www.finance.gov.au/obpr/about/index.html>.

Exemptions to Patent Infringement: Exemptions for Regulatory Studies

PROBLEM

Background

1. The aim of the patent system is to promote innovation. One way it meets this aim is by the grant of patent rights—the exclusive right to exploit inventions in Australia. In general, this right persists for a maximum of 20 years.[19]

2. After the expiry of a patent, any third party is able to exploit a product or process that was previously protected by the patent. For example, a competitor is then able to make and use the previously patented invention and sell previously patented products in competition with the former patent holder. These competing products are often referred to as 'generic' products.

3. This increased competition can reduce the prices to consumers:

- Overseas studies evidence that consumers can benefit greatly from the competition generic products provide. In the case of pharmaceuticals, entry into the market by generic manufacturers can lead to significant price reductions, up to 90 percent over time.[20]

- In Australia too, generic pharmaceuticals cost less to consumers than branded products.[21] For example, the average price of a generic pharmaceutical in Australia is about $13, while the average corresponding branded product is about $40.[22]

- A similar trend occurs in the field of agricultural chemicals. For example, when the insecticide Bifenthrin came off-patent in 2004, the price fell from $170 per kg to $70 per kg.[23]

4. The sooner after patent expiry a generic product can be released, the sooner the benefits to the consumer will accrue.

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[19] The exception to this is the extensions of term of standard patents relating to pharmaceutical substances, which are available under Part 3 of Chapter 6 of the Patents Act.
[20] US Food and Drug Administration, *'Generic Competition and Drug Prices'*, viewed on 28 July 2009 at <http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm129385.htm>. *Pharmaceutical Sector Inquiry Final Report*, European Commission, 8 July 2009, see eg para (212) which reports price drops of 80-90% in 'rare cases'.
[21] Beecroft G., 'Generic drug policy in Australia: a community pharmacy perspective', *Australia and New Zealand Health Policy*, 2007, 4:7, available at <http://www.anzhealthpolicy.com/content/4/1/7>.
[22] Beecroft G., 'Generic drug policy in Australia: a community pharmacy perspective', *Australia and New Zealand Health Policy*, 2007, 4:7, available at <http://www.anzhealthpolicy.com/content/4/1/7>.
[23] *Submission to the Senate Select Committee on the Free Trade Agreement between Australia and the United States of America*, Pastoralists and Graziers Association of W.A. (Inc) and Generic Agricultural Chemical Association, May 2004, accessed on 22 February 2010, <http://www.aph.gov.au/senate_freetrade/submissions/sub533.pdf>.

5. There are significant advantages for generic manufacturers who enter the market soon after the expiry of a patent. One report indicates that the first generic manufacturer can increase their market share by around 30 per cent over a period of at least 4 years[24], and another indicates that market shares can be increased by 50 per cent within one year.[25]

6. However, some products must undergo a regulatory approval process before they can be marketed. Such processes include those conducted by the Therapeutic Goods Administration (TGA) for medicines, medical devices etc, the Australian Pesticides and Veterinary Medicines Authority (APVMA) for agricultural and veterinary chemical products, and the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) for industrial chemicals.

7. This process takes some period of time, ranging from weeks to years—its duration differs for different technologies and for different products. There is evidence that review times can be as short as 3 to 8 weeks[26], can be around 12 to 18 months[27], or even take as long as 40 months.[28]

8. In the case of a generic version of a patented product, this regulatory approval process usually cannot be undertaken, at least in Australia, before patent expiry. The approval process frequently involves steps which would infringe the patent covering the branded product.[29]

9. So for products of this nature, regulatory approval processes can postpone entry of generic products onto the market. Entry of competing products can be postponed by two factors:

- the time taken for the generic manufacturer to perform the necessary research and development needed to perform whatever tests and trials might be required, and generate the data that are necessary, to obtain regulatory approval for the product

[24] Hollis A., "Economics of the Pharmaceutical Industry. The importance of being first: evidence from Canadian Pharmaceuticals', *Health Economics*, 11(8), pp. 723-734, 2003.
[25] *Misuse of patent and drug regulatory approval systems in the pharmaceutical industry: an analysis of US and EU converging approaches*, Jacques-Philippe Gunther and Charlotte Breuvart, European Competition Law Review, E.C.L.R. 2005, 26(12), 669-684.
[26] Department of Health and Ageing, Therapeutic Goods Administration, 2009, viewed on 25 September 2009 at < http://www.tga.gov.au/devices/dealfaq.htm>.
[27] Submission by The Royal Australian and New Zealand College of Ophthalmologists to the Review of Health Technology Assessment in Australia, viewed on 25 September 2009 at < http://www.healthyactive.gov.au/internet/main/publishing.nsf/Content/htareview-005/$FILE/005_The%20Royal%20Australian%20and%20New%20Zealand%20College%20of%20Ophthalmologists.doc>; Australian Pesticides and Veterinary Medicines Authority, 2009, viewed on 25 September 2009 at < http://www.apvma.gov.au/registration/time.shtml>.
[28] *Medical Devices for a Healthy Life*, Medical Devices Industry Action Agenda, Australian Government—Department of Industry Tourism and Resources, < http://www.innovation.gov.au/Section/Industry/Documents/MDIAA_Medical_Devices_AA_Report.pdf>.
[29] In New Zealand, this has been illustrated by two judicial decisions: *Smith Kline & French Laboratories Ltd v. Attorney General* [1991] 2 NZLR 560 and *Monsanto Co v. Stauffer Chemical Co* [1984] FSR 559.

- the time taken for the relevant regulatory approval body to conduct its approval processes.

10. This in effect provides patent holders with a bonus or *de facto* extension of their patent term, beyond the generally available 20 year period. This *de facto* extension can range from being relatively short to being quite protracted—from weeks to years, as indicated above.

11. In contrast, some countries' patent laws permit regulatory approval processes to commence even before patent expiry. The process of allowing the regulatory review process to be undertaken during the patent term is colloquially known as 'springboarding'. Legislation permitting springboarding ensures that patent laws do not prevent entry to market of competing generic products shortly after patent expiry.

12. Different countries implement springboarding measures in different ways. For example, provisions in New Zealand[30], Israel[31] and Canada[32] cover regulatory approvals pertaining to a wide range of products. In contrast, provisions in Europe[33] and the US[34] relate only to regulatory approval for medicines for human and veterinary use. The legislation in each of these countries provides explicitly that such 'springboarding' actions do not infringe patent rights.

The problem

13. The problem to be addressed relates to the interaction of regulatory approval processes with the patent legislation. Regulatory approval processes play an important role in protecting consumers. However, an unintended consequence is that these processes interact with patent laws to effectively extend patent terms beyond the generally applicable maximum of 20 years.

14. This is an *unintended* consequence. This contention is supported by a report of the dispute resolution body of the World Trade Organisation about legislation enacted in Canada to permit springboarding activities.[35] This report referred to the additional period of market exclusivity (*de facto* patent term extension) that would be available if generic manufacturers were not permitted to conduct testing prior to the expiry of a patent, and stated[36]:

> The additional period of market exclusivity in this situation is not a natural or normal consequence of enforcing patent rights. It is an unintended consequence of the conjunction of the patent laws with product regulatory laws, where the combination of patent rights with the time demands of the regulatory process gives a greater than normal period of market exclusivity to the enforcement of certain patent rights.

[30] Section 68B of the *Patents Act 1953* (NZ).
[31] Section 54A of the Israel *Patents Law, 5727-1967*.
[32] Section 55.2 (1) of the *Patents Act* (Can).
[33] Directives 2004/27/EC and 2004/28/EC of the European Parliament and of the Council, dated 31 March 2004.
[34] 35 U.S.C. 271 (e).
[35] *Canada – Patent Protection of Pharmaceutical Products*, WT/DS114/R, World Trade Organisation, <http://www.wto.org/english/tratop_e/dispu_e/7428d.pdf>.
[36] Note 35 at para 7.57.

15. This problem has the potential to impact adversely on Australian consumers and on Australian generics industries.

16. Patent owners effectively obtain exclusive monopoly rights in Australia for longer than the intended maximum period of 20 years. This can:

- delay the entry of competing generic products into the market, delaying the provision of cheaper competing products for consumers
- postpone or prevent Australian generics manufacturers from exploiting potential generics markets in Australia and overseas.

17. The consultation process outlined below has uncovered evidence of several other follow-on issues that arise as a result of the problem.

18. One issue arises from the ability to conduct springboarding activities in other countries which have more permissive springboarding provisions.

19. Some Australian generics manufacturers take advantage of this, and elect to conduct springboarding activities off-shore in such countries. But this increases their costs—this is more expensive to conduct and more difficult to manage than an Australian manufacturer conducting generic research and development work in Australia.

- This puts an Australian manufacturer conducting research and development overseas at a competitive disadvantage with:
  - overseas generic manufacturers which are able to conduct such work in their home countries

    and

  - the patent holder.
- An increased cost structure might also lessen the potential cost reductions that would otherwise flow to consumers.
- As a result, Australian researchers miss out on potential research and development work, to the detriment of the local research and development industry.

20. When Australian generics manufacturers do not conduct springboarding activities off-shore, they have found that overseas competitors working in jurisdictions with more permissive springboarding laws are able to launch generic products in Australia or overseas shortly after patent expiry, in advance of the Australian generics manufacturer.

21. There is also evidence that the overseas generics manufacturers which are based in countries with more expansive springboarding laws do not always target their activities at products which meet the needs of Australian users and industries.

22. Finally, although paragraph 8 above noted that some of the steps involved in the regulatory approval process will commonly constitute patent infringement, the Australian Patents Act is not explicit on this point. Nor is there any guiding Australian case law. During the consultation process described below, one patent attorney expressed the view that the legal position in Australia was not clear, which had made it difficult to provide useful advice to the attorney's client. A lack of clarity, or a perceived lack of clarity, in Australian laws has the potential to produce its own set of problems with associated costs.

23. The problem potentially arises across a wide range of technologies and industries. The impacts of the problem have chiefly been highlighted in two areas: the pharmaceuticals and agricultural chemicals sectors. There are other areas in which the problem has been acknowledged, such as medical devices, veterinary chemicals, genetically modified products, and animal health products.

Existing government regulation

Existing springboarding legislation

24. The existing government regulation dealing with this issue consists of section 119A of the Patents Act, *Infringement exemptions: acts for obtaining regulatory approval of pharmaceuticals*.

25. This provision was introduced by the *Intellectual Property Laws Amendment Act 2006*, and replaced an earlier, narrower springboarding provision.[37]

26. This provision exempts from patent infringement exploitation of a 'pharmaceutical patent' if it is solely for the purpose of obtaining regulatory approval for pharmaceuticals in Australia or overseas. A 'pharmaceutical patent' is defined in subsection 119A (3) as a patent which claims a pharmaceutical substance or a method, use or product relating to a pharmaceutical substance.

27. The existing government regulation is of narrow application, only permitting springboarding on pharmaceutical patents. In other areas of technology, it has no application.

Other government regulation

28. There is no other existing government regulation in Australia to deal with this problem.

OBJECTIVE OF GOVERNMENT ACTION

29. The objective is to ensure that the entry to market of competing generic products soon after patent expiry is not unduly delayed as a result of the interaction between the patent system and various other regulatory laws.

[37] Subsection 78 (2) of the Patents Act, as in force immediately prior to the commencement of Schedule 7 to the *Intellectual Property Laws Amendment Act 2006*.

OPTIONS THAT MAY ACHIEVE THE OBJECTIVE

30. Three options have been considered:

- Option 1—Maintain the *status quo*.
- Option 2—Amend the Patents Act to provide that activities related to obtaining the information required for regulatory approval do not infringe patent rights.
- Option 3—Introduce a statutory licensing scheme for activities related to obtaining the information required for regulatory approval.

31. These are considered in more detail below.

IMPACT ASSESSMENT

Who would be affected by each option?

32. The groups which would be impacted by each of these options are, broadly speaking:

- Patent holders. (This group will be taken to include applicants for patent rights whose applications have not yet been determined.)
- Manufacturers of generic products.
- Consumers.
- Government. (This group will be taken to include all arms of government which are involved in the administration of the patent system: the executive arm of government, the Parliament, and the courts.)

Impacts of each option

33. The anticipated impacts of the options are outlined below.

Option 1: Maintain the *status quo*

34. This option maintains the present regime whereby springboarding provisions apply only to pharmaceutical patents.

35. The impacts of the *status quo* are outlined above (‘The problem’).

36. This option would not achieve the desired objective.

Option 2—Introduce a springboarding exemption to patent infringement

37. Under this option, the Patents Act would be amended to provide explicitly that acts done solely for the purpose of obtaining regulatory approval of goods, under an Australian law or under the law of a foreign country, do not infringe patent rights.

38. As existing section 119A of the Patents Act already provides a springboarding exemption to patent infringement for some pharmaceutical products, this new exemption could either apply only to goods not already covered by that provision, or could replace that provision in its entirety. This implementation detail does not impact on the following analysis.

Costs

Patent holders

39. The key cost to patent holders would relate to gaining familiarity with the new legislative arrangements.

40. The proposal would not impose any other direct costs onto patent holders.

41. There are several costs to patent holders which could be alleged under this option, which are dealt with, and dismissed, below. In short, these are:

- The costs of monitoring the activities of generic manufacturers.
- Eroding the exclusive rights of patentees.
- Increased competition sooner after patent expiry.
- Disincentive to innovate.

42. Although patent holders might consider that they would be required to monitor the activities of generic producers for potential infringing activities—for example, to ensure that any activities that generic producers undertake do not extend beyond what is allowable by the statutory exemption—this could hardly be considered to be a *new* cost. Patent holders are already liable for any policing or enforcement of their patent.[38]

43. Additionally, patent holders might consider that this infringement exemption erodes their exclusive rights under the Patents Act, representing a cost to them, for example, by reducing the value of their intellectual property portfolio. However, under this option, no generic manufacturer would be able to compete with the patent holder during the term of the patent—this option would not impact on the patentee's commercial interests *during the term of the patent*.

44. The key impact on patent holders would be increased competition, soon after patent expiry. But as soon as a patent has expired, a patent holder no longer has any exclusive rights under the patent system. So they could hardly complain about competition as soon as or shortly after their period of exclusivity has expired.

45. In any event, a patentee may face competition from generic manufacturers soon after patent expiry at present, so long as the otherwise infringing steps for regulatory approval are undertaken in a foreign country which permits such actions to be taken.

[38] This is common around the world—see for example *WIPO Intellectual Property Handbook: Policy, Law and Use*, WIPO Publication No.489 (E), World Intellectual Property Organisation, accessed on 17 February 2010, <http://www.wipo.int/about-ip/en/iprm/> at paragraph 4.5.

So this would not represent a *new* adverse impact for patent holders in Australia. There could potentially be *additional* competition under this option. However, as this competition would only arise after expiry of the patent, it could still not be reasonably thought to impinge on or derogate from the patent holder's exclusive rights.

46. Patent holders could argue that this option would represent a disincentive to innovate, which would represent a cost both to patent holders and to society. This argument seems to assume that the *de facto* patent extension which patent holders may now enjoy is part of the incentive to innovate which is provided by the patent system. So, policy action which removes this *de facto* extension would remove this incentive. However, this argument has been given little weight for two reasons:

- This *de facto* extension of term is not an incentive to innovate which the patent system ever intended to provide. Instead, as outlined above, it is an unintended consequence arising from the interaction of the patent laws and the laws regarding regulatory approval of products. The incentive to innovate which the patent system intends to provide is limited to the 20 year period.

- In any event, even under present arrangements, patent holders can face competition from generic manufacturers soon after patent expiry, for example, from overseas generics companies. So it is questionable whether this *de facto* extension period does actually provide any real incentive to innovate, as it may not be available in many or even any cases.

Manufacturers of generic products

47. The cost identified at paragraph 39 above is also expected to apply to manufacturers of generic products.

48. The proposal would not impose any other direct or indirect costs onto manufacturers of generic products.

Consumers

49. The option is not expected to impose any direct or indirect costs onto consumers.

Government

50. Key costs on government under this option include the costs involved in amending and administering the new legislative provisions.

51. Under this option, government will bear some of the costs of resolving any legal disputes which may arise under the new legislation. But as government already bears some of the costs of resolving disputes arising under patent legislation, this is not a wholly new cost, and may not represent an additional cost over the *status quo*.

Benefits

Patent holders

52. This option would not provide any benefits to patent holders.

Manufacturers of generic products

53. The key benefits of this option to manufacturers of generic products are:

- Patent rights would no longer prevent generic manufacturers from undertaking the regulatory approval process during the patent term. They would thus be able to seek regulatory approval sooner, and be in a position to launch generic versions of off-patent products sooner after patent expiry.

- Australian generic manufacturers would be able to undertake springboarding work in Australia, obviating the costs involved in doing this work offshore. This would have flow-on benefits to the Australian research and development industry.

- Australian generic manufacturers would be in a better position to compete with overseas generic companies whose patent laws permit springboarding activities within the patent term.

Consumers

54. The key benefit to consumers would be the possibility of more and earlier competition in the market for off-patent generic products. This greater competition would provide for more consumer choice and would tend to lower prices for products.

Government

55. This option would not provide any particular benefits to government.

Option 3—Statutory licensing scheme for springboarding activities

56. Under this option, springboarding work would continue to constitute infringement of a patent. However, a statutory licensing scheme would be set up to permit generic manufacturers to conduct springboarding activities even without obtaining the permission of the patent holder. Remuneration would be payable under this statutory licence, either to the patent holder directly or to a body set up to administer the statutory licensing scheme, which would then pass the remuneration onto the patent holder.

57. Statutory licensing schemes are known within intellectual property law, for example, under the *Copyright Act 1968* (Cth). There are none existing at present under the Patents Act. The Advisory Council on Intellectual Property (ACIP) has explored statutory licensing schemes in its 2005 report *Consideration of patents and experimental use* (ACIP experimental use report).[39]

Costs

[39] ACIP, 2005, < http://www.acip.gov.au/library/ACIP%20Patents%20&%20Experimental%20Use%20final%20report%20FINAL.pdf>.

Patent holders

58. Patent holders would be impacted by the cost identified at paragraph 39 above.

Manufacturers of generic products

59. Manufacturers of generic products would face the costs of:

- ascertaining and assessing relevant patents which their activities might infringe
- any administrative and compliance costs related to the statutory licensing scheme
- the price of the statutory licence itself
- the cost identified at paragraph 39 above.

60. Under this option, Australian manufactures of generic products would be in a relatively disadvantageous position compared to manufacturers of generic products in other countries which have more generous springboarding provisions. Such overseas manufacturers would not face the kinds of costs outlined in paragraph 59 above. So under this option, the Australian generic manufacturers would be relatively worse off than their overseas competitors.

Consumers

61. The option would not impose any direct or indirect costs onto consumers.

Government

62. Key costs on government under this option include:

- the costs identified at paragraph 50 above
- any costs that may be involved in administering the statutory licensing scheme.

Benefits

Patent holders

63. This proposal would benefit patent holders by the payment to them of licensing fees under the statutory licensing scheme.

Manufacturers of generic products

64. This option would deliver the same benefits to manufacturers of generic products as outlined above.

Consumers

65. This option would deliver the same benefits to consumers as outlined above.

Government

66. This option would not provide any particular benefits to government.

CONSULTATION

The consultation process

67. There has been public discussion about extending springboarding provisions to other industries for some years.

68. This issue was raised in one submission to the ACIP experimental use report.[40] In 2006, IP Australia consulted on extending springboarding provisions while formulating a response to this report. The issue was also canvassed in 2006, when the then Senate Economics Legislation Committee tabled its report *Provisions of the Intellectual Property Laws Amendment Bill 2006*.[41]

69. IP Australia conducted some initial investigations into this issue in that year with the release of an issues paper entitled *Public Consultation Paper on the ACIP Report 'Patents and Experimental Use'*, seeking views on the springboarding issue. That paper asked for submissions about whether respondents' industries had been impacted by the absence of an exception from infringement for activities undertaken prior to the end of the initial patent term relating to obtaining regulatory approval, and for details of any such impacts.

70. Twenty responses were received, with 10 of these commenting explicitly on the springboarding issue.

71. Submissions to this consultation process were considered by an Interdepartmental Committee (IDC) which included representatives from a range of government Departments. As reported in the follow-up consultation paper *Overview of Responses to the Public Consultation Paper on the ACIP Report 'Patents and Experimental Use'*[42], there appeared to be limited support at that stage for expanding the existing springboarding provisions.

72. IP Australia consulted extensively on extending springboarding once again during the 2009-2010 consultation process *Toward a Stronger and More Efficient IP Rights System*. This process included the release of a public consultation paper entitled *Exemptions to Patent Infringement*.[43]

73. This consultation process commenced with a Ministerial announcement by the Minister for Innovation, Industry, Science and Research, Senator the Hon Kim Carr, early in 2009. The ensuing three-stage consultation process consisted of:

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[40] Letter to the ACIP secretariat from Mr Bernard Lee on behalf of Nufarm Limited, dated 30 April 2004, see <http://www.acip.gov.au/expusesubs/Nufarm.PDF>.

[41] <http://www.aph.gov.au/Senate/committee/economics_ctte/completed_inquiries/2004-07/intellectual_property/report/index.htm>.

[42] IP Australia, 2006, http://www.ipaustralia.gov.au/pdfs/news/Overview%20of%20Responses%20to%20the%20Public%20Consultation%20Paper.pdf.

[43] See <http://www.ipaustralia.gov.au/pdfs/news/ip_reforms_exemptions.doc>.

- A first round, consulting on broad policy positions. The consultation papers were circulated to individuals and groups who were known to have an interest in the consultation topics, and were placed onto IP Australia's web site and the government's business consultation web site, to invite submissions from any interested member of the public and from business and industry. Several face-to-face round-table meetings were then held in State capital cities with interested stakeholders.

- A second round, consulting on detailed policy positions, including draft versions of the drafting instructions that were to be submitted to the Parliamentary drafters. These consultation papers were circulated to all parties who made submissions to the first-round consultation papers, and were once again placed onto IP Australia's web site and the government's business consultation web site.

- A third round, comprising limited release of an exposure draft of the amending legislation.

74. More than 120 written submissions were received to the consultation process, and IP Australia met with over 150 interested stakeholders in the face-to-face round-table meetings. Thirty-six of those written submissions commented explicitly on the *Exemptions to Patent Infringement* consultation paper, and this was discussed extensively at many of the stakeholder round-tables. In addition, IP Australia discussed this and other consultation papers with various government agencies.

Views expressed during the consultation process

75. The views expressed during the consultation process can perhaps be best summarised by a patent attorney at one of the stakeholder round-tables, who commented that generic and innovator companies will never agree on the issue of springboarding.

76. Some of the principal issues voiced during consultation are summarised below.

Manufacturers of generic products

77. Generics companies outlined disadvantages they were suffering as a result of the existing state of affairs, and supported extending Australian springboarding provisions.

78. These disadvantages include:

- The restrictions on springboarding in Australia prevent Australian-based companies from undertaking much of the research and development needed for the regulatory approval process within Australia. One company finds that it must conduct these operations off-shore, which is more difficult, time consuming and costly.

- International competitors based in countries with more expansive springboarding laws tend to enter foreign markets at the expiration of a patent more quickly than Australian-based companies are able to. They

thus have a competitive advantage—they can have generic products available, especially in the key US market, much sooner than Australian-based companies are able to.

- Smaller Australian generic producers are placed at a disadvantage to multinational and larger generic producers, as they must await patent expiry before they are able to carry out regulatory approval work.

79. On the other hand, if Australian-based companies were able to conduct springboarding work in Australia, the consultation revealed that:

- Australian-based businesses would be able to use Australian workers to do the necessary research and development, and would be able to conduct field trials in Australian rural and regional areas.

- This would produce associated increases in local science and technology employment opportunities. It could encourage foreign companies to undertake research and development projects in Australia.

- This would also enable the development of products targeted for particular uses in Australian agriculture, which would directly benefit Australian farmers.

- If springboarding were to be extended to all industries, smaller Australian generics producers would be able to compete on equal terms with larger overseas companies. In the agricultural field, this would enable smaller companies to work with farmer and grower groups to develop solutions for minor crops that may not be economically viable for larger research and development companies.

80. Generics producers supported option 2. One commented that this is logical and consistent with promoting ongoing innovation and development. A representative from one university described the option as a ‘no brainer’.

Consumers

81. An industry body which represents several thousand farm businesses in Australia gave a perspective from the point of view of a consumer of agricultural chemicals. This body noted that the current inability to springboard in Australia has a detrimental effect on the research being done on agricultural chemicals. As Australia is considered a small market compared to other countries such as the USA, Australian farmers have often not been able to access newer chemistry-based products until years after the overseas competitors. This can potentially lead to older, more dangerous and costlier products being used in Australia because the alternatives are not yet available.

82. This body also considers that the existing regulation is slowing down access for farmers to valuable new products. One of the most important resources available to Australian farmers is Australian-based research, but the current restrictions on springboarding are hindering Australian-based research and are encouraging research overseas.

83. On the other hand, extending springboarding provisions would:

- provide an incentive for companies to invest in Australian research
- enable the development of products targeted for particular Australian uses, especially for 'minor' use requirements in agriculture for which there is currently little incentive for research.

Patent holders

84. Innovator companies raised a number of issues. One agricultural chemicals innovator company was not aware of any instances of adverse impacts of broader springboarding provisions, and expressed a lack of support for any changes, at least without further studies of any potential impacts.

85. In the main, innovator companies and IP professionals—which tended to express views from the patent owners' perspective—were not opposed to an expansion of springboarding provisions *per se*, but raised several issues:

- One suggested that there should be a requirement to notify patent owners of any springboarding use.
- The issue of 'compensatory' patent term extensions was raised repeatedly. As springboarding provisions would compensate generic manufacturers for delays in bringing generic products to market caused by regulatory approval processes, patent term extensions would compensate patent holders for facing similar delays.
- One pharmaceutical company was concerned that a general regulatory review exemption could adversely impact on the innovative pharmaceutical industry in Australia.
- Another innovator company emphasised that care be taken to ensure that any exemption is restricted to the activities required for regulatory approval.
- One company was concerned that commercial quantities of pharmaceuticals could be exported to another country under the guise of obtaining regulatory approval in that country, and then re-imported back into Australia—it could be difficult to identify the infringing product.

86. Two patent attorneys gave a good contrasting view of the different positions at one of the stakeholder round-tables:

- One patent attorney argued that in the agricultural chemical industry, innovation has fallen and patenting has dropped off in recent times—less research is underway and money is not being spent in Australia on innovation. This attorney was concerned that option 2 would make innovation even harder in Australia—it favours generic companies, but they would not spend on innovation. So the option would produce less of an incentive to research as it would reduce patentee rights.

- But another patent attorney was concerned that other countries permit springboarding on patents other than pharmaceutical ones; generic companies can do research and testing in other countries which *do* allow springboarding. So without such a provision in Australia, research activity would shift offshore.

87. Some submissions referred to some of the international treaties to which Australia is a party, and emphasised the need to comply with Australia's obligations under these treaties.

Government

88. Government agencies expressed support for option 2.

How stakeholders' views have been taken into account

89. The majority of the dissenting stakeholder views have been addressed in the Impact Assessment above, and these comments are not repeated here.

90. The calls for consultation and analysis of the impacts on affected industries have been addressed by the consultation process outlined above. No innovator company has yet indicated that extending springboarding would adversely impact on its decisions regarding research and development in Australia. Comments of this nature were always expressed very generally and non-specifically. In contrast, several generics companies have indicated that option 2 would positively impact on their future activities.

91. Some submissions called for compensatory patent term extensions. But such a suggestion runs contrary to the objective of government action outlined above, which relates to delays in bringing generic products to market following patent expiry. Extending patent terms would *further* delay generic entry.

92. Issues such as compliance with treaty provisions have been taken into account through standard governmental processes.

CONCLUSION AND PREFERRED OPTION

93. Option 2 is the preferred option.

94. The objective of government action is to ensure that the entry to market of competing generic products soon after patent expiry is not unduly delayed as a result of the interaction between the patent system and various other regulatory laws.

95. Option 1 will not achieve this objective, so is not the preferred option.

96. Options 2 and 3 will achieve this objective.

97. Both options 2 and 3 share several advantages:

- Both benefit generic manufacturers by permitting them to seek regulatory approval during the patent term and introduce generic products to market sooner after patent expiry, removing the need to conduct research and

development overseas, and permitting Australian companies to compete better with their overseas rivals.

- Both benefit consumers by enhancing generic competition, leading to greater product choice and lower prices.

98. Both options also share the disadvantage that all parties would have to familiarise themselves with and work within new legislative arrangements.

99. However, option 2 has benefits over option 3:

- Although both require legislative change, legislative provisions implementing option 2 would be modelled more closely on the existing springboarding provisions—section 119A of the Patents Act—than would legislative provisions implementing option 3, for which there is no close precedent in the legislation. Therefore the costs associated with legislative change would be relatively lower for option 2.

- Option 3 would, unlike option 2, include additional costs to generic manufacturers—costs associated with the statutory licensing scheme and fee. These costs could either be passed onto consumers, thus increasing prices under option 3 relative to option 2, or could deter some generic producers from making use of the scheme, thus decreasing consumer choice under option 3 relative to option 2.

100. Option 3 has a further disadvantage, in that:

- Some person or body would have to administer the statutory licensing scheme, thus introducing additional systemic costs.

- There may be additional compliance costs involved with the statutory licensing scheme—this would vary with the final form of any scheme which may be arrived at.

101. Hence although both options 2 and 3 would achieve the stated objective, option 2 would achieve this objective more efficiently and to a greater degree than would option 3, and is thus the preferred option.

102. It is therefore recommended that option 2 be endorsed.

IMPLEMENTATION AND REVIEW

103. The Patents Act would require amendment to implement option 2.

104. As with other matters relating to patent infringement, enforcement of the new springboarding exemption would be at the hands of patent owners, rather than government.

105. Review of the provision is anticipated to be in accordance with the Government's five-yearly review requirements.[44] No specific requirements or arrangements would be required.

106. It is possible that the provision could be reviewed either before or after the standard 5-year period, as appropriate—in view of the operation of the patent system and the industries involved, it may become apparent with time that some other review period is more desirable.

107. Information relevant to a decision when to conduct such a review could come from a variety of sources, for example, from ACIP or from other consultative bodies which IP Australia coordinates. These groups meet several times a year, and members include a cross section of stakeholders in the intellectual property system, drawn from business and manufacturing sectors, the patent attorney and legal professions, government, the tertiary and research sectors, and technology and commercialisation groups.

[44] See the Office of Best Practice Regulation's *Best Practice Regulation Handbook*, August 2007, Chapter 2. See <http://www.finance.gov.au/obpr/about/index.html>.

Preliminary Matters

Notes on clauses

Clause 1: Short Title

Upon enactment the Bill will be known as the *Intellectual Property Laws Amendment (Raising the Bar) Act 2011*.

Clause 2: Commencement

Most provisions in the Bill will commence 12 months after the day the Bill receives Royal Assent. The extended period before commencement is necessary for two reasons.

First, the Bill will require substantial regulation changes to be made before it commences. Many of these changes are technical and involve complex interactions between the Act and Regulations.

A number of stakeholders have requested that the Government ensure that sufficient time is given for consultation about the regulation changes. This will reduce the risk of the regulations introducing unintended consequences and ensure that the best possible regulations are developed to give effect to the Act. An extended 12 month period is necessary in order to provide sufficient time for consultation

Second, an extended commencement will give stakeholders time to consider how best to proceed with their applications, particularly in relation to the amendments that raise the substantive requirements for patents. The new higher standards will apply to existing applications or patents that have been filed, but where examination has not been requested at commencement (see below at item 55 for further explanation). An extended commencement will give applicants time to decide whether to request examination or amend their application before the changes take effect.

The commencement provisions specify a fixed date to give stakeholders certainty. It is preferable that there be no facility for the executive to shorten the 12 month commencement period, as this would make it difficult for users of the IP system to plan how they prosecute their IP rights. Accordingly, there is no executive discretion to proclaim an earlier commencement date.

The extended commencement will not apply to schedule 2, and item 87 of Schedule 6. These items clarify that certain acts do not constitute infringement. These provisions will not require regulations and will not affect how applicants prosecute their applications. Given this, it is desirable to provide certainty sooner by commencing these provisions on the day after Royal Assent.

Clause 3: Schedules

The *Patents Act 1990, Trade Marks Act 1995, Copyright Act 1968, Plant Breeder's Right Act 1994* and the *Designs Act 2003* are to be amended or repealed as set out in Schedules 1 to 6 of the Bill.

Schedule 1 - Raising the quality of granted patents

Introduction

This schedule contains a number of amendments to strengthen the key tests for patentability and ensure rigorous scrutiny of patent applications. The amendments address concerns that patent thresholds in Australia are too low, making patents too easy to get and discouraging follow-on innovation. The amendments also seek to give patentees and the public greater certainty in the validity of granted patents.

Broadly, the amendments are intended to achieve four objectives:

First, the amendments seek to ensure that standard patents are only granted for inventions that add significantly to what was previously known and available to the public at the time an application for the invention was first filed.

Secondly, the amendments seek to bolster the requirement that a patented invention be useful.

Thirdly, the amendments seek to ensure that the public receives sufficient disclosure of the invention in return for the monopoly granted to the patentee.

Fourthly, the amendments allow for more rigour and breadth in the scrutiny of patent applications prior to grant.

Item 1: Definitions

[s 3]

This item inserts 'preliminary search and opinion' into the list of definitions in section 3 to account for a new preliminary search and opinion scheme described in item 11 below.

Item 2: Inventive step - common general knowledge

[s 7]

This item removes the restriction that the common general knowledge taken into account when assessing the inventive step of an invention is limited to the common general knowledge in Australia only.

It is a fundamental requirement that a patented invention possess an 'inventive step' (in the sense that the new invention adds significantly to what was previously known). Inventive step is considered in the light of the 'common general knowledge', which is the knowledge available to all in the trade[45] and that every worker in the art may be expected to have as part of his or her technical equipment.[46] Currently, common general knowledge for inventive step is restricted to what is known in Australia.

[45] *Minnesota Mining and Manufacturing Co v Beiersdorf (Australia) Ltd* [1980] HCA 9.
[46] *Automatic Coil Winder Co Ld v Taylor Electrical Instruments Ld* (1944) 61 RPC 41.

This geographical restriction is not present in the patent laws of Australia's major trading partners or under the Patent Cooperation Treaty (PCT). In these jurisdictions, and under the PCT, it is the common general knowledge of the worker in the relevant art that is taken into account, not the knowledge of the worker in a specific geographical location. This restriction in Australian law means that a patent that would not be granted elsewhere may be granted in Australia. Granting these patents leaves innovators in Australia with less room to practice follow-on innovation around patented inventions than innovators elsewhere, and reduces competition in the Australian marketplace. It also does not reflect the global nature of innovation and research, where researchers have access to many overseas sources of information regarding their field of technology.

The geographical restriction may also imposes constraints in court and opposition proceedings, where the parties often lead expert evidence on what is the common general knowledge. The geographical restriction often means that only Australian-based experts are best placed to give this evidence. However, such experts may be in short supply, making it difficult for parties to obtain expert evidence.

The item addresses these problems by clarifying that the common general knowledge for inventive step is the common general knowledge of a person skilled in the art as it existed before the priority date of the relevant claim, without geographical limitations.

The amendment will result in greater consistency with other major patent jurisdictions, allowing parties in court and opposition proceedings a larger pool of experts from which to draw evidence.

The general approach to determine what is the common general knowledge is expected to be the same, in that the decision-maker would have regard to the evidence as to what background information and knowledge was generally available to the worker in the art. The only difference will be that the question is not posed in terms of the worker in any specific geographic location.

In opposition or court proceedings, where the expert evidence differs between an Australian and a foreign expert, or between two foreign experts, the decision-maker would resolve the issue by weighing the evidence. This is not expected to be substantially different from the present situation, where conflicting evidence from different Australian experts has to be resolved.

This item also amends the heading for section 7 to clarify that the section relates to inventive and innovative step.

Item 4 below introduces the same change in respect of the common general knowledge taken into account when assessing the innovative step of innovation patents.

Item 3: Inventive step - prior art

[s 7]

This item amends subsection 7(3) to remove the requirement that prior art for the purposes of assessing the inventive step of an invention is restricted to only that

information that would be 'ascertained, understood and regarded as relevant' by a skilled person in the art.

A key principle of the patent system is that protection is only given for things that are a significant advance over what was known and what was available to the public at the priority date of the patent. A granted patent can be a powerful exclusive right: as such, it is appropriate that the inventive step requirement be sufficiently stringent.

In countries that are our major trading partners, and under the PCT, inventive step is assessed against a prior art base including *all* information available to the public before the priority date of the application.[47] In contrast, in Australia publicly available information is first restricted to only that information that the skilled person could be reasonably expected to have 'ascertained, understood and regarded as relevant'. Inventive step is then assessed against this restricted pool of information.

There are several problems with this restriction.

The first problem is that information that is clearly relevant may be excluded on the basis that the skilled person would not have 'ascertained' the information. For example, in the Emperor Sports decision,[48] a device of removable tags for playing 'touch' Rugby League or Australian Rules football was considered. Despite a similar system being the subject of several US patents (in respect of American football), the conclusion that the skilled person (in this case a Rugby League or Australian Rules coach, referee, umpire or administrator) could not reasonably be expected to search for and consult a US patent document meant that these documents were disregarded. The exclusion of this relevant information (which nowadays is readily available through the internet) undermines the principle that patents should not be granted for routine modifications of what was already publicly available.

Secondly, while the requirements that prior art be 'understood' and 'regarded as relevant' are implicit in the pre-existing tests for inventive step, they are currently expressed as a threshold limitation on the prior art base. This complicates the provision unnecessarily, without having any substantial effect on the outcome of the inventive step inquiry.

Thirdly, the current restrictions on the prior art base are out of alignment with the patent systems of our major trading partners. In other jurisdictions, the state of the art for the purpose of assessing an inventive step includes all information made publicly available before the priority date. This means that there are unnecessary differences in how the inventive step considerations are applied and, more significantly, foreign patentees may receive broader patent protection in Australia than they could in their own country.

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[47] See eg *Patents Act 1977* (UK), s 2 (2); *Convention on the Grant of European Patents (European Patent Convention)*, opened for signature 5 October 1973, 1065 UNTS 199 (entered into force 7 October 1977), art 54 (2); *Patent Cooperation Treaty*, opened for signature 19 June 1970, [1980] ATS 6 (entered into force 24 January 1978), Article 33, Rule 33.1 (a).

[48] *Commissioner of Patents v Emperor Sports Pty Ltd* [2006] FCAFC 26 (10 March 2006) (Emperor Sports).

The item addresses these problems by removing the terms ‘ascertained, understood and regarded as relevant’ from subsection 7(3). Thus the prior art base for inventive step will be information made publicly available before the relevant priority date.

This better aligns the approach to inventive step in Australia with the approaches taken in other major jurisdictions.

Importantly, the changes are not intended to substantially change the operation of the existing tests for inventive step as applied to the prior art base or to permit hindsight analysis. While a skilled person is essentially deemed to be aware of and to have carefully read the publically available information, the inventive step tests are otherwise applied in the context of what the skilled person would have known and done before the priority date of the claims in question. The tests will therefore continue to take account of factors such as whether the skilled person would have understood and appreciated the relevance of the prior art to the problem the invention was seeking to solve and whether it would be considered a worthy starting point for further investigation or development.

It also remains the case that individual pieces of prior art information can only be combined where the skilled person would have been reasonably expected to have combined them.

Broadening the information that can be considered will make it less likely that a patent will be granted in Australia for an invention that would be considered obvious in other jurisdictions.

Item 4: Innovative step - common general knowledge

[s 7]

The background, problem and policy intent of this item is the same as for the related amendments to subsection 7(2) (see item 2 above). This item is intended to implement the same policy in respect of innovation patents.

Item 5: Consequential amendment to ‘note’

[s 7]

This item is consequential upon item 17, which amends section 98. This item amends the note in section 7 to reflect the amended number of section 98. It does not otherwise change the note.

Item 6: Usefulness - ‘specific, substantial and credible’

[s 7A]

This item amends the definition of ‘useful’ to require that the specification discloses a ‘specific, substantial and credible’ use for the claimed invention.

Usefulness in paragraph 18(1)(c) of the Patents Act is a key criterion for patentability. Patents should not be granted for inventions that are not useful: that have no practical application or do not work. Broadly speaking the claimed invention must actually

achieve what is promised by the patentee.[49] This does not mean that an invention must equate to a commercial product in order to be useful, rather it must achieve the use promised by the patentee in the specification.

Two reviews have recommended clarifying the meaning of 'usefulness' to accord more closely with the meaning of 'useful' in US patent law. The Intellectual Property Competition Review Committee (IPCRC) Report[50] recommended ensuring in examination practice that the use described in the specification is specific, substantial and credible to a person skilled in the art. The Australian Law Reform Commission (ALRC)[51] went further and recommended amending the Patents Act to provide that an invention will satisfy the requirement of 'usefulness' only if the patent application discloses a specific, substantial and credible use. These amendments are intended to implement the ALRC recommendation.

The specific, substantial and credible use test is not intended to displace the existing Australian case law on usefulness. An invention must have both a specific, substantial and credible use that is disclosed in the patent specification *and* meet the requirements of the existing case law (broadly that the invention must achieve the promised benefit).

There is also concern that in some fields the uses claimed are often speculative and that the current provision does not effectively prevent the claiming of such speculative inventions.[52]

The item bolsters the existing requirement that the claimed invention be useful with the requirement that the invention has a specific, substantial and credible use. The intent is that specific, substantial and credible be given the same meaning as is currently given by the US courts and the United States Patent and Trade Mark Office (USPTO).

Currently, the US courts interpret the terms as follows:

- 'specific' means a use specific to the subject matter claimed and can 'provide a well-defined and particular benefit to the public.'[53]

- 'substantial' means the claimed invention does not require further research to identify or reasonably confirm a 'real world use'. 'An application must show that an invention is useful to the public as disclosed in its current form, not that it prove useful at some future date after further research'.[54]

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[49] *Rescare Ltd v Anaesthetic Supplies Pty Ltd* (1992) 111 ALR 205 at 231; *Rehm Pty Limited v Webster's Security Systems (International) Pty Limited* (1981) 81 ALR 79 at 96; *Welcome Real-Time SA v Catuity Inc* (2001) 113 FCR 110 at 144; *Fawcett v Homan* (1896) 13 RPC 398 at 405; and *Lane Fox v Kensington & Knightsbridge Electric Lighting Co Ltd* (1892) 9 RPC 411 at 417.
[50] IPCRC, *Review of intellectual property legislation under the Competition Principles Agreement*, September 2000 (the 'Ergas Report').
[51] ALRC, *Review of Gene Patenting and Human Health, Genes and Ingenuity: Gene Patenting and Human Health*, 2004.
[52] ALRC, *Review of Gene Patenting and Human Health, Genes and Ingenuity: Gene Patenting and Human Health*, 2004 at 6.100.
[53] *In re Fisher*, 421 F.3d 1365, 1371, 76 USPQ2d 1225, 1230 (Fed. Cir. 2005).
[54] *In re Fisher*, 421 F.3d at 1371, 76 USPQ2d at 1371.

- an asserted use will be 'credible' 'unless there is evidence that the invention is inoperative (i.e. does not operate to produce the results claimed by the patent application) or there is reason to doubt the objective truth of the statements in the specification.'[55]

The relevant principles are set out in more detail by the USPTO.[56]

The amendment will strengthen the test for usefulness and prevent the speculative claiming of inventions that would require further experimental effort before they could be put into practice.

The specific, substantial and credible use must be disclosed *in the specification*. This could be an explicit disclosure. Alternatively, it need not be explicit if the skilled person could appreciate the use, with their background knowledge in the art and without undue burden. If however, further invention would be required to ascertain the use, then the specification would not meet the requirement. This ensures that the public is given sufficient information in the specification to understand how the invention is useful and how to put that use into practice.

Item 7: Provisional specifications

[s 40]

This item amends the disclosure requirements for provisional specifications to align them with the amended disclosure requirements for securing an earlier priority date (item 10) and for complete specifications (see following item 8).

Prior to filing a complete application, an applicant may file a provisional application under the Patents Act. The provisional application allows an applicant to secure an early priority date while they test or assess the commercial viability of their invention and decide whether to file an international application or applications in specific countries under the Paris Convention. The applicant has 12 months from the filing date of the provisional application to decide whether or not to file a complete application in Australia, and international application under the PCT or convention applications in particular Paris Convention countries. [57]

Currently a provisional application need only 'describe' the invention generally in its rough state, and does not need to 'enter into all the minute details as to the manner in which the invention is to be carried out'.[58] In contrast, a complete specification must 'describe the invention fully' (noting that this requirement is being strengthened by item 8 to include a 'enablement across the width of the claim' requirement). The

[55] *In re Marzocch*i, 439 F.2d 220, 223, 169 USPQ 367, 369 (CCPA 1971).
[56] See sections 2107 – 2107.03 of the *Manual of Patent Examining Procedure* (http://www.uspto.gov/web/offices/pac/mpep/mpep.htm).
[57] Article 4 of the *Paris Convention for the Protection of Industrial Property*, opened for signature 20 March 1883, 74 LNTS 289 (entered into force 1 June 1928). The Paris Convention provides, among other things, for an applicant to seek patent protection in one member state and then use that application as a basis to seek subsequent protection in another member state. An applicant has 12 months to do this. The subsequent application will be given the same priority date as the earlier application.
[58] *Anaesthetic Supplies v Rescare* [1994] FCA 1065; (1994) 122 ALR 141 (1994); AIPC 91-076 (5 May 1994); 26 IPR 383.

descriptive requirement for a provisional application is therefore quite low and does not include an enablement requirement.[59] This is necessary to secure priority in most other patent jurisdictions and will be required in Australia under the amended priority date requirements in item 10.

Consequently the item amends subsection 40(1) to require a provisional specification to disclose the invention in a manner which is clear enough and complete enough for the invention to be performed by a person skilled in the relevant art. This mirrors the related amendment in item 10 concerning the disclosure requirements to obtain an earlier priority date for complete applications filed in Australia. It will also align the descriptive requirement for a provisional specification with that of a complete specification—paragraph 40(2)(a), with the exception of the requirement to include a best method of performance (see item 8). This is intended to ensure that applicants provide a comprehensive enabling disclosure of the invention in the provisional application and increase certainty that a provisional application filed in Australia will serve as an effective basis for priority in Australia and in other countries.

Item 8: Requirement to describe the invention fully

[s 40]

This item amends paragraph 40(2)(a) by imposing the requirement that a patent specification must disclose the invention in a manner which is clear enough and complete enough for the invention to be performed by a person skilled in the relevant art. This is intended to align the disclosure requirement with that applying in other jurisdictions with the effect that sufficient information must be provided to enable the whole width of the claimed invention to be performed by the skilled person without undue burden, or the need for further invention. This more clearly reflects a fundamental principle of the patent system: in exchange for the exclusive rights given to the patentee, the patentee must share with the public the information necessary to make and use the invention.

An application for a standard patent must be accompanied by a complete specification, which fully describes the invention for which patent protection is sought—s 40(2)(a). There are two aspects to this requirement:[60]

- the specification must make the nature of the invention plain; and
- the specification must make it plain how to make or perform the invention.[61]

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[59] In *Coopers Animal Health Australia Ltd v Western Stock Distributors Pty Ltd* (1987) 11 IPR 20 at 27, Fox J cited with approval the statement by Lloyd-Jacob J in *Imperial Chemical Industries Ltd (Clark's) Application* [1969] RPC 574 at 583 that 'there is no real need for a description that would enable the reader to make the embodiment for himself'.

[60] *Patent Gesellschaft AG v Saudi Livestock Transport and Trading Company* (1997) 37 IPR 523 at 530.

[61] Note that, although the patentee has a monopoly during the patent term, any person may use the invention afterwards: this person must be able to make the invention. Additionally, item 1, Schedule 2 is intended to clarify that other people may use the invention for certain research and regulatory approval purposes during the monopoly period: again, for this to be effective, these other people must be able to make or perform the invention.

The person reading the specification is assumed to have reasonably competent knowledge of and skill in the relevant technical field.[62]

Recent case law has clarified the extent of the current description requirement. It is met if the applicant discloses enough to enable the person reading the specification to produce *something* within each claim without new inventions or additions or prolonged study of matters presenting initial difficulty.[63] Despite the fact that multiple examples or embodiments of the invention may be claimed, enabling only one is sufficient. There are two problems with this:

- a patentee may gain protection over something which they have not sufficiently disclosed: the monopoly extends beyond the knowledge that the patentee has shared with the public; and

- other innovators do not have the information necessary to allow them to improve on embodiments that have not been disclosed: this hinders follow-on innovation and denies to the public the benefits of subsequent improvements on the invention.

An alternative to the existing Australian description requirement is the more stringent requirement that the skilled person reading the specification must be able to perform the invention across the whole width of the claims, not merely in relation to one among other embodiments within their scope. This requirement is consistent with the principle that the description accords with the scope of the monopoly granted.

The item is intended to modify the wording of paragraph 40(2)(a) of the Act so as to require enablement across the full width of the claims, while adopting language that is consistent with that used in other jurisdictions. The wording in the amendment is similar to s 14(3) of the UK patents legislation,[64] which has been interpreted as imposing this requirement.[65] The wording is also similar to art 83 of the European Patent Convention,[66] which has been interpreted with similar effect.[67] The intention is that paragraph 40(2)(a) be given, as close as is practicable, the same effect as the corresponding provisions of UK legislation and the European Patent Convention

A specification that provides a single example of the invention may satisfy the requirements, but only where the skilled person can extend the teaching of the specification to produce the invention across the full width of the claims, without undue burden, or the need for further invention.

However, it is expected to be more likely that, where the claims are broad, the specification will need to give a number of examples or describe alternative

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[62] *Universal Oil Products v Monsanto* (1973) 46 ALJR 658.
[63] *Kimberly-Clark Australia Pty Ltd v Arico Trading International Pty Ltd* (2001) 207 CLR 1 at 17; *Lockwood Security Products Pty Ltd v Doric Products Pty Ltd* (2004) 217 CLR 274 at 297; *Pfizer Overseas Pharmaceuticals v Eli Lilly and Company* (2005) 225 ALR 416; [2005] FCAFC 224 at [330].
[64] *Patents Act 1977* (UK).
[65] *Biogen Inc v Medeva plc* [1997] RPC 1; *Generics (UK) Limited v H Lundbeck A/S* [2008] EWCA Civ 311, [2008] RPC 19 at [27].
[66] *Convention on the Grant of European Patents (European Patent Convention)*, opened for signature 5 October 1973, 1065 UNTS 199 (entered into force 7 October 1977).
[67] See European Patent Office (EPO), Board of Appeal decision **T 409/91,** OJ 1994, 653; **T 722/95** OJ 1/2001, 1.

embodiments or variations extending over the full scope of the claims. This ensures that the monopoly extends only to that which could reasonably be said to be disclosed and no further.

If, on its face, the specification would appear to the skilled person to lack sufficient disclosure, the onus of establishing that the invention is described in enough detail lies with the applicant (see item 14).

The item also clarifies that the existing requirement for a complete specification to include the best method known to the applicant of performing the invention remains unchanged.

Item 9: Fair basis

[s 40]

This item amends the Act to replace the 'fair basis' requirement with a 'support' requirement.

Subsection 40(3) of the Patents Act requires the claims of a complete specification to be, among other things, 'fairly based' on the matter described in the specification. The concept of 'fair basis' in Australian patent law is intended to achieve two results:

- ensuring consistency between the monopoly claimed in the patent and the description of the invention; and

- ensuring that the claims of a patent are entitled to the priority date which the patent applicant asserts.

A lengthy body of case law has developed interpreting the 'fair basis' requirement, culminating in the High Court decision *Lockwood Security Products Pty Ltd v Doric Products Pty Ltd.*[68] This decision clarified the application and operation of the fair basis requirement: the requirement being met where there is consistency between what is claimed and *what the body of the specification read as a whole discloses as the invention.*[69] The High Court also noted that recent UK case law on 'support' is of no assistance in interpreting fair basis under the Australian patents legislation.[70]

Overseas law generally requires there to be a relationship between the claims and the description, and between the claims and any document from which priority is being claimed. This is expressed by the requirement that a claim be 'supported by'[71] or 'fully supported by'[72] the description. Broadly speaking, the terms 'support' and 'full support' pick up two concepts:[73]

- there must be a basis in the description for each claim; and

[68] *Lockwood Security Products Pty Ltd v Doric Products Pty Ltd* (2004) 217 CLR 274
[69] ,*Lockwood Security v Doric Products* [2004] HCA 58 at 99
[70] *Lockwood Security Products Pty Ltd v Doric Products Pty Ltd* (2004) 217 CLR 274 at 299
[71] European Patent Convention, Article 84; UK *Patents Act* 1977, paragraph 14 (5) (c).
[72] Patent Cooperation Treaty, Article 6; draft Substantive Patent Law Treaty, May 2004, Article 10 (3).
[73] *Guidelines for Examination in the European Patent Office*, European Patent Office, April 2009, at 6.1, accessed 6 November 2009.

- the scope of the claims must not be broader than is justified by the extent of the description, drawings and contribution to the art.

Despite the underlying concept and policy between fair basis and support being similar, the different terminology has produced different substantive law in different countries.

The difference in substantive law in different countries causes unnecessary complexity and uncertainty for applicants seeking protection in Australia and other jurisdictions. As discussed above (see item 7), having different standards in different countries imposes costs on global innovators, who must familiarise themselves with the varying requirements.

This item is intended to align the Australian requirement with overseas jurisdictions' requirements (such as the UK). Overseas case law and administrative decisions in respect of the 'support' requirement will be available to Australian courts and administrative decision-makers to assist in interpreting the new provision.

There must also be consistency, or basis, for each claim in the description.

Item 10: Priority dates

[s 43]

Item 10 aligns the requirement for securing a priority date from an earlier filed application with the requirement for disclosure in a complete application (see item 8 above).

Each claim in a patent specification has a priority date (the date at which the patentability of the invention is assessed, with the result, for example, that their application takes precedence over a second application filed after than date). Currently, the test for determining the priority date is whether the claim is 'fairly based on' what is disclosed in the document identified by the applicant as their priority document. That is, the test for determining priority mirrors the 'fair basis' test in subsection 40(3). This test is currently imposed in the Patents Regulations.

The item amends paragraph 43(2)(b) to provide that, if prescribed circumstances apply in relation to the claim and the prescribed document discloses the invention claimed in that claim in a manner that is clear and compete enough for the claimed invention to be performed by a person skilled in the art, the priority date of the claim will be the date that is determined under the Regulations. For the intended operation of the 'clear enough and complete enough' test, see the notes relating to item 8 above.

The item is intended to achieve two objectives:

First, the amendment is intended to maintain consistency between the requirement of subsection 40(2) and the requirement for priority. Applicants should not be able to secure a priority date on the basis of a disclosure in a provisional or other relevant application that is less complete than required in a complete specification. Otherwise the applicant is in a position to deter competitors before they have fully realised the

invention.[74]. Since an enabling disclosure will be required, the amendment will also align the requirements for securing a priority date with most other major patent jurisdictions.

Secondly, the amendment is intended to increase the transparency of the Act. The priority date is fundamental to the validity of a patent. Accordingly, it is more appropriate that the key aspect ('clear and complete enough') of such an important test for priority is explicit in the Act. However, the less crucial procedural details of how the test is to apply are prescribed in the Regulations. This will permit the other aspects of the existing priority date test to be re-made in the Regulations.

Item 44 of Schedule 6 is a related item. This item repeals subsections 43(5) and (6). These subsections set out the procedural requirements for establishing the priority date for a claim in a divisional application of an innovation patent.[75] The procedural requirements will be moved to the Regulations, consistent with the arrangements for determining the priority dates of claims in other types of patent applications.

Item 11: Preliminary search and opinion

[s 43]

This item amends the Act to allow the Commissioner to conduct a 'preliminary search and opinion' on a standard complete patent application.

Australia has a deferred system of examination, under which the search and examination process does not take place until the applicant requests examination. This may not occur for a number of years after filing of the application.

Most Australian patent applications are filed in one or more other jurisdictions, with the majority filed through the Patent Cooperation Treaty (PCT). Applications filed through the PCT and some other jurisdictions are subject to a preliminary search and/or examination report early in the life of the application; often well before the application proceeds to full examination. Such information early in the life of an application can provide a useful indication to the applicant of the shortcomings in their application. It can also provide the public with useful information about the likelihood of a patent being granted and the likely scope of any monopoly.

However, applicants filing only in Australia (about 3% of all applications) generally do not have the benefit of an early preliminary search and examination of their application. This prolongs the period of uncertainty where the applicant does not yet have important information about the patentability of their invention and competitors and the public do not know where they are free to operate.

The item amends the Act to allow for a 'preliminary search and opinion' to be carried out on a standard patent application.

The circumstances and manner in which a 'preliminary search and opinion' are to be carried out will be prescribed in the Regulations. It is intended that the Australian

[74] Intellectual Property and Competition Review Committee, *Review of intellectual property legislation under the Competition Principles Agreement*, 2000, p 160 ('Ergas Report').
[75] Divisional applications are discussed in Schedule 3

'preliminary search and opinion' be similar to an international search and preliminary examination conducted under the PCT. The preliminary report would be issued to the applicant before the application was open for public inspection (OPI), noting that the OPI date is also prescribed in the Regulations[76] and published with the application at OPI.

A 'preliminary search and opinion' would only be required where no other early report was likely to be made available from a major equivalent patent office. This avoids unnecessary duplication of work by the Patent Office.

The preliminary opinion is not intended to be a final or binding determination of the validity of the application, or to replace the normal full examination processes. The applicant may make submissions and amendments in response to the preliminary report but these will only be considered if the application proceeds to a full examination at a later date.

Item 12: Examination of standard patents - useful

[s 45]

This item expands the patentability requirements considered during examination to include consideration of whether a claimed invention is useful.

A key requirement of patentability is that the invention must be useful.[77] Currently, the usefulness of an invention is not assessed during examination of a standard patent application (or an innovation patent – see item 20).[78] Consideration of this ground is restricted to opposition proceedings before the Commissioner and to revocation proceedings before a court.

In the absence of consideration of usefulness during examination there is the increased risk of an application being accepted and a patent granted for an invention that does not work. For the public this means uncertainty about whether or not patented inventions actually work (in the way promised in the specification) and reduced confidence in the validity of granted patents. For the applicant it means an accepted application may be successfully opposed or a granted patent successfully revoked on the ground that the invention does not work in the way disclosed in the specification. Again the result is reduced confidence in the validity of granted patents. Added to this is the cost of dealing with the issue in opposition or court proceedings, rather than the less expensive and earlier option of resolving the issue in examination.

The item resolves these problems by requiring the Commissioner to examine and report on whether an invention claimed in an application for a standard patent is useful. This ensures that the question of whether or not an invention is useful can be dealt with earlier and in a less expensive way and gives greater certainty that a patent granted by the Commissioner will withstand challenge in a court.

Further changes to the usefulness requirement are detailed in item 6 above.

[76] Patents Act, s 54 (3) (b).
[77] Patents Act, s 18 (1) (c) and 18 (1A) (c).
[78] Patents Act, s 45 (1) and s 101B (2).

Further changes to the examination of standard patents are detailed in item 13 below.

Item 13: Consideration of prior use during examination

[s 45]

A patented invention must be novel and inventive when compared to the prior art base as it existed at the priority date of the invention. Among other things, the prior art base consists of information made publicly available through the doing of an act (eg by sale or public demonstration of the invention). This is known as 'prior use'. Currently, prior use can only be considered during opposition and court revocation proceedings[79] and cannot be considered at examination or re-examination.[80]

Historically, this approach made sense because information about prior use was not easily accessible by examiners. However, with the advent of the internet, information of prior use is now more readily available.

Where prior use cannot be considered during examination there is the risk that an application will be accepted, or a patent granted, for an invention that is not novel. For the public this means uncertainty about the validity of granted patents. Similarly, for the applicant it means uncertainty about whether their accepted application or granted patent will stand up to challenge and the potential cost of dealing with such a challenge in opposition or court proceedings.

The item addresses this problem by repealing the provision that previously barred the Commissioner from considering prior use during examination. The effect of this will be that the Commissioner can consider all 'prior art information',[81] including information made publicly available by the doing of an act.

Further changes to examination are discussed above in item 12.

The amendments are intended to permit the consideration of prior use information if the examiner is aware of that information in the ordinary course of examination, or where evidence of prior use is provided to the Commissioner under section 27. They are not intended to impose an obligation on the Commissioner to conduct exhaustive searches specifically for prior use. The reason for this is that, while some prior use information is readily available on the internet, other information is not (for instance, a public demonstration that is not filmed or photographed). Imposing a duty on examiners to find such information would be unrealistic. Such prior use information could still be raised during opposition or court revocation proceedings.

Item 14: Acceptance of standard patents - standard of proof

[s 49]

This item sets the requirement that a higher standard of proof be applied by the Commissioner when deciding whether or not to accept a standard patent application.

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[79] Sections 59 (b) and 138 (3) (b), Patents Act.
[80] Sections 45 (1A), 48 (1A) and 98 (2) (standard patents) and s 101B (3) and 101G (5) (innovation patents), Patents Act.
[81] Section 7 and schedule 1 (definitions of 'prior art base' and 'prior art information'), Patents Act.

Historically, the patent legislation required the Commissioner to accept a lower standard of proof than a court. The Commissioner was required to accept a patent application 'unless it appears practically certain'[82] or 'clear'[83] that it would be invalid. In contrast, a court applies the ordinary civil standard of proof by deciding the matter on the balance of probabilities. This meant that the Commissioner had to accept borderline invalid patents, which would subsequently be vulnerable to revocation by a court.

The rationale for this approach has been explained as[84]:

- the Commissioner will not normally have enough material necessary to form a concluded opinion. Hence 'it is only in a clear case, where it is obvious that a patent cannot be granted, that the Commissioner should reject an application altogether'.[85] (This was a 'benefit of the doubt' test.); and

- whereas refusal of acceptance is final, acceptance is not. An application may be opposed after acceptance, and if a patent is granted, its validity can be challenged in proceedings for infringement or for revocation.

However, this rationale is no longer persuasive.

- First, the Commissioner conducts extensive searches and inquiries during an examination and has access to a wide variety of technical resources and expertise. Powerful new electronic search tools and the availability of the internet gives the Commissioner access to a much wider array of information than previously. Accordingly, there is no reason why the Commissioner does not have sufficient information to make a decision based on a higher standard of satisfaction than is presently the case.

- Secondly, a decision to refuse by the Commissioner can nowadays be more easily challenged as an applicant has a right of appeal to the Federal Court under section 51. (Prior to the establishment of the Federal Court the only route was directly to the High Court).

Subsequent amendments to the Act have raised the standard of proof in respect of some grounds for rejection only. This was done by requiring that the Commissioner be 'satisfied' regarding the grounds of novelty and inventive step.[86] The intention of these amendments was to eliminate the 'benefit of the doubt' test, in favour of a more stringent standard.

However, concerns continued to be raised that the low standard of proof in respect of the other grounds of examination was leading to poor quality patents being accepted.

The Australian Law Reform Commission has considered these concerns and has recommended that the balance of probabilities standard apply to *all* statutory

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[82] *Commissioner of Patents v Microcell Ltd* (1959) 102 CLR 232 at 244.
[83] *F Hoffman-la Roche v New England Biolabs* 99 FCR 56 at 66 – 70 and the cases cited therein.
[84] *Commissioner of Patents v. Microcell Ltd* [1959] HCA 71; (1959) 102 CLR 232.
[85] *McDonald v. Commissioner of Patents* [1913] HCA 10; (1913) 15 CLR 713.
[86] *Patents Amendment Act 2001*, which came into force on 1 April 2002

requirements for patentability that are relevant at the stage of examination.[87] This amendment is intended to implement this recommendation.

This item amends section 49 by requiring the Commissioner to accept a patent application if she is satisfied, on the balance of probabilities, that: the invention is novel, inventive and useful; the specification complies with section 40; and other requirements prescribed in the Regulations are met. Importantly, the same standard of proof is intended to apply to all grounds. Where the Commissioner is not so satisfied then she can refuse the application.

The main benefit of this amendment is that the Commissioner will have a greater role in ensuring that invalid applications do not proceed to acceptance and grant. Patentees and the public will have greater confidence that granted patents will withstand court challenge. Parties are also less likely to have to resolve borderline patentability disputes in expensive court proceedings.

It has been suggested by stakeholders that the amendment will impose an obligation on the Commissioner to undertake additional enquiries beyond what is normally done during examination. However, it is not intended that the amendments impose any requirement on the Commissioner to conduct further enquiries than are already undertaken. The Commissioner already conducts extensive searches of prior art and consults the relevant technical literature during examination. It is intended that this will constitute any 'reasonable enquiry' obligation imposed by the amendments.

Where the Commissioner identifies a problem this is raised with the applicant. The applicant then bears the onus of providing the Commissioner with information sufficient to satisfy her that the issue has been resolved.

Items 15, 18, 19, 21, 26 and 28 are related items dealing with instituting requirements for a higher standard of proof to be applied by the Commissioner when making decisions relating to the grant, refusal or revocation of standard patents or patent applications and certification or revocation of innovation patents.

This item also adds the requirement that the invention is useful to the requirements on which the Commissioner must be satisfied before accepting an application. This amendment is consequential to the expansion of examination grounds discussed above in item 12.

Item 15: Refusal to grant a standard patent following opposition – standard of proof

[s 60]

This item introduces a requirement that a higher standard of proof be applied by the Commissioner when deciding whether or not an application should be refused in whole or part because a ground of opposition has been made out.

The policy background and intention of the amendments is the same as the related changes to require a higher standard of proof at acceptance of a patent application (see

[87] ALRC 99, *Genes and Ingenuity: Gene Patenting and Human Health*, 2004, 8.77.

item 14 above, and related items 18, 19, 21, 26 and 28). The intention is to give the Commissioner the ability to refuse applications where the Commissioner is satisfied, on the balance of probabilities, that a granted patent would be invalid, rather than only permitting the Commissioner to refuse the patent application if she is practically certain the granted patent would be invalid.

The amendment also ensures that the Commissioner gives the applicant a reasonable opportunity to remove the ground of opposition before refusing the application.

Items 16 and 17: Re-examination of standard patents

[s 97]

These items amend the Act to improve transparency with respect to how re-examination of standard patents must be carried out and to expand the grounds for re-examination of standard patents.

In certain circumstances, the Commissioner will re-examine a patent application or granted patent.[88] This usually happens because the Commissioner or a third party becomes aware of previously unknown information which may affect the patentability of the application or patent.

[s 97]

Item 16 amends the Act to clarify that the procedures for court-directed re-examination are set out in the Regulations. This improves transparency and is consistent with the approach taken to other re-examination provisions, where the Act explicitly refers to Regulations setting out procedural requirements.

[s 98]

Item 17 expands the grounds reported on during re-examination of a standard patent application or granted patent. It also allows the Commissioner to consider prior use when examining for novelty and the presence of inventive step. Prior use is discussed in detail in item 13.

Novelty and inventive/innovative step are currently the only grounds that can be considered and reported on during re-examination.[89] This is because the information that the Commissioner or third party becomes aware of is most often prior art information relevant to the novelty or inventive/innovative step of the invention (i.e. a document showing that someone else had performed the same or a similar invention before).

However, although not as common, there are circumstances where the Commissioner or a third party may become aware of information that casts doubt on other aspects of an invention's validity. For example, clinical trials of a new drug may show that a drug does not deliver the use disclosed in the specification, for example does not treat a particular disease, and therefore is not useful.[90] If the Commissioner is not able to

[88] See generally Chapter 9 and Chapter 9A, Part 2 of the Patents Act
[89] Patents Act, s 98 (1) and 101G (3) and (4)
[90] Patents Act, s 18 (1) (c).

re-examine in such circumstances then there is uncertainty as to the validity of an accepted application or granted patent and the applicant/patentee and their competitors may be forced to resolve the issue in more expensive opposition or court revocation proceedings.

The item addresses this issue by expanding the grounds considered and reported on at re-examination of standard patents to include all the substantive grounds considered during examination of standard patents. In addition to novelty and inventive step, the Commissioner will be able to consider and report on whether the invention is a manner of manufacture, is useful, or for a human being or is for a process for creating human beings.[91] The Commissioner will also be able to consider and report on whether the specification adequately discloses and supports the claimed invention.[92]

This will ensure that the Commissioner can resolve all patentability issues quickly and cheaply when relevant information comes to light post-examination.

The item also removes the existing requirement that information about prior use be disregarded when examining for novelty. Prior use is discussed in detail in item 13.

Item 18: Refusal to grant a standard patent after re-examination – standard of proof

[s 100A]

This amendment introduces the requirement that a higher standard of proof be applied by the Commissioner when deciding whether or not to refuse a patent application that has been re-examined.

The policy background and intention of the amendment is the same as the related changes to introduce a higher standard of proof at acceptance of a patent application (see item 14, and related items 15, 19, 21, 26 and 28). The intention is to give the Commissioner the ability to refuse to grant a patent where the Commissioner is satisfied, on the balance of probabilities, that a granted patent would be invalid, rather than only permitting the Commissioner to refuse to grant a patent if she is practically certain the granted patent would be invalid..

Item 19: Revocation of a standard patent after re-examination – standard of proof

[s 101]

This amendment introduces the requirement that a higher standard of proof be applied by the Commissioner when deciding whether or not to revoke a granted patent that has been re-examined.

The policy background and intention of the amendments is the same as the related changes to introduce a higher standard of proof at acceptance of a patent application (see item 14, and related items 15, 18, 21, 26 and 28). The intention is to give the Commissioner the ability to revoke a patent where the Commissioner is satisfied, on

[91] Patents Act, s 18 (1) (a), 18 (1) (c) and 18 (2).
[92] Patents Act, s 40 (2) and 40 (3).

the balance of probabilities, that the patent is invalid, rather than only permitting the Commissioner to revoke the patent if she is practically certain the patent is invalid.

Item 20: Examination of innovation patents – grounds of examination

[s 101B]

This item expands the grounds considered during examination of an innovation patent to include consideration of whether a claimed invention is useful. The background, problem and intended solution are essentially the same as described above in respect of the examination grounds for standard patents (see notes on item 12).

The Commissioner will be required to examine and report on whether an invention claimed in an innovation patent is useful. This ensures that the question of whether or not an invention is useful is dealt with earlier and in a less expensive way and gives greater certainty that a patent certified by the Commissioner will withstand challenge in a court.

Further changes to the usefulness requirement are detailed in item 6.

The item also removes the existing requirement that information about prior use be disregarded when examining for novelty and the presence of an innovative step. Prior use is discussed in detail in item 13.

Item 21: Certification of innovation patents - standard of proof

[s 101E]

This amendment introduces the requirement that a higher standard of proof be applied by the Commissioner when deciding whether or not to certify an innovation patent.

The policy background and intention of the amendments is the same as the related changes to introduce a higher standard of proof at acceptance of a patent application (see item 14 above, and related items 15, 18, 19, 26 and 28). The Commissioner is only required to certify an innovation patent where she is satisfied, on the balance of probabilities, that it meets the required standards. Where she is not so satisfied then the Commissioner can revoke the patent.

The intention is to give the Commissioner the ability to refuse to certify an innovation patent where the Commissioner is satisfied, on the balance of probabilities, that the patent is invalid, rather than only permitting the Commissioner to refuse to certify the patent if she is practically certain the patent is invalid..

The item also adds the requirement that the invention is useful to the requirements on which the Commissioner must be satisfied before certifying an innovation patent. This amendment is consequential to the expansion of examination grounds discussed above in item 20.

The item also clarifies that the Commissioner's decision to certify an innovation patent is not a legislative instrument. It is not legislative in character as it does not create, vary or remove the existing rights: it is merely a step in applying the existing

legislative criteria. Subsection 3 is inserted to assist readers by clarifying that the written decision is not a legislative instrument within the meaning of section 5 of the *Legislative Instruments Act 2003.* It is intended to be declaratory of the law: it is not intended to imply that the written decision would otherwise be a legislative instrument without the provision.

Item 22: Revocation of an innovation patent after examination

[s 101F]

This item clarifies the existing circumstances under which the Commissioner must revoke an innovation patent following examination.

The amendment does not change the circumstances under which a patent is revoked; rather it clarifies the three pre-requisites for revocation:

- the patent must have been examined,
- the Commissioner must also have decided not to certify the patent and
- the patent must not have ceased.

Item 23: Re-examination of innovation patents

[s 101G]

This item clearly flags the presence of Regulations setting out procedural requirements for re-examination of innovation patents. Currently, the Act is silent about procedural requirements for re-examination in the Regulations.

Item 24: Grounds for revocation of innovation patents following re-examination

[s 101G]

This item expands the grounds for revocation of an innovation patent following re-examination to include all the substantive grounds considered at examination.

The policy background and intention of this change is the same as for the related changes to expand the grounds for re-examination of standard patents (see item 17).

This will ensure that the Commissioner can resolve all patentability issues quickly and cheaply when relevant information comes to light post-examination.

Further changes to the usefulness requirement are detailed in item 6.

Item 25: Re-examination of innovation patents – prior use

[s 101G]

This item removes the existing requirement that information about prior use be disregarded when re-examining an innovation patent for novelty and the presence of an innovative step. Prior use is discussed in detail in item 13.

Item 26: Revocation of innovation patents following re-examination – standard of proof

[s 101J]

This amendment ensures that the same standard of proof is applied to the Commissioner's decision to revoke an innovation patent following re-examination as to the Commissioner's decisions to accept, refuse or grant standard patents and certify or revoke innovation patents.

The policy background and intention of the amendments is the same as the related changes to introduce a higher standard of proof at acceptance of a patent application (see item 14, and related items 15, 18, 19, 21 and 28). The intention is to give the Commissioner the ability to revoke an innovation patent where the Commissioner is satisfied, on the balance of probabilities, that the patent is invalid, rather than only permitting the Commissioner to revoke the patent if she is practically certain the patent is invalid.

Item 27: Grounds of opposition – innovation patents

[s 101M]

This item expands the grounds for opposition of an innovation patent to include the ground that the invention is not useful. Currently, although the ground that an invention is not useful is a ground for revocation of an innovation patent in the courts, it is not a ground for examination, re-examination or opposition. This creates uncertainty about the validity of certified innovation patents for the public and patentees. It also means that the only avenue for challenging a patent on the ground that it is not useful is in costly court proceedings.

The item addresses the problem by adding the ground that the invention is not useful to the grounds for opposition. This ensures that the question of whether or not an invention is useful can be dealt with in a less expensive way than in court proceedings and gives greater certainty that a patent granted by the Commissioner will withstand challenge in a court.

Item 24 above, which expands the grounds for revocation to include the ground that an invention is not useful is a related item.

Further changes to the usefulness requirement are detailed in item 6.

Item 28: Revocation of innovation patents following opposition – standard of proof

[s 101N]

This amendment introduces the same standard of proof to which the Commissioner must be satisfied when deciding to revoke an innovation patent.

This amendment ensures that the same standard of proof to which the Commissioner must be satisfied when deciding that an innovation patent should be revoked because a ground of opposition has been made out.

The policy background and intention of the amendments is the same as the related changes to require a higher standard of proof at acceptance of a patent application (see item 14, and related items 15, 18, 19, 21 and 26). The intention is to give the Commissioner the ability to revoke an innovation patent where the Commissioner is satisfied, on the balance of probabilities, that the patent is invalid, rather than only permitting the Commissioner to revoke the patent if she is practically certain the patent is invalid.

Item 29: Amendments not allowable

[s 102]

This item amends the Act to require an applicant to meet the disclosure requirements at the time of filing the complete specification. It is intended to avoid the situation where patent rights accrue in the period before the applicant has fully described their invention.

The Federal Court has recently clarified that an invention need only be fully described at the date of grant.[93] This means that it is possible for an applicant to file an inadequate description that can be subsequently remedied by amendment in order to meet the full description requirements before the date of grant.

This situation is problematic for two reasons.

First, it means that a patentee may gain protection for the period *before* they have adequately met their obligation to provide the public with a complete disclosure of the invention.[94]

Second, it creates uncertainty for the public and competitors in the period between publication of the patent specification and grant. Without full details of the invention, the public and competitors may not be able to determine where they can safely operate without infringing the patent. They also may not be able to experiment on, or improve the invention.[95]

In contrast to Australia, other countries' patent laws require the disclosure requirements to be met at filing and do not allow the addition of any material that could not be directly derived from the information in the specification at filing. This includes not allowing the addition of new material to overcome an objection of lack of

[93] *Pfizer Overseas Pharmaceuticals v Eli Lilly* [2005] FCAFC 224; (2005) 68 IPR 1 at [347] and [356].
[94] The term of the patent starts at the filing date: s 65 and s 67, Patents Act. The patentee's rights are enforceable from the date that the specification is made open to public inspection: s 57 (1), Patents Act. Grant may not occur until well after these dates.
[95] Note the related item 1, Schedule 2 that clarifies that researchers may conduct certain experiments on a patented invention

full description. For the reasons above, this result is preferred to the current Australian position.

The item introduces a provision preventing amendment of a complete patent specification after filing to add new matter that would go beyond the disclosure contained in the specification at its filing date. An applicant would not be able to amend the specification to add any material that the hypothetical skilled person could not directly derive by reading the information in the specification as filed.

Under the amended provision, where a specification did not meet the full description requirement (noting that this requirement is being strengthened by item 8), the applicant would not be able to expand their disclosure: rather they would have to reduce the scope of the monopoly sought to accord with what they had originally disclosed. Alternatively, they could file a new application covering the expanded information, which would have a later priority date.

The item also clarifies the disclosure in other prescribed documents which may be considered for the purposes of subsection 102(1). Sometimes information disclosing the invention is included in filed documents that do not technically constitute 'the specification' (eg abstracts). Sometimes also amendments are made where a part of the specification is missing at filing. Under regulation 3.5A and equivalent provisions of the PCT missing parts of the specification can be subsequently incorporated and taken to be contained in the specification at its filing date.

To ensure that applicants are not unfairly disadvantaged by a technicality, this item provides for the regulations to prescribe such documents as forming part of the baseline disclosure against which the proposed amendment is assessed.

Item 30: Consequential amendment to section 102

[s 102]

This item is consequential to the amendment set out in item 21, which replaces section 101E with an amended provision. It accounts for the amended paragraph numbering in new section 101E.

Item 31: Regulation making power to prescribe non-allowable amendments

[s 102]

This item makes amendments to improve transparency and consistency of how amendments are dealt with by the Commissioner and the courts.

The patents legislation prohibits certain amendments. Some of these are set out in the Act. Others are in the Regulations but are not alluded to in the Act, with the result that someone reading the Act only may not realise that there are further non-allowable amendments in the Regulations.

The Regulations also prohibit the Commissioner but not the courts from allowing certain amendments. This produces different outcomes for the same amendments before different decision makers.

The item addresses these problems by amending section 102 to enable regulations to be made prescribing further amendments which are not allowable. This makes non-allowable amendments in the Regulations more visible and ensures that the same prohibitions apply to the courts as to the Commissioner.

Item 32: Exceptions to non-allowable amendments

[s 102]

This item is a consequential amendment to clarify that the new amendment provisions (see item 29) do not apply to amendments to correct a clerical error or obvious mistake or to include details of a micro-organism deposit made under the Budapest Treaty.[96]

This ensures that the existing exceptions to non-allowable amendments continue to apply. An applicant will still be able to amend their application to correct a clerical error or an obvious mistake made in relation to the complete specification.

An applicant can also continue to amend their application to add deposit details after filing. This covers situations where the deposit was made in time but there was a delay in the depositary institution providing the deposit details to the applicant. It is broadly consistent with other jurisdictions, which allow deposit details to be added after filing.

Item 33: Priority date of claims of certain amended specifications

[s 114]

This amendment is consequential to the changes to section 102 (see item 29).

Despite best intentions, sometimes amendments that should not be allowed are inadvertently allowed. Section 114 provides a mechanism for dealing with this situation by giving claims relying on such an amendment the priority date[97] prescribed by the Regulations. This will generally be the date the amendment was made.

The item amends section 114 to ensure that the provision continues to apply in circumstances where an amendment that should not be allowed under section 102 is inadvertently allowed.

The item also amends the section to make the requirements for priority explicit in the Act, consistent with the changes discussed in item 10 above.

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[96] *Budapest Treaty on the International Recognition of the deposit of Microorganisms for the Purposes of Patent Procedure*, signed 28 April 1977, [1987] ATS 9 (entered into force 19 August 1980).

[97] The priority date is generally the date from which patentability criteria are assessed. The priority date may be established by filing a provisional application or earlier application in a Paris Convention country (see items 7, 10 and 11). Otherwise the priority date is usually the filing date of the complete application.

The item also amends the heading of section 114 to clearly indicate that the section applies equally to amendments to the claims and to the descriptive parts of the specification. The heading has been changed to better describe its purpose and the change is not intended to affect the operation of the section.

Item 34: Consequential amendment to section 114A

[s 114A]

This amendment is consequential to the amendments to sections 102 and 114 (see items 29 and 33).

Section 114A specifies that, in circumstances where an amendment is inadvertently allowed, the objection of lack of inventive step cannot be taken to the invention claimed in the amended application in light of the invention disclosed in the application prior to amendment.

The item amends section 114A to ensure that the provision continues to apply to circumstances where an amendment that should not be allowed under section 102 is inadvertently allowed.

The item also amends the section to make the requirements for priority explicit in the Act, consistent with the changes discussed in item 10.

Item 35: Consequential amendment to section 143

[s 143A]

This item is consequential to the amendment set out in item 21, which replaces section 101E with an amended provision. It accounts for the amended paragraph numbering in new section 101E.

Item 36: Regulation making power

[s 228]

This item inserts a provision for making regulations in relation to procedures for conducting preliminary search and opinions. Preliminary search and examination opinions are discussed at item 11.

Item 37: Definition of preliminary search and opinion

[Schedule 1]

This item inserts a definition of ‘preliminary search and opinion’. Item 11 provides the background and detail of the preliminary search and opinion.

Item 38: Definition of certified

[Schedule 1]

This item amends the definition of ‘certified’ to account for a change in numbering in section 101E.

Part 2 – Balance of probabilities test

Items 39 – 54

The items amend existing references to the Commissioner being ‘satisfied’ to confirm that the standard of proof is the ‘balance of probabilities’.

The provisions covered by items 39 to 54 currently use the term ‘satisfied’ on its own to refer to the standard of proof applied by the Commissioner. It was intended to mean the higher ‘balance of probabilities’ standard, and this is how it has been applied by the Commissioner.

The amendments are not intended to change the standard of proof applied by the Commissioner, rather they are intended to make the wording of these provisions consistent with the wording of s 49, 60, 100A, 101, 101E, 101G, 101J and 101N (as amended by items 14, 15, 18, 19, 21, 26 and 28 respectively), and put beyond doubt that the standard to be applied is the standard of ‘balance of probabilities’.

Part 3 – Application, savings and transitional provisions

Item 55: Application of amendments

The principles underpinning the application provisions are that the changes should:

- take effect as soon as possible, to quickly bring about a better balance and operation to the intellectual property system;
- not unduly prejudice users of the system, particularly with respect to not affecting rights granted prior to implementation of the changes, or making incorrect a decision of the Commissioner made prior to the changes.
- give applicants control and certainty over whether the old or new rules apply to their patent application or innovation patent.

Sub-item (1): The amendments made by items 2, 3, 4, 6, 8, 9 and 10 relate to raising patentability standards. These changes raise the standards set for inventive and innovative step (items 2 to 4), ‘usefulness’ (item 6), disclosure in complete patent specifications (item 8), claim support (item 9) and valid priority (item 10).

These changes are to apply in relation to the following:

- standard and innovation patents for which the complete application was made on or after the day of commencement (paragraph a);

- standard patents for which the application was made before the day of commencement, but where the applicant has not yet requested examination of the application relating to the patent on or before that day (paragraph b);

- innovation patents granted on or after commencement, if the application relating to the patent was made before that day (paragraph c);

- complete innovation and standard patent applications made on or after the day of commencement (paragraph d);

- standard patent applications made before the day of commencement, but where the applicant has not requested examination of the application before that day (paragraph e);

- innovation patent applications made before the day of commencement but not granted at that day (paragraph f); and

- innovation patents granted before the day of commencement, but where the Commissioner has not received a request to examine the patent or has not decided to examine the patent on or before that day (paragraph g).

This means that the changes will only apply to applications and patents where, at commencement, the applicant has not yet asked for examination of whether the application meets the substantive requirements of the Act. This strikes a balance between implementing the changes as soon as possible, addressing the need to raise patentability standards, and giving applicants control and certainty over whether the old or new rules apply to them. If an applicant wishes to avoid the new higher standards they can request examination before the commencement: the old rules will apply for the life of the application and any subsequent patent. Additionally, the fixed 12 month commencement period (see clause 2 above) will give applicants time to consider their business needs and decide whether to request examination under the old or new rules.

Sub-item (2): The amendments made by item 7 relate to raising standards for disclosure in provisional patent applications. This change will apply to provisional applications filed on or after the day of commencement.

Sub-item (3): The amendments made by items 11 and 37 relate to introduction of the preliminary search and examination scheme. These changes will apply to standard complete patent applications filed on or after the day of commencement.

Sub-item (4): The amendments made by items 12, 13, 14, 15 and 18 relate to examination or re-examination of standard patent applications.

The amendments expand the scope for substantive examination and raise the threshold for acceptance of patent applications and grant of patents.

Item 12 expands the grounds for examination to include usefulness. Item 13 removes the prohibition on the Commissioner considering prior use when examining for novelty. Items 14, 15 and 18 require a higher standard of proof be applied by the Commissioner when deciding to whether or not to accept patent applications

following examination (item 14) or to refuse to grant a patent following opposition (item 15) or re-examination (item 18).

Consistent with the other changes to raise standards (see sub-item (1)), the change applies to:

- standard patent applications made on or after the day of commencement; and
- standard patent applications made before commencement, but where the applicant has not requested examination before commencement.

Sub-item (5): The amendments made by items 16 and 17 expand the grounds for re-examination of standard patent applications and patents and allow prior use to be considered when examining for novelty. The changes will apply to all standard patents and patent applications, regardless of when the applications were made or the patents granted.

Sub-item (6): The amendment made by item 19 requires a higher standard of proof be applied by the Commissioner when deciding whether or not to revoke a standard patent following re-examination.

Consistent with the other changes to raise standards (see sub-item (1)), the change applies to:

- standard patents for which the complete application is made on or after commencement; and
- standard patents for which the complete application was made before commencement, but where the applicant has not requested examination before commencement.

Re-examination provides a cost effective and expedient mechanism for the Commissioner to re-consider her decision to accept an application or to grant a patent where new information relevant to validity of a patent comes to light. This meets both public and applicant interests in having certainty in the validity of granted patents.

It is appropriate that the Commissioner should be able to re-examine in respect of the full range of substantive grounds on which a patent can be revoked, regardless of when the application for the patent was filed, or the patent granted. This achieves the objective of increasing certainty in the validity of granted patents.

Sub-item (7): Items 23, 24 and 25 expand the grounds for re-examination of innovation patents. Item 25 allows prior use to be considered during re-examination for novelty. The changes will apply to all innovation patents, regardless of when the applications were made or the patents granted.

As discussed in sub-item 5, it is appropriate that the Commissioner should be able to re-examine in respect of the full range of substantive grounds on which a patent can be revoked, regardless of when the application for the patent was filed, or the patent granted. This achieves the objective of increasing certainty in the validity of granted patents without changing the patentability threshold.

Sub-item (8): The amendments made by items 20, 21, 22, 26, 27, 28, 30, 35 and 38 relate to examination, opposition and re-examination of innovation patents.

The amendments expand the scope for substantive examination and opposition and raise the threshold for revocation of innovation patents.

Item 20 expands the grounds for examination to include usefulness and to allow prior use to be considered when examining for novelty. Items 21, 22 and 26 require a higher standard of proof be applied by the Commissioner when deciding whether or not to certify an innovation patent following examination (items 21 and 22) or to revoke an innovation patent following re-examination (item 27). Items 27 and 28 expand the grounds for opposition of innovation patents and clarify that the standard of proof applied to the Commissioner's decision to revoke an innovation patent following opposition is the same as the standard applied to other decisions to revoke. Items 30, 35 and 38 are consequential to item 21.

Consistent with the other changes to raise standards (see sub-item (1)), the change applies to:

- complete innovation patent applications made on or after the day of commencement (paragraph a);
- innovation patent applications made before the day of commencement but not granted at that day (paragraph b);
- innovation patents granted before the day of commencement, but where the Commissioner has not received a request to examine the patent or has not decided to examine the patent on or before that day (paragraph c);
- innovation patents for which the complete application was made on or after the day of commencement (paragraph d); and
- innovation patents granted on or after commencement, if the application relating to the patent was made before that day (paragraph e).

Sub-item (9): The changes made by items 29 and 31 to 34 ensure that any requests or directions to amend made in respect of the following applications or patents are assessed according to the amendment provisions existing prior to commencement:

- standard patents granted, and innovation patents certified, prior to commencement;
- standard patent applications where the applicant has requested examination of the patent application prior to commencement; and
- innovation patents where the patentee or another person has requested examination of the patent, or the Commissioner has decided to examine the patent, prior to commencement.

This will apply regardless of whether the request or direction to amend the application or patent was made prior to, on or after commencement.

Requests or directions to amend made on or after commencement in respect of the following applications or patents are, however, assessed according to the amendment provisions existing after commencement:

- standard patent applications where the applicant has not requested examination of the patent application before commencement, and patents granted on these applications; and

- innovation patents where the patentee or another person has not requested examination of the patent, or the Commission has not decided to examine the patent, before commencement.

Sub-item (10): The amendments made by items 39, 41, 45, 48, 49 and 50 are to apply in the same way as the amendment made by items 12, 13, 14, 15 and 18, discussed in sub-item (4) above.

Sub-item (11): The amendments made by items 40, 43, 44, 46, 47 and 52 apply in relation to patents granted on or after commencement.

Sub-item (12): The amendment made by item 42 applies in relation to

- applications for innovation patents made on or after commencement;

- applications for innovation patents made before commencement but not granted at commencement; and

- innovation patents granted before commencement but where the patentee, or another person, has not requested examination, or the Commissioner has not commenced examination at commencement.

Sub-item (13): The amendments made by items 51 and 54 apply in relation to applications made on or after commencement.

Sub-item (14): The amendment made by item 53 applies in relation to acts required to be done on or after commencement.

Item 56: Transitional provision – approved form

This item relates to certification of an innovation patent following re-examination. Certification is provided for under section 101E and occurs via the issue of a certificate of examination in the form approved by the Commissioner.

The transitional provision is consequential upon the changes that repeal the existing section 101E and replace it with a new section 101E. The provision ensures that a certificate issued in the approved form under existing section 101E has the same force as it had before the changes were made, and as a form issued under the amended provisions will have.

Schedule 2 - Free access to patented inventions for regulatory approvals and research

Introduction

This schedule contains two amendments that give researchers greater certainty about where they have freedom to operate around patented technology.

The first amendment expands the existing exemption from patent infringement for activities necessary to gain regulatory approval for pharmaceutical products to all technologies. The second amendment introduces an exemption from patent infringement for research and experimental activities.

Item 1: Infringement exemptions

Acts for obtaining regulatory approval

[s 119B]

This item amends the Patents Act to introduce an exemption from patent infringement for activities undertaken for the purpose of obtaining information required for regulatory approval of a non-pharmaceutical product.

The patent system seeks to strike a balance between rewarding primary innovations and allowing subsequent competition. Twenty years is currently accepted by most countries as the appropriate maximum duration of patent protection for most technologies. After the expiry of a patent, any third party is able to market the previously patented product in competition with the former patent holder. These competing products are referred to as 'generic' products.

However, this balance can be upset where a generic manufacturer must seek regulatory approval before marketing their product. The approval process often involves making or using the patented invention, with the result that the generic manufacturer must wait until the term of the patent has ended before seeking regulatory approval in order to avoid infringing the patent. This has the effect of giving the patent owner a *de facto* extension of the patent term beyond the 20 years ostensibly given by the Patents Act.

The issue was first addressed in regards to pharmaceutical patents. The *Intellectual Property Laws Amendment Act 1998* introduced, and the *Intellectual Property Laws Amendment Act 2006* subsequently extended, an exemption from infringement for certain acts to gain regulatory approval in respect of pharmaceutical patents only. This permitted generic manufacturers to obtain regulatory approval during the term of the pharmaceutical patent so they could compete with the patentee as soon as the term expired.

However, pharmaceutical patents are not the only type of patentable product where pre-market regulatory approval is required. For example agricultural chemicals and certain medical devices require regulatory approval. There is no reason, in principle, why non-pharmaceutical technologies should be treated differently and why patentees in non-pharmaceutical technologies should be afforded a *de facto* extension of term.

Accordingly, this amendment seeks to extend the regulatory approval exemption to all technologies. The new exemption will apply to activities undertaken solely for purposes connected with obtaining regulatory approval of goods (other than the pharmaceutical goods covered by section 119A) under Australian law or under the law of a foreign country, or both.

The use of 'solely' ensures that a generic manufacturer may not use the exemption for purposes other than seeking regulatory approval. For example, they may not, in the process of seeking regulatory approval, stockpile the patented product for sale upon expiry of the patent, or manufacture the product for export to another country.

The amendments are not intended to limit the type of regulatory approval for which the exemption may be used, save for the requirement that it must be imposed by law (in Australia or another jurisdiction). The provision is intended to account for changes in existing regulatory requirements. It is also intended to cover regulatory requirements that do not exist now, but may be imposed in the future as new regulatory regimes are created.

The exemption is not intended to cover experimental uses of the patented invention. Rather, experimental uses are intended to be dealt with under the related amendment discussed below.

Acts for experimental purposes

[s 119C]

This item amends the Patents Act to exempt experimental activities from patent infringement.

The patent system exists to encourage innovation and promote the dissemination of technical knowledge. It rewards the innovator who has invented a new and useful product with a time-limited exclusive right to exploit their invention. In exchange the inventor must disclose their invention to the public. In this way innovators gain a competitive advantage to commercialise their inventions, while the public and the research community gain access to information about new technology. Researchers can then study, test and improve on the new technology for the benefit of society as a whole.

However, the benefits of this system are diminished where there is uncertainty about the extent to which patent rights impinge on freedom to do research.

Uncertainty discourages researchers from working in areas where there are patents, and where they may be at risk of being sued for infringement. It also leads to researchers expending effort and expense on obtaining advice, where they have concerns about how their experiments intersect with the patent system. These inefficiencies detract from the system.

Concerns have been raised that the lack of a statutory exemption from infringement for research and experimental activities in Australia is causing uncertainty and disincentives in the research community, and for follow-on innovators. Although it is generally accepted that some form of implicit experimental use exemption exists,

there has been no litigation of this under Australia's current patent legislation. As a consequence the existence and scope of any implicit exemption remains uncertain.

The issue of an experimental use exemption has previously been considered by both the Australian Law Reform Commission[98] (ALRC) and the Advisory Council on Intellectual Property[99] (ACIP). Both confirmed that the lack of a statutory exemption was creating uncertainty for the research community. Both recommended introduction of an explicit exemption.

The item implements these recommendations by introducing a statutory exemption from infringement for research and experimental activities.

It is intended that 'experimental' be given its ordinary English meaning. The exemption should apply to tests, trials and procedures that a researcher or follow-on innovator undertakes as part of discovering new information or testing a principle or supposition.

To provide certainty and clarity for researchers, an additional inclusive list of activities that are deemed to be experimental has been included. This list is not intended to be exhaustive and a court may find that other activities also fall within the meaning of 'experimental'.

The exemption is not intended to apply only to circumstances where activities are undertaken solely for experimental purposes. This would ignore the reality of the current research environment, where research is frequently undertaken for mixed purposes.

For example:

- a researcher may be contracted and paid to undertake experiments;
- research may be conducted with a view to ultimately commercialising the end-products of the experimentation; and
- research may be undertaken with, and partially funded by, a commercial partner.

In each of these circumstances the exemption should apply as long as the specific acts are undertaken for the predominant purpose of gaining new knowledge, or testing a principle or supposition about the invention. Thus if an activity is conducted primarily for the purpose of improving a patented invention, the activity would still be exempt, even if the person also had in mind commercialising the improvement in the future.

However, the exemption is not intended to apply where the main purpose of the acts is to commercialise the invention, or to manufacture it for the purpose of sale or use for commercial purposes. Additionally, 'market research' on a patented invention (eg making and using the invention to test the likely commercial demand for a product) is not intended to be exempt. This too has a predominantly commercial purpose.

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[98] ALRC Report 99, *Genes and Ingenuity: Gene Patenting and Human Health* (the ALRC 99 Report), published June 2004, available through www.alrc.gov.au.

[99] Advisory Council on Intellectual Property', November 2005, available through www.acip.gov.au.

The amendment requires that the experiments be ‘related to’ the patented invention. This choice of words is intended to achieve two ends.

First, it is intended to cover circumstances where experiments inherently include the subject matter of a patent, perhaps as part of a larger or more complex experiment, but the researcher is unaware of the existence of the patent. This is consistent with the policy objective of freeing researchers to innovate. Researchers should not have to conduct extensive patent searches before starting every experiment.

Secondly, it is not intended to exempt the use of patented ‘research tools’ from infringement. A ‘research tool’ is something that is used to facilitate an experiment, rather than something that is the subject of the experiment. For example, a researcher testing the effect of a particular herbicide on different plants might use a patented wetting agent to facilitate uptake of the herbicide. Here use of the wetting agent should not be exempt from infringement. The agent is being used as a tool: the experiments do not relate to it.

Research tools are often used exclusively or primarily in research. If the experimental use exemption were to apply to such tools it would substantially diminish the economic incentive to develop better research tools.

The amendments explicitly preserve any implicit experimental use defence that may be found by a court. The addition of an explicit exemption is not intended to detract in any way from any existing protection that researchers may enjoy.

Item 2: Application provision

The amendments to exempt from infringement acts for experimental purposes or obtaining regulatory approval will apply to any acts done on or after the date of commencement.

Schedule 3 - Reducing delays in resolution of patent and trade mark applications

Introduction

This schedule implements a number of changes to reduce delays in the finalisation of patent and trade mark applications. The changes seek to better balance the public interest in early certainty as to the scope of granted rights with applicants' interests in having sufficient time to get their applications in order for acceptance. The changes address delays in two areas.

First, the changes address problems with the strategic use of divisional patent applications to delay resolution.

Divisional applications allow an applicant to 'divide out' parts of an earlier application and prosecute them as separate applications. This is particularly useful where an application discloses more than one invention (subsection 40(4) of the Act specifies that the claims must relate to one invention). The applicant may prosecute each divisional application as a separate application, with the divisional applications retaining the same priority date as the earlier 'parent' application, as long as certain conditions are met.

Currently, a divisional application can be filed at any time up to grant of the parent application, including during opposition proceedings (opposition proceedings are discussed below). A standard patent application can also be converted to a divisional application, at any time up to grant of the divisional application, including during opposition proceedings.

As well as being used to 'divide out' inventions described in a parent application, divisional applications can be used tactically to continue prosecution of an invention that is the same, or substantially the same, as an invention claimed in the parent application – these are colloquially called "continuation divisionals". This happens where an applicant has been unable to resolve issues raised during examination of the parent application within the time limit set for examination, or where the parent application has been opposed. In these circumstances, the applicant allows the parent application to lapse and pursues the same invention via a divisional application.

This causes problems where a continuation divisional is filed late in opposition proceedings. It causes the opponent unnecessary expense in opposing the parent application, and then monitoring, and possibly opposing, the divisional application. It also disadvantages the public, as the period of uncertainty over the eventual monopoly is prolonged.

Conversion of a standard application to a divisional application can also be problematic where the conversion is made late in the opposition period. This generally happens where prior art raised by the opponent is an application filed by the same applicant which was inadvertently missed during examination of the opposed application. If the opposed application discloses the same invention and was filed before the earlier application was accepted, lapsed or withdrawn, it can be converted

to a divisional application of the earlier application. The opposed application is given the priority date of the earlier application and the earlier application is no longer prior art for the opposed application. Often this means that one of the main grounds of opposition is no longer available.

This leads to unnecessary costs for an opponent, who has prepared evidence based on a citation that is no longer relevant, and a priority date that no longer applies. It can also lead to extended periods of uncertainty for the public about the likely validity of the opposed application.

The amendments in items 3, 4 and 5 address these problems by limiting the time within which a divisional application can be filed, or a standard application converted to a divisional application.

Secondly, the changes in this schedule seek to reduce delays and complexity in patent and trade mark opposition proceedings. Opposition proceedings result where a third party opposes the grant of a patent or the registration of a trade mark following examination and acceptance of the application by the Commissioner (patent applications) or the Registrar (trade mark applications).

Oppositions meet an important objective of preventing the grant of invalid IP rights. They give the Commissioner or Registrar the opportunity to give close scrutiny to an application, with the benefit of submissions from the applicant and opponent. They also present a mechanism for taking account of the interests of business competitors and other interested parties in the patent and trade mark processes.

Oppositions are intended as a relatively swift, straightforward and inexpensive process to settle disputes: an alternative to more costly court proceedings. However, there are problems with the current opposition schemes, including appeals from opposition decisions, which result in undue delays and complexity in resolving opposed applications. This can cause difficulties for applicants, who are keen to start using their IP rights. The inability to do so for an unreasonable time can be commercially oppressive. It can also cause difficulties for opponents, who want a quick decision that the patent granted on the application would be invalid and therefore not a commercial threat to them.

The amendments in items 6 to 32 implement changes intended to better streamline the IP system and to reduce complexity and delay in the resolution of opposed patent and trade mark applications.

Patents Act 1990

Items 1 and 2: Patent opposition - consequential amendments

[s 26]

This amendment is consequential upon the insertion of new section 112A (see item 10 below). The item amends subsection 26(2), which deals with amendments in contravention of section 112 to also refer to new section 112A.

[s 61(1)]

This amendment is consequential upon the insertion of new paragraph 210A(2)(a) (see item 15). It amends subsection 61(1), which deals with grant of a standard patent, to also refer to new paragraph 210A(2)(a).

Item 3: Divisional applications - standard patents

[s 79B]

This item amends the Act to permit the regulations to prescribe an earlier deadline for filing a divisional application, to require that a divisional application include prescribed particulars and to limit the period within which a standard application can be converted to a divisional application.

As discussed above, currently a divisional application can be filed at any time up to grant of the parent application, including late in opposition proceedings.

The amendment provides for regulations to be made restricting the period within which a divisional application can be made. The period will be up to the end of the time within which a notice of opposition to grant of the parent application can be filed (three months after advertisement of acceptance of the parent application).

This means an applicant will be unable to file a divisional application once the period for commencing opposition proceedings on the parent application has expired.

This strikes a balance between preserving patent applicants' interests in being able to 'divide out' multiple inventions and the public interest in preventing undue delays in determination of applications.

The amendment also provides for regulations to be made requiring that certain details are provided with the divisional application. These will include particulars claiming divisional status for the application and details of the parent application.

This promotes transparency and treats divisional applications in the same way that other applications are treated with respect to disclosure of priority details. Currently, the Act and the Regulations do not explicitly mention the requirement for divisional applications to identify their parent application. Rather, the legislation requires that the patent request, which provides particulars of the application, must be in the 'approved form', being the form approved by the Commissioner.[100] The approved form then requires that the applicant identify the parent application. This contrasts with other types of applications, where the requirements to specify priority applications are explicitly required by the Act or prescribed by the Regulations.

Regulations will also be made under chapter 10 of the Regulations (the chapter dealing with rules for amendments) to specify that the particulars can only be amended during the period that a divisional application could ordinarily be filed (see above), or no later than acceptance of the divisional application, thus restricting the time within which a standard application can be converted to a divisional application.

This strikes a balance between giving applicants time to decide whether they need to convert a standard application to a divisional (perhaps because they have two

[100] Sections 79B (1) and 29 (4) and Schedule 1, Patents Act; Paragraph 6A.1 (a), Patents Regulations.

applications that relate to the same or very similar inventions) and avoiding unnecessary delays and costs for the public and other parties.

Items 4 and 5: Divisional applications - innovation patents

[s 79C]

Item 5 amends the Act to permit the regulations to require that a divisional application of an innovation patent include prescribed particulars.

The intent and policy objective of this change are the same as discussed above (item 3) for divisional applications of standard patents. The changes improve transparency. They also strike a balance between giving applicants time to decide how to best proceed with their applications, and avoiding unnecessary delays and costs for the public and other parties.

Item 4 is consequential upon item 5. It removes an unnecessary reference to the regulations.

Item 6: Patent opposition - amendments directed by the court

[s 105]

This item amends the Patents Act to provide that a court may consider and decide on amendments to a patent application during an appeal from a decision of the Commissioner.

Currently, during an appeal from a decision of the Commissioner the Court must confine itself to the same subject matter as considered by the Commissioner.[101] This means that where an applicant has amended their specification subsequent to the Commissioner's decision, the Court cannot consider the amended specification, even where the amendments may overcome the grounds on which the decision is being appealed.

This adds complexity to the appeals process and to resolution of opposed patent applications.

The item addresses this problem by giving a court power to consider and decide upon any amendments proposed by the applicant while an appeal is on foot. These amendments would be considered under the existing provisions under which courts may direct amendments.[102]

The provision applies only to amendment of patent applications, not to amendment of granted patents.

Existing section 105 applies to amendment of patents. It is expected that in exercising their discretion under new subsection 105(1A), the courts will give account to the different factors that are relevant to applications, in contrast to those applying to patents.

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[101] *New England Biolabs Inc v F Hoffmann-La Roche AG* [2004] FCAFC 213
[102] Section 105, Patents Act.

Items 7, 8 and 9: Patent opposition - consequential amendment

[s 105]

These items are consequential upon the insertion of new subsection 105(1A) (see item 6 above). They ensure that subsections 105(2), (3) and (5) apply to both existing subsection 105(1) and new subsection 105(1A).

Item 10: Patent opposition - decisions on appeal

[s 112A]

This item inserts a new provision, section 112A.

This item is consequential upon item 6 above, which gives a court the discretion to consider and decide on amendments to a patent application during an appeal from a decision of the Commissioner.

The item specifies that only the Court can deal with amendments to an application during an appeal to the Court against a decision of the Commissioner relating to that application. This is similar to an existing prohibition, where there are court proceedings in respect of a granted patent.[103] The intention is to avoid having the same issues dealt with by different decision makers.

Item 11: Patent opposition - withdrawal of applications

[s 141]

This item amends the Patents Act to permit the Commissioner to refuse an applicant's request for leave to withdraw their opposed patent application.

The ability to withdraw an application under section 141 is a useful method of getting an application 'off the books' if the applicant no longer wishes to pursue it.

However, withdrawal can be used to side-step opposition proceedings. Where an application has been opposed, an applicant can withdraw the opposed application and pursue the invention in a divisional application.

This allows the applicant to avoid the scrutiny of opposition proceedings whilst continuing to pursue the opposed invention in the divisional application. This frustrates the public interest in early determination of an application. It can also put an opponent to the unnecessary expense of having to prepare for an opposition that does not proceed, then having to monitor and possibly oppose the divisional application.

The item addresses this problem by giving the Commissioner the power to refuse leave to withdraw an opposed application. The Commissioner can then refuse withdrawal of an opposed application where the applicant has filed a divisional application claiming the same, or substantially the same, invention (a "continuation divisional").

[103] Section 112, Patents Act.

The existing rules will continue to apply to unopposed applications. This will ensure that applicants are still able to withdraw an application that they genuinely have no interest in pursuing.

A decision of the Commissioner to refuse leave to withdraw an opposed application will be reviewable by the Administrative Appeals Tribunal (see item 16).

Item 12: Patent opposition – repeal of criminal sanctions

[ss 179 to 181]

This item is consequential upon item 14 below. The item repeals the criminal sanctions for failure to comply with a summons, a refusal to give evidence before the Commissioner, or failure to produce documents or articles required by the Commissioner. The sanctions will be replaced with new non-criminal sanctions, discussed in item 15 below.

The majority of patent applicants are foreign persons or companies, as are many of the persons or companies who oppose patent applications. As discussed below (item 15), concerns have been raised about whether the Commissioner's powers can be exercised against entities outside Australia.

Given that the amended power will apply to foreign entities, criminal sanctions are not appropriate as they may be difficult, or impossible to enforce. This item addresses this issue by repealing the current criminal sanctions.

Item 13: Patent oppositions - consequential amendment

[s 210]

This item is consequential upon item 14. It amends section 210 to account for the two new subsections inserted by item 14 below. It does not otherwise change the operation of section 210.

Item 14: Oppositions – Commissioner's powers

[s 210]

The Commissioner currently has the power to summon witnesses, receive evidence or require the production of documents or articles – section 210. These powers are usually exercised during opposition proceedings at the request of one of the parties – for example, to require a party to produce a document that the other party may wish to use in the proceedings. Currently, there are criminal sanctions for non-compliance with the Commissioner's request.

The objective of this provision is to ensure that the Commissioner has access to the information and evidence necessary for her to come to the correct decision in an opposition proceeding.

There are problems with the current provision. Under the current provision, it is difficult for the Commissioner to refuse a request to summon a witness or require production of documents or articles, regardless of whether the oral evidence or

material is likely to be of relevance or benefit to the proceedings. This introduces delays, as parties respond to, or challenge, the Commissioner's order to produce, that are not necessarily counterbalanced by the likelihood of the material contributing to a more correct outcome from the proceedings.

The item addresses this problem by amending the Patents Act to introduce a new higher threshold test that must be satisfied before the Commissioner can exercise her power to summon witnesses, or require the production of documents or articles.

Currently, the test that must be satisfied before the Commissioner can require production is quite low – the material sought need only be 'on reasonable grounds, arguably relevant to the issues in the litigation'.[104] This results in many requests for the exercise of the power by the Commissioner, even where there is little likelihood that the material will actually assist the Commissioner to resolve the issues in dispute.

The amendment raises the threshold test to require that the Commissioner be satisfied that the document or article or oral evidence will likely be of substantial relevance before exercising her power. This is intended to permit the Commissioner to reject requests where she believes that the material is of limited relevance to the proceedings. With respect to summoning of witnesses, the provision also requires that the summoning of a witness is necessary. However, where evidence can be provided in written form, for example as a statutory declaration, then the Commissioner will request evidence be provided in this way, rather than by summoning a witness and hearing oral evidence.

The benefits of this amendment are reduced costs for the party that is the subject of the request, fewer delays in the resolution of opposition proceedings and a better focus on the material that actually is relevant to the opposition proceedings.

The item also amends the Patents Act to clarify that the Commissioner's power extends to entities outside of Australia, but only where the entity is a party to proceedings before the Commissioner.

Currently the Act does not explicitly specify in what area the Commissioner's powers may be exercised. This creates uncertainty over whether the Commissioner's powers extend to the many foreign entities that appear before the Commissioner.

The amendments are intended to resolve this uncertainty and clarify that the Commissioner's powers can extend to foreign entities where they are parties to proceedings before the Commissioner. Consistent with international law, such parties are able to be brought within the 'prescriptive jurisdiction' of Australia, as they have a legal interest in the proceedings before the Commissioner.

This will ensure greater certainty and clarify that the power can extend to the majority of patent applicants and opponents who are foreign entities.

The amendment also clarifies that, where the Commissioner exercises her power to summon witnesses or require production of documents of a body corporate, those powers extend to any officer, agent or employee of that body.

[104] *G S Technologies v Commissioner of Patents* (1997) 39 IPR 583.

Item 15: Patent opposition – sanctions for non-compliance

[s 210A]

This item amends the Patents Act to replace the criminal sanctions discussed in item 12, with a new non-criminal sanction for non-compliance with an exercise of the Commissioner's powers.

The current criminal sanctions in sections 179 to 181 may be difficult, if not impossible to enforce against a party outside of Australia. Accordingly, this item provides for a new non-criminal sanction where the Commissioner has the discretion to take one of the following actions where a person fails to comply with a requirement made under section 210 (see item 14 above):

- refuse to grant a patent, if the person who fails to comply with the requirement is the applicant for the patent;
- draw an inference unfavourable to the person's interest in the proceedings before the Commissioner – this could include dismissal of the proceedings or award of costs, where appropriate; or
- actions of a kind prescribed by the regulations.

This provision gives the Commissioner flexibility to apply a sanction appropriate to the particular circumstances and to the person's role and interest in the proceedings.

Consistent with the existing provisions in sections 179 to 181, the sanction may not apply where the person to whom the power is directed has a reasonable excuse or has not been offered payment of reasonable expenses for complying with the order.

Item 16: Patent opposition – review of decisions

[s 224]

This item is consequential upon item 11. The item ensures that a decision made by the Commissioner under new subsection 141(1) to refuse leave to withdraw an application is appealable to the Administrative Appeals Tribunal.

Trade Marks Act 1995

The following items seek to better streamline and reduce complexities in the trade marks opposition process. Simple and streamlined processes are particularly important for trade mark oppositions where many applicants are individuals and small businesses with limited experience of opposition proceedings.

Trade mark opposition procedural requirements are largely set out in the regulations. Consistent with this, most of the changes below relate to amendments to permit the regulations to prescribe additional requirements.

Item 17: Trade mark opposition – consequential amendment

[s 11]

This item is consequential upon item 21. It amends paragraph 11(1)(a) to include 'lapsing' under new section 54A as one of the conditions defining the end of the period during which a trade mark is regarded as 'pending'.

Item 18: Trade mark opposition – notice of opposition and statement of grounds and particulars

[s 52]

This item amends the Trade Marks Act to remove the requirement that the opponent serve a notice of opposition on the applicant.

Currently, a person wishing to oppose an application is required to both file the notice of opposition with the Trade Marks Office[105] and then serve a copy of the notice on the applicant.[106]

With the changes in place the opponent will still be required to file the notice of opposition with the Trade Marks Office, but the Office, not the opponent, will send the notice to the applicant. This will better streamline the process of commencing an opposition and reduce complexity for opponents, many of whom are private individuals and small businesses. It will also give the Trade Marks Office greater control over ensuring that the notice of opposition is provided to the applicant in a timely manner.

The requirement for the Trade Marks Office to send a copy of the notice of opposition to the applicant is intended to be implemented in the regulations.

The item also permits regulations to be made prescribing the form in which the notice of opposition must be filed.

Opponents are currently required to state the grounds on which they intend opposing an application when they file their notice of opposition. However, they are not required to set out the particulars of those grounds. Frequently, this means that the opponent sets out all possible grounds, whether or not they have any intention of relying on them. As a result, the trade mark applicant may be faced with a number of grounds to deal with and no indication of which are key to the opposition until late in the opposition proceedings and sometimes not until the hearing itself.

This makes it difficult for the applicant to prepare their case. It also increases costs as the applicant is obliged to prepare a case in response to all grounds raised in the statement of grounds, including those on which the opponent may no longer rely.

The amendment addresses this problem by allowing for regulations to be made to require the opponent to file a statement of particulars of the grounds on which they intend to oppose. This will help focus oppositions earlier, reducing costs and unnecessary effort for the applicant.

The particulars will describe the material facts but will not be required to set out the evidence by which those facts will eventually be proved. This will be provided at a

[105] Section 52 (2), Trade Marks Act.
[106] Section 52 (3), Trade Marks Act.

later stage of the opposition proceedings. The particulars will be required to be filed within 1 month of filing the notice of opposition.

Item 19: Trade mark opposition - notice of intention to defend

[s 52A]

This item inserts section 52A, which requires the trade mark applicant to file a notice stating their intention to defend their application in the opposition proceedings.

Not all applicants defend their applications in opposition proceedings. This may be for a variety of reasons. For example, they may be persuaded by the opponent's case or they may no longer wish to pursue trade mark registration because of changing business circumstances. Where this occurs it still takes some months for the matter to be finalised, and frequently the opponent must still go to some time and expense preparing their case.

In contrast, some overseas trade mark opposition systems require applicants to provide notice that they intend to defend their trade mark. If the applicant does not give notice that they intend to defend then the application is deemed withdrawn or abandoned. This permits an uncontested opposition to be resolved in a more streamlined and efficient manner.

The item introduces a similar requirement, where an applicant must file a notice of intention to defend their opposed application. The penalty for not filing a notice will be the application lapsing (see item 21). This allows an uncontested opposition to be resolved many months sooner and with significantly less effort on the part of the opponent.

There will be no fee associated with filing the notice.

If an applicant inadvertently fails to file a notice of intention to defend, they will be able to seek an extension of time to file that notice under Part 5 of the Trade Mark Regulations.

Item 20: Trade mark opposition – dismissal of opposition

[s 54]

This item amends the Trade Marks Act to provide a power for the Registrar to dismiss a trade mark opposition in prescribed circumstances.

This provides a sanction where an opponent does not comply with their obligation to file a statement of grounds and particulars (see item 18 above). The statement of grounds and particulars performs an important function in informing the applicant of the likely case that they will have to respond to. The applicant can then make an informed decision at an early stage whether to go to the time and expense of defending the opposition.

Given the consequences for an opponent if their opposition is dismissed, it is appropriate that the new power is through the primary legislation. As the procedural details of the opposition process are generally in the regulations, the exact

circumstances in which the power is enlivened will be prescribed in the regulations. This will permit the circumstances for dismissal to be amended quickly if there are any changes to the statement of grounds and particulars requirements, which will also be implemented in the regulations.

Item 21: Trade mark opposition – lapsing of applications

[s 54A]

This item amends the Trade Marks Act to provide for lapsing of applications in prescribed circumstances.

This power is necessary to provide a sanction for an applicant who fails to provide a notice of intention to defend (see item 19). Its purpose is to avoid putting the opponent to unnecessary expense in preparing an opposition that the applicant never intended to defend. Consistent with other procedural aspects of the opposition process, the requirement for a notice of intention to defend will be implemented in the regulations.

As the consequences for a failure to comply are significant for the applicant, it is appropriate that the power to lapse is explicit in the Act. Consistent with the other aspects of the procedural system, the details of the circumstances in which it would apply are left to the regulations. This will allow for the prescribed circumstances to be amended quickly if this is required by changes to the notice of intention to defend requirement (also imposed in the regulations).

Items 22 and 23: Trade mark oppositions – consequential amendment

[s 55]

These items are consequential upon item 21.

Section 55 sets out the procedure for deciding opposition proceedings where an opposition has not been discontinued or dismissed. The item amends the section to take account of lapsing under new section 54A (see item 21).

Items 24 and 25: Trade mark opposition – amending the notice of opposition and statement of grounds and particulars

[s 66]

These items amend the Trade Marks Act to provide that prescribed documents cannot be amended under section 66. The changes are consequential upon proposed changes which will require an opponent to provide a statement setting out the grounds on which they are opposing the application and the particulars of those grounds (see item 18). The proposed changes will be implemented in the regulations.

The intention is that the notice of opposition and statement of grounds and particulars be prescribed documents. The regulations will only permit the opponent to amend the statement of grounds and particulars under tightly controlled circumstances.

Together the notice of opposition and the new statement of grounds and particulars provide the applicant with a clear idea of the case they will have to meet early in the opposition process. They can then make an informed decision whether to defend their application or let it lapse. Restricting the circumstances under which an opponent can amend these two documents ensures that complete information is filed in the first instance. An opponent will not be able to use the broad power under section 66 to later add grounds of opposition or particulars that should have been included when the documents were first filed.

Item 26: Trade mark opposition – registration of trade marks

[s 68]

This item clarifies that the Registrar is obliged to register a trade mark application where an opposition has been dismissed under section 54. Existing subsection 68(2) only obliges the Registrar to register a trade mark following dismissal of an opposition under section 222. The item amends subsection 68(2) to also oblige the Registrar to register a trade mark following dismissal of an opposition under subsection 54(2).

Item 27: Trade mark opposition – lapsing of applications

[s 68]

This item is consequential upon item 21. It inserts a note to clarify that an opposed trade mark application will lapse where a notice to defend the application is not filed.

Item 28: Trade mark opposition – notice of opposition to an application for removal of a trade mark from the Register

[s 96]

This item amends s 96 to permit regulations to be made prescribing the form and manner in which the notice of opposition must be filed when opposing an application for removal of a trade mark before the Registrar.

Similar to the processes for opposing an application to register a trade mark, an application to remove a trade mark may also be opposed before the Registrar. For the same reasons given in relation to the changes at item 18 above, it is intended the regulations be able to prescribe that an opponent must also file a statement of grounds and particulars.

Note that the changes apply only to oppositions before the Registrar. Oppositions before a court will follow the existing court procedure, in accordance with the form approved by the court and the court rules.

Item 29: Trade mark opposition – removal of a trade mark from the Register

[s 97]

This item is consequential upon item 30. The item clarifies that the Registrar must remove a trade mark from the Register if an opposition to an application to remove the trade mark from the Register for non-use has been dismissed (see item 29).

Item 30: Trade mark opposition - dismissal of opposition to application to remove a trade mark from the Register

[s 99A]

This item gives the Registrar the power, in prescribed circumstances, to dismiss an opposition to a non-use application. A non-use application is an application to remove an unused trade mark from the Register.

The circumstances leading to dismissal would be similar to those discussed in item 20, where a statement of grounds and particulars (see item 28 above) is not filed, or is insufficient.

Given the consequences for an opponent if their opposition is dismissed, it is appropriate that the new power is introduced through the primary legislation. As the procedural details of the opposition process are provided for in the regulations, the exact circumstances in which the power is enlivened will be prescribed in the regulations.

Item 31: Trade mark oppositions – regulation making power

[s 231]

This item amends the Trade Marks Act to include a new broader power to make regulations in respect of opposition proceedings.

Currently, the legislation governing the trade marks opposition system is mostly contained within the regulations. However, a number of procedural aspects of the system are currently contained in the Act.[107] This is in contrast with the current system for patent oppositions, where almost all of the procedural requirements are provided in the regulations.[108]

Putting the detail of procedural requirements in the regulations allows greater flexibility to finetune the system and to respond to changing requirements. It also ensures greater alignment between the Trade Marks and Patents legislation, making for a more consistent approach for users of both systems.

This item provides a broad opposition regulation-making power for trade marks which is consistent with the current opposition regulation making power in the Patents Act.[109] The provisions providing for the right to oppose an application[110] and the rights of the parties to be heard[111] will remain in the primary legislation.

[107] See eg , section 52(2) and section 52(3), Trade Marks Act.
[108] See section 59 and section 60, Patents Act and Chapter 5, Patents Regulations.
[109] Section 228(2)(h), Patents Act.
[110] Section 52(1), Trade Marks Act.
[111] Section 54(1), Trade Marks Act.

Part 2 – Application and transitional provisions

Item 32: Application of amendments

The principles underpinning the application provisions are that the changes should:

- take effect as soon as possible, to quickly bring about a better balance and operation to the intellectual property system; and
- not unduly prejudice users of the system, particularly with respect to not affecting rights granted prior to implementation of the changes, or making decisions of the Commissioner or Registrar made prior to the changes incorrect.

Sub-item (1): Items 1 and 10 relate to amendments to patent applications during an appeal to the court. The amendments prohibit the Commissioner from dealing with amendments while court proceedings are afoot. The changes should apply to:

- requests to amend made on or after the day of commencement; and
- requests to amend made before commencement, if the Commissioner has not dealt with the request on or before that day.

Sub-item (2): Items 2, 13, 14, and 15 relate to sanctions for non-compliance with the Commissioner's requirements for a person to appear in proceedings and for the production of documents and articles. The sanctions should apply to requirements made by the Commissioner on and after the day of commencement.

Sub-items (3) and (4): Items 3, 4 and 5 relate to requirements for filing divisional applications of standard and innovation patents. The requirements should apply to all applications filed on or after the day of commencement.

Sub-item (5): Items 6, 7, 8, and 9 relate to giving the court the discretionary power to direct amendment of a patent application during an appeal from a decision of the Commissioner. The changes should apply to:

- appeals made on or after the day of commencement; and
- appeals made before commencement, but not determined, dismissed or disposed of at commencement.

Sub-item (6): Items 11 and 16 relate to the Commissioner refusing to grant leave to withdraw an opposition. The changes should apply to any application for withdrawal made on or after commencement, in respect of any application made on, before, or after the day of commencement.

Sub-item (7): Items 17 to 31 relate to the process of dealing with patent and trade mark oppositions. The changes should apply to all opposition proceedings commenced by notices of opposition made on or after the day of commencement.

Item 33: Transitional provisions – regulations

This item provides that existing regulations relating to withdrawal of applications during opposition proceedings remain in force after commencement. The regulations require the Commissioner to publish a notice of withdrawal and specify periods within which applications may not be withdrawn. The regulations are unaffected by the changes made to the Act.

Schedule 4 - Assisting the operations of the IP profession

Introduction

The Patents Act and the Trade Marks Act regulate classes of professionals known as patent attorneys and trade marks attorneys. Attorneys provide a valuable service to innovators, in that they assist and advise on intellectual property protection matters. Patent and trade marks attorneys must satisfy specific requirements, relating to matters such as character and technical qualifications, in order to be registered under the legislation.

However, there are two aspects of the regulatory regime for attorneys that are in need of reform.

Incorporated patent and trade marks attorneys

First, companies are prohibited from describing themselves as a patent or trade marks attorney, or from providing patent attorney services.[112] This limits the flexibility of attorneys to choose the most appropriate structure for their business.

Most other professions, including lawyers,[113] are permitted to practise through a corporate structure. In particular, the prohibition against attorneys practising through a corporate structure creates difficulties where the same firm includes both attorneys and other professionals (firms containing both legal practitioners and attorneys are common). If the other professionals practise through a corporate structure, then the firm must maintain a separate unincorporated partnership for the attorney arm of the business. This creates unnecessary expense.

The items in this schedule address this problem by permitting companies to provide patent attorney services and advertise themselves as patent and trade marks attorneys. The amendments include a scheme to provide for the registration and regulation of incorporated patent attorneys. The scheme seeks to strike a balance between ensuring adequate protection for users of attorney services and avoiding unnecessary regulation for the profession.

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[112] Section 201 (5), Patents Act; Section 156, Trade Marks Act. Note that, although there is no explicit prohibition in s 156 against a company describing itself as a trade marks attorney, it is currently impossible for a company to satisfy the knowledge and character requirements for registration as a trade marks attorney. Note also that there is no prohibition on companies (or anyone else) providing trade marks services.

[113] See eg *Legal Profession Act 2004* (NSW); *Legal Profession Act 2004* (Vic); *Legal Profession Act 2007*(Qld). See also proposed National Legal Profession Law currently the subject of Council of Australian Governments (COAG) consultation (available at: http://www.ag.gov.au/www/agd/agd.nsf/Page/Consultationsreformsandreviews_AbetterframeworkforFederalCourts-Consultation_CouncilofAustralianGovernments(COAG)NationalLegalProfessionReformconsultationpackage).

The scheme is broadly based on the existing laws regulating incorporated legal practices, with appropriate adjustments to reflect the difference between lawyers and patent and trade marks attorneys. Adopting such a scheme has several benefits. The model has already proven to be successful in regulating a similar profession. Additionally, given the overlap between the legal and attorney professions, having similar regulatory schemes is likely to reduce compliance costs for joint lawyer-attorney firms.

Client-attorney professional privilege

Secondly, although communications with Australian attorneys attract professional privilege, communications with a foreign attorney are not so privileged. Given the global nature of many IP matters (where the same trade mark or invention is registered in a number of different countries) many applicants and rights holders depend upon advice from foreign patent and trade marks attorneys. The fact that these communications do not attract privilege places these parties at a disadvantage.

The restricted nature of client-attorney privilege also contrasts with the legal profession, where client-lawyer privilege extends to communications with foreign legal professionals. It is appropriate that client-attorney communications be afforded the same degree of privilege.

This schedule rectifies the problem by extending to patent and trade mark attorneys the same 'advice' privilege as is extended to legal professionals. This extends privilege to client communications with foreign attorneys and to some documents prepared by a third party.

Patent attorney incorporation and privilege

Items 1 to 8: Definitions

[s 3]

These items amend section 3 to provide cross references to new terms that will be defined in Schedule 1 of the Patents Act.

Item 9: Liability

[s 132]

This item removes the reference to 'his or her' professional capacity from section 132, substituting it with a reference to 'a' professional capacity.

This amendment is consequential to the amendment in item 21 which will permit bodies corporate (in addition to natural persons) to become registered patent attorneys. The amendment will ensure that the privilege that section 132 provides to registered patent attorneys is not limited to natural persons.

Items 10 to 13: Penalties for false representation

[ss 177, 178 and 182]

These items amend various offence provisions of the Patents Act to express the penalties in penalty units instead of dollar amounts.

The amendments do not change the actual penalties currently applicable to the offences.

Items 14 and 15: Information disclosed to the Australian Securities and Investment Commission

[s 183]

These items amend section 183 to clarify that the Designated Manager may disclose information, including personal information, to the Australian Securities and Investments Commission (ASIC), where that information was obtained as a result of the performance of functions and duties, or the exercise of powers, in relation to incorporated patent attorneys.

The Designated Manager is an SES employee (currently the Director-General of IP Australia) charged with administering the system of registration for patent attorneys.[114] In the course of administering the system the Designated Manager may obtain information in relation to an incorporated patent attorney that would be relevant to ASIC. For instance, the Designated Manager may obtain information alleging fraud on the part of the company. It is in the public interest that the Designated Manager be able to disclose such information to ASIC. State laws governing incorporated legal practices have similar provisions authorising disclosure to ASIC.[115]

This provision will only apply to information obtained during the Designated Manager's official duties. Furthermore, the information must be relevant to the functions of ASIC. These restrictions ensure that only appropriate information is disclosed.

Item 16: Registration of patent attorney individuals

[s 198]

This item is consequential upon the changes that permit a company to be registered as a patent attorney (see item 21).

Subsection 198(4) sets out the circumstances under which the Designated Manager must register a patent attorney. It relates to registration of an individual, not a corporation. The item replaces 'person' in the current provision, with 'individual' so that the subsection will continue to only apply to natural persons.

Registration of companies as patent attorneys is dealt with separately in the new subsection 198(9) (see item 21).

[114] See s 200A and, generally, Chapter 20, Patents Act
[115] See eg s 155, *Legal Profession Act 2004* (NSW); s 2.7.26, *Legal Profession Act 2004* (Vic); s 134, *Legal Profession Act 2007* (Qld).

Item 17: Regulations relating to registration of patent attorneys

[s 198]

This item amends the Patents Act to provide that the Regulations may specify additional requirements to be met before the Designated Manager is required to register an individual as a patent attorney.

Consistent with the existing structure of the Patents Act, this allows for procedural and administrative requirements associated with registration of an individual patent attorney to be prescribed in the Regulations.

Items 18 to 20: Registration of an individual as a patent attorney

[s 198]

These items are consequential upon the amendments that permit a company to be registered as a patent attorney. The items replace the term 'person' with 'individual'. As discussed in item 16 above, this ensures that the provisions continue to only apply to natural persons.

Item 21: Registration of a company as a patent attorney

[s 198]

This item amends the Patents Act to provide that the Designated Manager must register a company as a patent attorney if it meets certain requirements.

This is one of the key provisions designed to give greater flexibility to patent attorneys. Consistent with most other professions, patent attorneys will be able to practise through a corporate structure.

Apart from the existing regulatory safeguards that apply to companies generally (such as obligations under the *Corporations Act 2001*), the scheme includes a number of specific requirements intended to ensure the quality and integrity of services provided by incorporated patent attorneys.

The first key requirement is that an incorporated patent attorney must have at least one patent attorney director. A patent attorney director must be both validly appointed as a company director and registered as an individual patent attorney. This will ensure that senior management includes a person who meets the technical and character requirements to provide patent attorney services (see subsection 198(4)) and who can oversee the company's provision of patent attorney services. This is intended to safeguard the interests of the public and users of attorney services.

The second key requirement is that the company must notify the Designated Manager of its intention to act as a patent attorney. This will ensure that the Designated Manager is aware of all companies permitted to provide patent attorney services. It will also permit the Designated Manager to publish a list of registered incorporated patent attorneys, so that consumers can easily check if a company is so registered.

The amendment also provides for the Regulations to prescribe additional criteria to be met before a company can be registered as a patent attorney. It is not anticipated that further regulations will be required. However, the regulation-making power will provide the flexibility to impose further requirements in the future if it becomes apparent that further regulation is required.

Item 22: Extending client-attorney privilege

[s 200]

This item extends to patent attorneys the same client privilege as is extended to legal professionals.

A recent court decision has clarified that client communications with *foreign* patent attorneys are not privileged in the same way and to the same extent as client communications with lawyers.[116] Under the *Evidence Act 1995* (Cth) client-legal privilege extends to confidential communications with a foreign lawyer for the dominant purpose of the foreign lawyer providing legal advice to a client.[117]

The majority of Australian patent applications come from applicants located outside Australia.[118] Accordingly, many foreign applicants use patent attorneys in their own country. In particular, many patent applicants hold global patent portfolios, including a number of patents for the same invention in different jurisdictions. This means that a dispute in relation to a single invention may be prosecuted through litigation or negotiations simultaneously in a number of different jurisdictions. It is not always desirable or practical for such applicants to limit their requests for advice to Australian patent attorneys. Excluding communications with a foreign patent attorney is a significant issue for many patent applicants and is a disincentive for them to exercise their freedom to choose their preferred advisers.

The amendments are intended to rectify this situation. The amendments expand the definition of 'patent attorney' to include, in addition to Australian registered patent attorneys, an individual authorised to do patents work under the law of another country or region**.**

Patents work is defined in new section 197A (see item 7). Broadly speaking it is defined as work done in relation to patents or patent applications, done on behalf of someone else for gain. This is consistent with the kinds of work done by Australian attorneys. The intention is that the privilege provision captures communications between clients and foreign intellectual property professionals who are authorised to perform work similar to the work done by their Australian counterparts.

This will include not only persons authorised under the law of a nation state, but also persons registered under an international treaty, such as art 134 of the *European Patent Convention 1973*, which authorises persons to do patents work before the European Patent Office.

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[116] *Eli Lilly & Company v Pfizer Ireland Pharmaceuticals (No 2)* [2004] FCA 850.
[117] Sections 117 (definition of 'lawyer', paras (b) and (c)) and 118.
[118] For instance, of the 26568 complete patent applications filed in 2008, only 2596 originated from Australia: see IP Australia, *Fact Sheet (Patent Data)* available at (http://www.ipaustralia.gov.au/pdfs/factsheets/ip_rights_statistics.pdf).

Importantly, the scope of the privilege is limited to the scope of a person's authority to perform the work in their home country or region: if a person is only authorised to do patents, but not trade marks, work in their home country then they will only receive privilege in Australia for their patents advice.

The amendment also makes a number of changes to align the wording in the Patents Act with the wording of section 118 of the Evidence Act. Thus the communication, record or document must be for the 'dominant' purpose of a patent attorney providing intellectual property advice in order for the communication, record or document to attract the privilege. This will ensure that the test for client-attorney privilege is consistent with the test for client-lawyer 'advice' privilege.

Note that the client attorney privilege is not intended to mirror client-lawyer 'litigation' privilege (see section 119 of the Evidence Act). Attorneys do not have the same rights as lawyers do to initiate proceedings and represent parties in court. Accordingly, it is inappropriate to extend attorney-client privilege to include 'litigation' privilege: this should be the sole preserve of lawyers.

Note that, for lawyers, different types of privilege apply at particular stages of the judicial process: the common law applies at pre-trial and non-curial proceedings and the Evidence Act applies to trial proceedings. It is intended that any future developments in the common law relating to legal professional privilege for advice would apply to patent attorneys.

The privilege is intended to apply in the same way and to the same extent for patent attorneys as is does for lawyers. In particular, if the Evidence Act would apply to lawyers, then the Evidence Act provisions would govern the privilege that applies to attorneys. It is only in a situation in which a lawyer could rely on the common law privilege that the common law rules would govern the privilege that applies to attorneys. It is not intended that attorney privilege would exist in a situation where there would be no equivalent privilege for lawyers.

The amendment also includes a definition of 'intellectual property advice'. This limits the scope of the privilege to only those fields in which patent attorneys have specialist qualifications and knowledge.

Item 23: Client-attorney privilege – definition of intellectual property advice

[s 200]

This is a consequential amendment to repeal the previous definition of 'intellectual property matters'. The relevant concept is now covered by the new definition of 'intellectual property advice' (see item 5). This is more consistent with section 118 of the Evidence Act, which refers to 'legal advice', not 'legal matters'.

Item 24: Offences relating to companies that act or describe themselves as patent attorneys

[ss 201, 201A and 201B]

This item amends the Patents Act to:

- permit incorporated patent attorneys to act and describe themselves as patent attorneys;
- introduce new sanctions for incorporated patent attorneys that do not meet their obligations; and
- provide for situations where an incorporated patent attorney suddenly loses its sole patent attorney director.

Permitting corporations to provide patent services – s 201 (5) and (6)

Existing section 201 prohibits a company from acting or describing itself as a patent attorney. The item amends the section to account for the changes to allow attorneys to incorporate (see item 21).

It will no longer be an offence for a company to carry on business, practices or act as a patent attorney, or be described as a patent attorney if the company is registered as an attorney. It will, however, continue to be an offence if the company does these things without being registered as a patent attorney.

The item also amends the penalties for an offence under this section to introduce penalty units, rather than dollar amounts. Consistent with the existing penalties in subsection 201(5), a company that commits an offence under these provisions may be liable for a maximum penalty of 150 penalty units.

Definition of patents work – s 201A

This item makes two minor changes to the existing definition of carrying on business, practising or acting as a patent attorney (referred to 'acting' in this memorandum). The first change is consequential upon permitting bodies corporate to become patent attorneys (see item 21). It replaces the term 'person or a company' with 'person'. This recognises that companies are legal persons and recognises that both corporate and natural persons are covered by the use of 'person'.

The second change is consequential upon the changes to client-attorney privilege (see item 22). It introduces the concept of 'patents work'. This term is key to changes made to client-attorney privilege and is discussed in item 22.

Sanctions for incorporated patent attorneys – s 201B (1) and (2)

Users of patent attorney services risk considerable loss if those services are not provided competently. They may lose valuable intellectual property rights or be liable for infringement if they are poorly advised. In recognition of this, a company registered as a patent attorney must have a registered patent attorney as a director, to oversee the company's provision of patent attorney services (see item 21).

This item inserts a new provision, section 201B, to provide sanctions for incorporated patent attorneys that fail to meet their director requirements.

The offence in section 201B(1) applies where an incorporated patent attorney ceases to have a patent attorney director and fails to notify the Designated Manager of that fact within 7 days. This notification requirement serves two important purposes.

First, it ensures that the Designated Manager is aware that the incorporated patent attorney has no patent attorney directors so that the Designated Manager can take appropriate action to deal with the company's existing clients (see further below in this item).

Secondly, it permits the Designated Manager to update the register so that users and the public are informed if the company is no longer permitted to act or describe itself as a patent attorney.

The 7 day period provides a short period of 'grace' in which the company may provide the notice. For instance, where the sole patent attorney director dies suddenly, it may be unreasonable to expect the remaining directors or employees to notify the Designated Manager instantaneously. The seven day period is consistent with the corresponding grace period for incorporated legal practices.[119]

The offence in s 201B(2) applies where an incorporated patent attorney acts as a patent attorney, despite not having had a patent attorney director for 7 days. This sanction prevents an incorporated patent attorney from continuing to provide patent services for an extended period without a patent attorney director. This is intended to prevent the provision of services where no qualified attorney is in charge. Again, there is a small grace period of 7 days, consistent with the grace period for notifying the Designated Manager.

Consistent with the existing penalties for other corporate offences in the Patents Act, a company that commits an offence under these provisions may be liable for a maximum penalty of 150 penalty units.

Sudden loss of patent attorney director – s 201B (3) to (7)

An incorporated patent attorney may suddenly find itself without an incorporated patent attorney director - for instance if the sole patent attorney director dies or resigns unexpectedly. While it would be prudent for incorporated patent attorneys to have contingency plans in place for such a situation, there may be situations where this nonetheless occurs.

This amendment introduces a provision giving the Designated Manager the power to temporarily appoint another registered patent attorney to take charge of the patents

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[119] See eg s 142 (2), *Legal Profession Act 2004* (NSW); s 2.7.12, *Legal Profession Act 2004* (Vic); s 119 (1), *Legal Profession Act 2007*(Qld). See also proposed s 3.7.5 (1), National Legal Profession Law currently the subject of COAG consultation (available at: http://www.ag.gov.au/www/agd/agd.nsf/Page/Consultationsreformsandreviews_AbetterframeworkforFederalCourts-Consultation_CouncilofAustralianGovernments(COAG)NationalLegalProfessionReformconsultationpackage).

work of the company and act as a *de facto* director of the company. The appointee could be an existing employee of the company or a person from outside the company. The appointment is at the discretion of the Designated Manager, so that the Designated Manager has the flexibility to deal with the circumstances as appropriate. The appointment can only be made with the appointee's consent.

Such a person is taken, for the purposes of the Patents Act, to be a patent attorney director. This enables the company to continue to provide patent services without breaching the offence provisions in subsections 201(5) and (6). It also ensures that existing clients of the company, who may have urgent matters being prosecuted at the time the company loses its patent attorney director(s), are not disadvantaged.

The appointee may remain in place while the company finds a new permanent patent attorney director. Alternatively, the appointee may remain in place for a short period, pending deregistration of the company, while the existing clients make arrangements to transfer their business to another firm.

The new provision provides that neither the appointee nor the Designated Manager is taken to be a director of the company because of the appointment. The purpose of such an appointment is to protect the interests of parties in respect of matters done under the Patents Act. It would be unreasonable to expect the appointee or the Designated Manager to be subject to the broader company director duties that may apply under the *Corporations Act 2001*.

Given the temporary nature of any appointments by the Designated Manager and that the appointee is not taken to be a director of the company, other than with respect to patent attorney services, merits review of the Designated Manager's decision is not appropriate.

Existing offences with no major change – s 201 (1) to (4)

These amendments re-enact the same substantive offences as exist for unqualified individuals and partnerships that act or describe themselves as patent attorneys. The offences have been re-worded slightly to make them clearer, and to express the penalty in penalty units rather than dollar amounts. The substantive elements of the offences and the actual penalties applicable remain the same.

Existing exceptions to offences with no major change – s 201 (7) to (10)

These amendments re-enact a number of existing exceptions to the offence provisions. There are no substantive changes to the elements of the exceptions.

Item 25: Penalties for falsely preparing patent documents

[s 202]

This item amends the offence provision in section 202 to express the penalty in penalty units instead of in a dollar amount. The amendment does not change the actual penalty applicable to the offence.

Item 26: Documents prepared by incorporated patent attorneys

[s 202B]

This item introduces a new offence for an incorporated patent attorney, or an incorporated legal practice, where an employee or member prepares a patent specification (or an amendment to a patent specification) without either being a registered patent attorney, or being under the supervision or instructions of a registered patent attorney.

The drafting of patent specifications and amendments to patent specifications is a highly specialised skill. It requires detailed knowledge, not only of patent law, but of the relevant field of technology. A poorly drafted specification can deprive the applicant of valuable patent rights.[120] Historically, this service has been restricted only to patent attorneys, as lawyers and others may not have the specialised technical training necessary to competently draft a specification that adequately protects the applicant's rights. Sections 202 and 202A provide sanctions for legal practitioners and members of partnerships who are not registered patent attorneys and who draft patent documents.

New subsection 202B provides a similar sanction for a member of an incorporated patent attorney who drafts patent documents without being instructed or supervised by a registered patent attorney.

Consistent with the existing penalties in the Patents Act, a company that breaches this prohibition will be liable for a penalty up to 150 penalty units.

Item 27: Attendance at a patent attorney's office

[s 203]

This item amends section 203 to refer to an individual being in charge of the patents work at the office of a registered patent attorney.

The existing offence provision provides a sanction to prevent registered patent attorneys from acting or describing themselves as patent attorneys unless a registered patent attorney is actually managing the day-to-day patents work of the office. As a registered patent attorney may now be a company, this sanction has been amended to require that an *individual* registered patent attorney must be physically present at the office and managing the patents work.

The item also re-words the offence provision to make it clearer and to express the existing penalty in the modern format of penalty units. The substantive elements of the offence and the actual penalty remain unchanged.

Item 28: Assessing the conduct of patent attorneys

[s 228]

[120] Note that amendment proposed in Item 30 prohibiting certain amendments to specifications.

This item amends the Patent Act to clarify that the Regulations may provide for assessing the professional conduct of registered patent attorneys by reference to standards of practice established by the Professional Standards Board for Patent and Trade Mark Attorneys (PSB) from time to time.

The PSB is responsible for assessing complaints against attorneys and conducting disciplinary proceeds against attorneys.[121] Currently the PSB publishes a Code of Conduct (Code) which sets out the professional standards that patent attorneys are expected to meet.[122]

In the interests of ensuring transparent standards for attorneys and their clients, it is desirable that attorneys be legally bound by the Code and that it be clear in the primary legislation that the PSB is entitled to take a breach of the Code into account in assessing a disciplinary complaint against an attorney.

Accordingly, the amendments explicitly permit the regulations to provide for assessing attorneys' professional conduct against standards set by the PSB. This will enable regulations to be made clarifying the obligation of all attorneys (including new incorporated attorneys) to comply with the Code.

The wording of the amendment is intended to encompass amendments to the Code as are made from time to time, to avoid the necessity of amending the legislation every time the Code is amended. The Code will be registered as a Legislative Instrument under the *Legislative Instruments Act 2003* (Cth). The Government would consult with interested stakeholders prior to any future changes to the Code,[123] and would table any amendments to the Code for parliamentary scrutiny.[124]

Items 29 to 36: Amendments to Schedule 1 (definitions)

The following items insert definitions into Schedule 1 of the Act

Item 29 inserts a definition of a 'company', as defined in the *Corporations Act 2001* (Cth). This will ensure that the meaning of 'company' is able to change with changes to the Corporations Act.

Item 30 inserts a definition of 'director', as defined in the *Corporations Act 2001* (Cth). This will ensure that the meaning of 'director' is able to change with changes to the Corporations Act.

Item 31 inserts a definition of an 'incorporated legal practice'.

Incorporated legal practices are currently regulated under the laws of the various State and Territory Legal Profession Acts. Consistent with the existing policy for individual legal practitioners and legal practitioner partnerships, the amendments permit incorporated legal practices to act as a patent attorney (see item 24). However, it is not intended that the Designated Manager would have any role in regulating incorporated legal practices under the Patents Act (unless they were also incorporated patent

[121] Section 227A, Patents Act; reg 20.33, Patents Regulations.
[122] The current Code of Conduct is available at: http://www.psb.gov.au/pdfs/code.pdf
[123] Section 17, Legislative Instruments Act.
[124] Sections 38 and 42, Legislative Instruments Act.

attorneys). Consistent with the existing policy for individual legal practitioners and legal practitioner partnerships, the regulation of incorporated legal practices will be left to the relevant State, Territory or other Commonwealth laws.

Item 32 inserts a definition of 'incorporated patent attorney'. As this concept is crucial to patent attorney registration, the reader of the Act is referred back to the relevant provision in Chapter 20 where the concept is fully defined.

Item 33 inserts a definition of 'intellectual property advice'. As this concept is crucial to client-attorney privilege, the reader of the Act is referred back to the relevant provision in Chapter 20 where the concept is fully defined.

Item 34 inserts a definition of 'patent attorney director'. As this concept is crucial to patent attorney registration, the reader of the Act is referred back to the relevant provision in Chapter 20 where the concept is fully defined.

Item 35 inserts a definition of 'patents work'. As this concept is crucial to patent attorney registration and client-attorney privilege, the reader of the Act is referred back to the relevant provision in Chapter 20 where the concept is fully defined.

Item 36 inserts a definition of 'related company group'. This definition is the same as the previous definition in existing subsection 201(10).

Trade marks attorney incorporation and privilege

Generally, trade marks attorneys are regulated in a similar manner to patent attorneys. Similar problems arise in relation to the inability of trade marks attorneys to practise through a corporate structure and in relation to the privileges of foreign patent attorneys. Accordingly, the following items make amendments intended to achieve a similar effect for trade marks attorneys as the above amendments make for patent attorneys.

Item 37: List of defined terms in the readers guide

[Readers guide]

This item inserts new terms that are included in the list of terms defined in section 6. It is consequential upon several new definitions included at items 38 to 45 below.

Items 38 to 45: Definitions

[s 6]

These items incorporate a number of definitions for similar purposes to the amendments in respect of patent attorneys at items 1 to 8 and 29 to 36 above.

Items 39 and 43 cross reference the Patents Act to ensure consistent uses of key terms.

Item 46: Offences

[s 156]

This item amends the existing offence provisions to permit companies to describe themselves as trade marks attorneys or agents.

A key difference between patents and trade marks attorneys is that there is no restriction on who may do trade marks work. However, there is a restriction on who may describe themselves as a trade marks attorney (only registered trade marks attorneys) or a trade marks agent (only registered trade marks attorneys, registered patent attorneys and lawyers).

Although there is no explicit prohibition against companies using these titles, a corporate entity is not capable of satisfying the knowledge and character requirements for registration and so cannot use these titles. The amendments in item 53 below change this to permit the registration of a company as an incorporated trade marks attorney.

The new subsections 156(3) and (3A) permit companies to use the titles 'trade marks attorney' and 'trade marks agent'. Consistent with the existing policy for natural persons, only an incorporated trade marks attorney may describe themselves as a trade marks attorneys. Similarly, incorporated trade marks attorneys, incorporated patent attorneys and incorporated legal practices may describe themselves as trade marks agents. It will remain an offence for any other type of company to use these titles. Consistent with the offences in the Patents Act, the penalty is 150 penalty units.

The new subsections 156(1) and (2) merely restructure the existing offences for natural persons. The existing elements of the offences are set out more clearly in line with modern drafting practices. Note 4 and the reference to 'persons referred to in paragraph 135(1)(h) or (i) of the repealed Act' has been removed as this category is now redundant.

Item 47: Offences for incorporated trade marks attorneys

[s157]

This item introduces a new provision that makes it an offence for an incorporated trade marks attorney to fail to notify the Designated Manager or to continue to describe itself as a trade marks attorney if it does not have a registered trade marks attorney as a director. It also provides for the Designated Manager to temporarily appoint another registered trade marks attorney as a *de facto* director or to remove the company from the Register.

The policy and intended operation of this item is the same as the corresponding amendments in respect of incorporated patent attorneys at item 24 (new section 201B of the Patents Act) above.

Item 48: Note

[s 228A]

This item amends the note to refer to the definition of 'Designated Manager', which is now in section 6.

Items 49 to 52: Registration of trade mark attorney individuals

[s 228A]

These items amend the existing provisions to ensure they refer only to natural persons, as companies will be registered under separate provisions (see item 53). They also provide for the regulations to prescribe additional criteria for registration. The policy and intended operation of this item is the same as the corresponding amendments in respect of incorporated patent attorneys at items 16 to 20 above.

Item 53: Registration of a company as a trade marks attorney

[s 228A]

This item amends section 228A to provide for the registration of companies as incorporated trade marks attorneys. The policy and intended operation of this item is the same as the corresponding amendments in respect of incorporated patent attorneys at item 21 above.

Item 54: References to definitions

[s228A]

This item repeals the subsection as these definitions are now provided for in section 6.

Items 55 and 56: Foreign trade marks attorney privilege

[s229]

These items provide for communications with a foreign trade marks attorney to receive the same privilege as those with an Australia attorney. The policy and intended operation of this item is the same as the corresponding amendments in respect of incorporated patent attorneys at item 22 above.

Item 57: Disclosing information to ASIC

[s 229A]

This item permits the Designated Manager to disclose certain information to the Australian Securities and Investments Commission. The policy and intended operation of this item is the same as the corresponding amendments in respect of incorporated patent attorneys at item 15 above.

Item 58: Assessing the conduct of trade marks attorneys

[s 231]

This item clarifies that the Regulations may provide for assessing the professional conduct of registered trade marks attorneys by reference to standards of practice established by the PSB from time to time. The policy and intended operation of this item is the same as the corresponding amendments in respect of incorporated patent attorneys at item 28 above.

Schedule 5 - Improving mechanisms for trade mark and copyright enforcement

Introduction

Both copyright and trade marks are valuable assets for modern firms. Both are forms of personal property that individuals and businesses may have invested significant money in creating.[125] Accordingly, IP owners have a legitimate interest in deterring those who seek to free ride off their investment by selling or importing counterfeit goods.

Stakeholders have reported growing concerns in recent years about the extent of counterfeiting in Australia.[126]

This schedule addresses two key weaknesses in the existing enforcement regime.

Border protection

First, the current 'notice of objection' scheme for Customs to seize counterfeit trade mark or copyright goods lacks effectiveness.

Currently a copyright or trade mark owner (the 'objector') can lodge a notice of objection with Customs in respect of imported goods that infringe their IP right. Customs then may seize the suspected infringing goods at the border. The objector then has a period of time within which to bring infringement proceedings against the importer, otherwise the goods are returned to the importer.

However, loopholes in the current scheme enable importers of counterfeit or pirated goods to avoid prosecution and still retain the goods. The current provisions also make it difficult for copyright and trade mark owners to get the information necessary to determine if they should institute infringement proceedings.

The amendments revise the notice of objection scheme to address these problems.

Sanctions for trade mark counterfeiting

Secondly, the existing trade mark enforcement provisions are lacking in a number of respects.

The criminal and civil sanctions for trade mark infringement have lower penalties and are less comprehensive than the corresponding sanctions in the *Copyright Act 1968* ('Copyright Act'). This is despite the overlap between both forms of intellectual property (for instance, copyright may subsist in the same goods to which a trade mark is applied). Accordingly, the existing sanctions do not provide a sufficient deterrent to those who wilfully infringe trade marks and deceive consumers intending to purchase genuine goods.

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[125] Section 196 (1), *Copyright Act 1968* ('Copyright Act'); s 21 (1), Trade Marks Act.
[126] See ACIP, *Review of Trade mark Enforcement*, 2004, p 24. (http://www.acip.gov.au/library/reviewtmenforce.pdf) and IP Australia, *Review of Penalties and Damages*, 2008, p 3 (http://www.ipaustralia.gov.au/resources/news_new_archived_2008.shtml#58).

The amendments in this schedule strengthen the enforcement options available against counterfeiters. This includes stronger penalties, better tailored offence provisions, and new provisions for additional damages in civil infringement actions.

Part 1: Customs seizure

Copyright Act 1968

Part V of Division 7 of the Copyright Act sets out the current notice of objection scheme. The following items revise the scheme to address a number of problems.

Items 1 to 4: Definitions

[s 134B]

These items amend the Copyright Act to include definitions necessary for the related changes to the notice of objection scheme.

Item 1 provides a definition of the term 'action period'. This is necessary for the related changes at items 25 and 30, which specify the period during which the Customs CEO must retain the seized goods after a claim for return has been made, while the objector decides if they will institute infringement proceedings. Consistent with the existing subsection 135AC(3), the period will be prescribed in the regulations.

Item 2 provides a definition of the term 'claim period'. This is necessary for the related changes at items 25 and 30, which specify the period during which the Customs CEO must retain the seized goods while the importer decides if they will make a claim for return. Consistent with the existing subsection 135AC(3), the period will be prescribed in the regulations.

Item 3 is consequential upon the amendment in item 40 below. It ensures that 'personal information' is consistent with its meaning in the *Privacy Act 1988*.

Item 4 provides a definition of 'working day'. This definition is consistent with the definition in section 6 of the Trade Marks Act and is necessary to clarify the time period for doing certain acts under the scheme.

Items 5 to 9: Notice of seizure

[s 135AC]

These items amend section 135AC of the Copyright Act to provide for the Customs CEO to give the objector (the copyright owner lodging the notice of objection) information about the exporter as well as the importer.

Currently the Customs CEO is permitted to provide the objector with certain information about the importer. However, the Customs CEO is not generally permitted to provide information about the exporter or consignor (the person who provided the copies to the importer). Such information can usually only be obtained

by a court order, which is expensive and time consuming. This limits the ability of copyright owners to address infringement at its source and identify repeat offenders.

Items 5 and 6 restructure the existing provisions into a clearer and more readable format. The provisions make consequential references to the 'claim period' and 'action period', these references are made necessary by the 'claim for return' system implemented in item 14 below.

Items 7 and 9 permit the Customs CEO to provide any relevant information that the CEO has about the any person who made arrangements on behalf of the importer for the copies to be brought into Australia, whether that person is insider or outside Australia. This will include exporters and consignors and will allow the Customs CEO to provide copyright owners with the information that will assist them to enforce their rights.

Item 8 clarifies that the information may include personal information within the meaning of the *Privacy Act 1988* (such as an address, for example). Such information may be necessary for preventing counterfeiting. As a matter of policy, persons engaged in counterfeiting should not be able to use the provisions of the Privacy Act to avoid legal proceedings.

Items 10 to 12: Inspection, release etc of seized copies

[s 135AD]

These items amend section 135AD to clarify that the Customs CEO can permit the objector to inspect or remove multiple samples of the seized copies.

The current provision permits the Customs CEO to give the objector access to a single sample or copy of the seized copies. However, a seized consignment may contain both infringing and non-infringing copies. Granting access to a single, possibly legitimate, copy may not resolve the question of whether there are actually any infringing copies within the consignment.

The amendments permit the Customs CEO to allow the objector or importer to inspect multiple copies or samples. They also permit the Customs CEO to release multiple copies or samples to the objector or importer (upon that party giving the appropriate undertakings). This will allow access to a representative sample of the copies in question and will allow the parties to make a more accurate determination as to whether, and to what extent, the consignment contains infringing copies.

Item 13: Forfeiture of seized copies

This item consequentially amends subsection 135AE(3) to remove the requirement that the Customs CEO must dispose of forfeited copies in the manner prescribed in the regulations or as the CEO prescribes. This provision is no longer necessary as it is covered by a similar provision in item 14 (new section 135AI).

Item 14: Claim for release of seized copies

[s 135AF]

This item amends the Copyright Act to revise the scheme for dealing with copies seized under a notice of objection.

Currently, when copies are seized the objector has to institute infringement proceedings and notify the Customs CEO within a set time period (the action period) - otherwise the copies are returned to the importer.[127] The policy intent is that the importer should only receive the seized copies back if the objector decides that they do not wish to institute proceedings or, if proceedings are instituted, a court finds that the seized copies are not infringing.

Under the existing scheme an importer can frustrate an objector's efforts to commence legal action by making it difficult for the objector to contact them within the action period. An importer may avoid contact by:

- not responding to the seizure notice;
- providing a false name and/or address; or
- otherwise making themselves unavailable or unable to be contacted until after the period has expired.

Where importers are successful in frustrating an objector's efforts to take legal action, the outcome is that Customs returns the copies to the importer. It is undesirable that an importer of potentially infringing copies should be able to retain the copies while avoiding having to face infringement proceedings.

The amendment introduces a new scheme where an importer can only reclaim the seized copies by providing the objector with information necessary to identify and contact them. This ensures that importers are not able to reclaim the copies without giving the objector information that will assist the objector to test the matter in court.

The amendments are broadly modelled on Subdivision G of Division 1 of Part XII of the *Customs Act 1901* (Customs Act). The Customs Act scheme is preferred because it has proven successful in preventing similar behaviour. An added benefit is that the Customs officers who currently administer the Customs Act scheme will already be familiar with the new Copyright Act scheme, which should permit a quick and efficient implementation.

Claim for release of seized goods

New section 135AEA implements the key difference between the existing and the new scheme. An importer who wants the seized copies back must make a claim for return. The claim for return must include prescribed information, such as an address where the objector can serve legal documents on the importer. This will assist the objector in contacting the importer and instigating legal proceedings.

Additionally, the note to this section refers to other offences for providing false information to Customs officials. This provides a greater deterrent against importers providing false information on the claim for return.

[127] Section 135AF (1).

Objector to be notified of claim

The new section 135AED requires the Customs CEO to notify the objector of the claim for return and permits the CEO to provide the objector with information identifying the importer (such as the current address of the importer). Consistent with the changes in items 5 to 9 above, the CEO may also provide information regarding a person inside or outside Australia who made arrangements for the copies to be imported (which would include the exporter or consignor of the copies). This will better enable copyright owners to address counterfeiting at its source and identify repeat offenders.

On receipt of notification from the Customs CEO of a claim for return, the objector has a set period of time within which to institute infringement proceedings, otherwise the goods will be returned to the importer. The regulations will set the time period, which is intended to be of the same length of time as the 'action' period.

Seized goods forfeited if no claim is made

The new section 135AEB provides that if no claim for release, by the importer, is made within the claim period the copies are forfeited to the Commonwealth. This is a key provision that ensures that an importer who deliberately makes themselves unavailable (so as to avoid infringement proceedings) loses the right to reclaim the seized copies.

Release of seized goods to the importer

The new section 135AF provides that, if a claim for release is made, the Customs CEO must release the copies if:

- the objector consents;
- the objector does not institute infringement proceedings. The objector has a limited period of time to do this (the 'action period': see item 1), beginning from when a claim for return is made; or
- where infringement proceedings are instituted, a court does not, within 20 working days, order the Customs CEO to retain the copies (ie until the proceedings are finalised).

This ensures that the goods are returned to the importer if the objector does not institute infringement proceedings. It also provides for circumstances where an objector and importer have reached an agreement about the goods, for example the parties have negotiated a licence or payment for the goods.

Late claim for the release of seized goods

The new section 135AEC provides the Customs CEO with the discretion to accept a late claim for release of the copies after the end of the claim period. This accounts for exceptional circumstances, such as where the importer was legitimately overseas at the time the notice was issued. The discretion ensures that the Customs CEO is able to

refuse the late claim where the importer has deliberately made themselves unavailable.

Goods released but not collected are forfeited

The new section 135AFA is an ancillary provision providing that, where an importer makes a claim for release, but nonetheless fails to collect the seized copies within 90 days, the seized copies are forfeited to the Commonwealth. This ensures that Customs is not required indefinitely to store copies that the importer has lost interest in.

Item 15: Disposal of seized copies forfeited to the Commonwealth

[s 135AI]

This item amends the Copyright Act to allow the Customs CEO to deal with forfeited copies by disposing of them, and to ensure that importers of non-infringing copies are adequately compensated if their copies are disposed of by the CEO, but subsequently found by a court to be non-infringing.

Consistent with the existing section 135AE(3) (amended by item 13), the manner in which forfeited copies are dealt with is prescribed in the regulations. However, there are two important changes:

- First, the seized copies must not be disposed of for 30 days, where they are forfeited due to a failure of the importer to make a claim for return within the claim period. This provides a period where forfeited goods will still be able to be released under a later claim under the new section 135AEC (item 14).

- Secondly, where non-infringing copies were nonetheless forfeited and disposed of, the importer may seek compensation from the Commonwealth. The action must be brought in a court of competent jurisdiction and any compensation must be equal to the market value of the copies. This ensures that an innocent importer is not disadvantaged.

Items 16: Review of decisions

[s 195B]

This item amends the Copyright Act to provide that decisions made by the Customs CEO, under the new provisions in items 5 to 15, may be reviewed on their merits by the AAT. This provides aggrieved parties with an accessible and inexpensive process for challenging such decisions.

Trade Marks Act 1995

Part 13 of the *Trade Marks Act 1995* (Trade Marks Act) sets out the current notice of objection scheme.

The existing trade mark scheme is similar to the existing scheme in the Copyright Act. The same problems identified in relation to the copyright scheme apply to the trade marks scheme. It is also generally desirable to deal with enforcement of copyright and

trade marks in a consistent manner (noting that the same product may contain both copyrighted material and a registered trade mark). Accordingly, the following items amend the Trade Marks Act to align it with the amendments to the Copyright Act above.

Item 17: List of defined terms in the readers guide

[Readers guide]

This item inserts new terms that are included in the list of terms defined in section 6. It is consequential upon several new definitions included at items 18 to 20 below.

Items 18 to 20: Definitions

[s 6]

These items amend the Trade Marks Act to include definitions necessary for the related changes to the notice of objection scheme.

Item 18 provides a definition of the term 'action period'. This is necessary for the related changes at item 22, which specifies the period during which the Customs CEO must retain the seized goods after a claim for return has been made, while the objector decides if they will institute infringement proceedings. Consistent with the corresponding changes to the Copyright Act in item 10, the period will be prescribed in the regulations.

Item 19 provides a definition of the term 'claim period'. This is necessary for the related changes in item 22, which specifies the period during which the Customs CEO must retain seized goods while the designated owner decides if they will make a claim for return. Consistent with the equivalent changes to the Copyright Act in item 10, the period will be prescribed in the regulations.

Item 20 is consequential upon the amendment in item 21 below. It ensures that the definition of 'personal information' is consistent with its meaning in the *Privacy Act 1988*.

Item 21: Notice of seizure and inspection

[s 134]

Notice of seizure

This item amends section 134 to provide for the Customs CEO giving the objector information about both the designated owner, importer, or person who made arrangements on behalf of the designated owner to bring the goods to Australia (eg the exporter or consignor).

The policy background, issues and intended operation of the amendments are the same as the related changes to the Copyright Act in items 5 to 9 above.

Inspection, release etc of seized goods

This item clarifies that the Customs CEO can permit the objector to have access to multiple samples of seized goods.

Currently the Trade Marks Act has no power equivalent to section 135AD of the Copyright Act (which permits the Customs CEO to give the objector access to seized copies for the purpose of determining if they are infringing). However, trade mark objectors may also need to inspect or remove samples of seized goods for similar purposes. There is no policy reason to justify treating trade mark objectors differently.

Accordingly, this item provides a power for the Customs CEO to grant inspection or release of sample goods. The provisions correspond with section 135AD of the Copyright Act as amended by items 10 to 12.

Item 22: Claim for return scheme

[s 136]

This item amends section 136 to introduce a revised claim for return scheme for trade marks. The scheme corresponds to changes to the Copyright Act in item 14 and is intended to achieve the same effect, namely ensuring that designated owners cannot reclaim the seized goods if they make themselves uncontactable to avoid infringement proceedings.

Claim for release of seized goods

The item provides that the designated owner of seized goods must make a claim for return (with the claim including prescribed information) in order to get the seized goods back.

Seized goods forfeited if no claim is made

The item also provides that, if no claim for release is made within the claim period, the seized goods are forfeited to the Commonwealth.

Late claim for the release of seized goods

The item provides the Customs CEO with the discretion to accept a late claim for release of the goods after the end of the claim period.

Objector to be notified of claim

The item also requires the Customs CEO to notify the objector of the claim for return and permits the CEO to provide the objector with information (such as the current address) identifying the importer, designated owner, or other person who made arrangements for the goods to be brought into Australia.

Release of seized goods to the designated owner

The item provides that, if a claim for release is made, the Customs CEO must release the goods if:

- the objector consents;

- the Customs CEO becomes aware of information that shows the goods are not infringing and no proceedings have been instituted (this is consistent with existing subsection 136(3));

- the objector does not institute infringement proceedings within the action period; or

- where infringement proceedings are instituted and a court does not, within 20 working days, order the Customs CEO to retain the goods (i.e. until the proceedings are finalised).

Goods released but not collected are forfeited

Firstly, the item is an ancillary provision providing that, where a designated owner successfully makes a claim for release, but nonetheless fails to collect the seized goods within 90 days, the seized goods are forfeited to the Commonwealth.

The policy background, issues and intended operation of the amendments is the same as the related changes to the Copyright Act in item 14 (new section 135AFA) above.

Items 23 to 25: Action for infringement of a trade mark

[s 137]

These items make consequential amendments to align section 137 with the claim for return scheme implemented in item 22.

Item 26: Disposal of seized goods forfeited to the Commonwealth

[s 139]

This item amends section 139 to allow the Customs CEO to deal with forfeited goods by disposing of them, and to ensure that designated owners of non-infringing goods are adequately compensated if their goods are disposed of by the CEO but later found not to be infringing.

The policy background, issues and intended operation of the amendments is the same as the related changes to the Copyright Act in item 15 above.

Part 2: Trade mark offences

Item 27: Trade mark offences

[ss 145 to 149]

This item amends the Trade Marks Act to:

- increase the penalties for existing indictable offences;

- restructure the elements of the existing offences into a clearer and more consistent format; and

- introduce new summary offences (with lower penalties and lower fault elements) analogous to the existing indictable offences.

Registered trade marks are a valuable form of personal property. Counterfeiters seek to trade off the investment made and the goodwill developed by a trade mark owner in their brand. They also seek to deceive consumers, who may rely on a trade mark as a guarantee that the product they are purchasing is genuine.

Recognising this, the Trade Marks Act currently contains indictable offences designed to deter counterfeiting. However, the current offence provisions are lacking in a number of respects.

Maximum penalty for indictable offences

The maximum penalties are noticeably lower for trade mark offences than the penalties for similar offences in the Copyright Act.[128] The trade mark offence penalties are also lower than many other countries, including many of Australia's major trading partners.[129] This may make Australia an attractive target for counterfeiters.

The amendment rectifies these problems by raising the maximum penalties to align them with the penalties for similar indictable offences in the Copyright Act. This more accurately reflects the nature of these offences as serious violations of valuable personal property rights and is more likely to act as an appropriate deterrent.

Note that the fine to imprisonment ratio is higher than the usual ratio for Commonwealth offences (normally 5 penalty units to 1 month imprisonment).[130] The reason for this is that the potential financial gains from counterfeiting may be quite high. For example, in 2006 Customs seized a single shipment of counterfeit goods that was estimated to have been worth about $1 million if sold at full retail value of the genuine articles.[131] Accordingly, a higher pecuniary penalty is necessary to ensure that a fine acts as a sufficient deterrent.

Also, the existing structure of the offence provisions reflects outmoded drafting practices. The elements of some offences are not clearly set out and appear unnecessarily complex to readers of the Act. The offences have also been restructured consistent with modern drafting practices. The elements of each offence remain the same. However, the new structure separates the different elements more clearly and removes unnecessary references to fault elements such as 'knowing' and 'reckless'.

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[128] For example, compare s 132AL (3) of the Copyright Act (550 penalty units or 5 years imprisonment or both) with s 147 and s 149 of the Trade Marks Act (500 penalty units or 2 years imprisonment or both a fine and a term of imprisonment).

[129] IP Australia, *Review of Penalties and Damages*, 2008, p 32 (http://www.ipaustralia.gov.au/resources/news_new_archived_2008.shtml#58).

[130] See Attorney-General's Department, *Guide to Framing Commonwealth Offences, Civil Penalties and Enforcement Powers*, 2007, p 41.

[131] See Customs, *Media Release: Fake Designer Goods Seized*, 3 August 2006 (http://www.customs.gov.au/site/content7426.asp)

These fault elements are automatically provided for by section 5.6 of the *Criminal Code 1995* (Cth).

Summary offences

Secondly, the current regime of trade mark offences has only a single tier of indictable offences. This contrasts with the equivalent offences in the Copyright Act, which has a scheme involving a tiered system of both serious indictable offences and lesser summary offences (with lower penalties and lower fault requirements).[132] The trade mark scheme therefore lacks the flexibility to match the seriousness of the offence to the seriousness of the conduct.

The amendments rectify this by including corresponding summary offences after each indictable offence. This will permit a quicker resolution of more simple trade mark offences and assist with the efficient administration of justice.

The summary offences are the same as the corresponding existing indictable offences, except for two respects.

The first difference is that the fault requirements corresponding to physical elements that consist of a circumstance have been lowered from the default element of 'recklessness' under the *Criminal Code 1995* (Cth) to 'negligence'. This is consistent with the equivalent summary offences in the Copyright Act.[133]

It is appropriate to have a lower fault element of 'negligence' for the circumstance elements of the offences because of the unique nature of intellectual property rights. Despite the clear legal position that intellectual property is a form of personal property, evidence has shown that some people see the violation of intellectual property rights as trivial and a 'victimless crime'.[134] Such attitudes may extend to an unacceptable failure to ascertain the factual circumstances in which their conduct would be criminal. The introduction of an objective negligence standard will assist the effective administration of justice and perform an important educative role in ensuring that people take intellectual property crime seriously.

The other respect in which the summary offences differ from the indictable offences is the lower penalty. In view of the lower fault requirements, the penalty for the summary offences is considerably less than the penalty for the equivalent indictable offences. This will ensure that less serious criminal conduct corresponds with an appropriately lower sanction.

Strict liability for jurisdictional elements of the offence

The circumstance element of the offences regarding whether a particular offence was an offence under section 145 or section 146 is strict liability. This is consistent with the policy and existing law for the indictable offences.[135] As a general principle, a

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[132] See the suite of summary offences in ss 132AC – 132AJ, 132AL, 132AN – 132AO.
[133] See the suite of summary offences in ss 132AC – 132AJ, 132AL, 132AN – 132AO.
[134] See eg Australian Institute of Criminology, *Intellectual property crime and enforcement in Australia*, 2008, p 3 – 4 (http://www.ipaustralia.gov.au/pdfs/news/IP_crime_enforcement.pdf).
[135] Existing s 147 (4), Trade Marks Act

person should not escape liability through ignorance of the law. [136] The strict liability elements ensure that, once a person satisfies the subjective fault elements in paragraph (b) of the offence, they will not escape liability under paragraph (c) of the offence merely because they were not aware of the specific provisions of sections 145 and 146.

Part 3: Relief for infringement

Items 28 and 29: Additional damages for trade mark infringement

[s 126]

This item amends section 126 to give a court the discretion to award additional damages if the court considers it appropriate to do so.

Additional damages (also known as punitive or exemplary damages) are available for flagrant infringement of patents,[137] registered designs, [138] and copyright.[139] However, additional damages are not currently available for trade mark infringement.[140] This limits the ability of a court to mark its disapproval of the blatant violation of the trade mark owner's personal property rights under the Trade Marks Act.

Additionally, stakeholders have submitted that many counterfeiters do not maintain sufficient business records to enable a satisfactory calculation of ordinary damages or an account of profits: purely nominal damages may be regarded by counterfeiters as merely the 'cost of doing business', rather than an effective deterrent.[141] The absence of additional damages under the Trade Marks Act limits the ability of a court to provide an effective deterrent to intentional counterfeiting.

The amendment remedies these problems by giving the court the discretion to award additional damages. This aligns the remedies for trade mark infringement with other forms of intellectual property. It permits the court to provide a substantial deterrent and to mark its disapproval of flagrant infringement.

Consistent with the additional damages provisions in other IP legislation, the power to award additional damages is discretionary. The courts will therefore have sufficient flexibility to ensure that additional damages are only awarded in appropriate circumstances. In exercising its discretion, a court would have regard to all relevant matters. Consistent with the approach in the Patents Act,[142] there is also a list of specific factors to assist the courts as to when it may be appropriate to award additional damages.

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[136] See eg s 9.3 (1), Criminal Code.
[137] Section 122 (1A), Patents Act.
[138] Section 75 (3), Designs Act.
[139] Section 115 (4), Copyright Act.
[140] Section 126, Trade Marks Act.
[141] IP Australia, *Review of Penalties and Damages*, 2008 p 25 (http://www.ipaustralia.gov.au/resources/news_new_archived_2008.shtml#58).
[142] See s 122 (1A).

Schedule 6 - Simplifying the IP system

Introduction

This schedule addresses a number of procedural hurdles and inconsistencies that unnecessarily complicate the Australian patents, trade marks, designs and plant breeder's rights systems.

The amendments resolve complexities and streamline processes to better adapt the system to an increasingly electronic and globalised environment.

Amendments to the Designs Act 2003

Item 1: Definitions – convention country

[s 5]

This item amends the definition of 'convention country' to refer to section 5A. Section 5A is discussed in item 3 below.

Item 2: Definitions – federal court

This item clarifies that 'federal court' refers to the Federal Court of Australia. This definition is necessary as amendments below (see item 3) give the Federal Magistrates Court (FMC) jurisdiction over designs matters. The amendment avoids any ambiguity as to which court is being referred to in existing references to the 'federal court' throughout the Designs Act.

Item 3: Definitions – prescribed court

[s 5]

This item and items 5 to 19 amend the Designs Act to provide the FMC with jurisdiction to hear and decide design matters.

The FMC was established to provide a cheaper and quicker forum for less complex disputes. Many designs matters are relatively simple disputes. The Advisory Council on Intellectual Property (ACIP) has recommended that the FMC be given largely the same jurisdiction under the Designs Act as the Federal Court of Australia (FCA) currently has.[143]

This amendment implements the ACIP recommendation. The benefits for parties will be greater access to justice. In particular, small business may benefit from being able to prosecute their designs matters in a speedy, cost-effective and less formal tribunal.

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[143] ACIP, *Should the jurisdiction of the Federal Magistrates Service be extended to include patent, trade mark and design matters?*, 2003 (available at www.acip.gov.au) p 6. Note that ACIP's recommendation to extend the FMC jurisdiction to patent and PBR matters was not accepted by the then Government, as such matters are typically more lengthy and complex and better suited to the FCA (http://www.acip.gov.au/library/Brief%20Release%20Gov%20response%20ACIP%20FMS%20.pdf)

The FMC's jurisdiction will be the same as the FCA's jurisdiction under the Designs Act, with one exception. The FMC will have the same jurisdiction to hear appeals against decisions, directions and orders of the Registrar. Like the FCA, prosecutions will not be able to be commenced in the FMC. The jurisdiction of the FMC will be exercised by a single Federal Magistrate.

The exception is that the FMC will not be able to hear an appeal from another court under section 87. This is consistent with the FMC's position as a trial court and the FCA's position as an appellate court.

This item also provides that proceedings may only be transferred between the FMC and the FCA and vice versa, consistent with the ACIP recommendations. The existing provisions governing transfer between the two courts will apply.[144]

Item 4: Convention Country

[s 5A]

This item amends the Designs Act to define a 'Convention country' as prescribed in the regulations.

The Act currently requires the regulations to list each 'Convention country' (a member of the Paris Union or the World Trade Organisation) individually. This imposes costs on government in amending the regulations each time membership changes. This is unnecessary when the updated information is readily available on the official World Intellectual Property Organisation (WIPO) website. [145]

The amendments will permit the regulations to define a 'Convention country' by reference to parties to the Paris Convention of the Trade Related Aspects of Intellectual Property Agreement (TRIPS Agreement), as they may be in force from time to time. The regulations will also refer readers to an internet site where a list of Convention countries can be found.

The provision is not intended to change either the substantive domestic law or Australia's treaty obligations.

Items 5 to 19: Federal Magistrates Court

[ss 28, 50, 52, 54, 67, 68, 82, 83, 83A, 84, 85, 86, 87, 88 and 89]

These items are discussed above under item 3. They, and item 3, amend the Designs Act to provide the Federal Magistrates Court (FMC) with jurisdiction to hear and decide design matters.

Items 20 to 22: Designs sub-offices

[s 125]

[144] See s 32AB of the *Federal Court of Australia Act 1976* and s 39, *Federal Magistrates Act 1999*.
[145] www.wipo.int

Item 20 amends the Designs Act to replace the requirement that there is to be a sub-office of the Designs Office in each State with a provision that there 'may' be a sub-office in each State. The item also provides that the Registrar may abolish any sub-office.

The existing requirement that there be a sub-office in each State dates from a time before modern communication and IT systems were available, and when most transactions with the Designs Office had to be conducted 'over the counter'. However, the Designs Office is continually expanding and refining its electronic services and demand for over the counter transactions is likely to diminish further in the future.

The amendments recognise that over the counter services are necessary at present, and State sub-office services will continue immediately upon commencement. However, it is foreseeable that in the future e-business channels will be sufficiently reliable and convenient that State sub-offices will no longer be required. Accordingly, the provisions provide the flexibility for the Registrar to withdraw such services in the future.

[s 136A]

Item 21 is consequential upon item 20. It clarifies that there need not necessarily be sub-offices.

[s 144]

Item 22 clarifies that the 'prescribed means' is not limited to filing only at a sub-office, but applies to filing in general, and includes filing at the Designs Office. As with item 21, it also clarifies that there need not necessarily be sub-offices.

Amendments to the Patents Act 1990

Items 23 to 25: Definitions

[s 3]

Item 23 removes the reference to 'foreign patent office' from the list of definitions in the Act. This change is consequential upon items 49 and 50, which repeal modified examination.

Item 24 removes the reference to 'modified examination' from the list of definitions in the Act. This change is consequential upon items 49 and 50, which repeal modified examination.

Item 25 removes the reference to 'sealed' from the list of definitions in the Act. This change is consequential upon items 60 and 62, which replace the requirement to seal a patent with the requirement that the Commissioner enter the details of the patent in the Register.

Item 26: Flowchart

[s 4]

This item removes the flowchart setting out the steps in getting a patent. The flowchart is out of date and has been superseded by information on IP Australia's website. It is more appropriate to have this information available on the website, where it can be updated as soon as changes are made, ensuring that the information provided to the public is correct and current.

Item 27: Basic applications

[s 8]

This item repeals the section relating to disclosures in basic applications. Repeal of section 8 is consequential upon insertion of section 43AA (see item 45).

Items 28 and 29: Extension of secret use

[s 9(d)-(e)]

These items amend section 9 to provide that any use of the invention within the prescribed period is not to be taken as secret use, as long as a complete application for the invention is made within the prescribed period.

The effect of this is to extend the grace period (discussed in items 32 and 33 below) to secret use.

A ground of invalidity of a patent is that the invention was secretly used in Australia by, or with the consent, of the patentee before the priority date of the patent. The rationale for this is that allowing a patentee to secretly use their invention before seeking patent protection would defeat one of the purposes of the patent system, which is to provide the public with information about new technology and ideas as they develop.

Currently, other than in the limited circumstances already provided for in section 9, secret use before the filing will invalidate a patent. This is the case regardless of whether the use was accidental or not. In contrast, if that use is public, and the 'grace period' applies (grace period is discussed in items 32 and 33 below), it may not affect the validity of the patent. This gives rise to an absurd situation in which public use of the invention by a patentee within 12 months of filing a complete application does not impact on patentability of an invention, by virtue of the grace period, but secret use in the same period does.

The amendment addresses this absurdity by specifying that any use of an invention within Australia, within a prescribed period, is not secret use. The prescribed period will be within 12 months of filing a complete patent application, to correspond with the grace period.

Item 30: PCT and Convention applications – consequential amendment

[s 10]

This item is consequential upon repeal of Part 1 of Chapter 8 discussed in item 67 below. The item removes the reference to Chapter 8 in section 10.

Item 31: Patent ownership - invalidity

[s 22]

This item inserts new section 22A to specify that a patent is not invalid merely because the patent was granted to a person who was not entitled to it.

Section 15 of the Act sets out the categories of persons to whom a patent may be granted. 'Person' means legal person and can include a natural person or a body corporate. The categories are: the inventor(s); a person (or persons) entitled to have the patent assigned to them; and a person who derives title to the invention from the inventor.

On grant of a patent, certain details of the patent, including ownership details are recorded in the Register.

The courts have clarified that grant of a patent to a person named in the patent application as an applicant or inventor, who is not entitled to it, or to some but not all persons who are entitled to it, renders the patent void.[146] This creates difficulties because patent ownership issues can be complicated, and it can be unclear, even to the parties involved, who has entitlement to particular patent claims. In particular, amendments to a complete specification during prosecution can change the parties who are entitled.

The Act provides several mechanisms for correcting ownership and resolving ownership disputes. However, some of these mechanisms are unnecessarily complicated, making it onerous or difficult to correct ownership details. These remedies may also be ineffective if the error is only discovered after grant, and can leave the parties who can demonstrate entitlement to the invention without effective patent rights. Patentees are therefore exposed to serious consequences from what may have been an honest mistake in the first instance.

This item and items 36 to 41 below address the problem of overly complex procedures for resolving problems with patent entitlement.

This item ensures that a patent is not invalid merely because it was granted to the wrong person.

Items 36 to 41 below improve the operations of sections 32 and 36, which deal with ownership disputes in respect of patent applications.

[146] *Stack v. Brisbane City Council; GS Technology Pty Ltd v. Davies Shephard Pty Ltd* [1999] FCA 1279; on appeal *Davies Shephard Pty Ltd v. Stack* [2001] FCA 501, and see also *GS Technology Pty Ltd v. Elster Meeting Pty Ltd* [2008] FCA 17 and *Conor Medsystems Inc v. University of British Columbia (No. 2)* [2006) FCA 32, on appeal *University of British Columbia v. Conor Medsystems Inc* [2006] FCAFC 154.

Item 75 below clarifies that the court will only order revocation of a patent if it is satisfied, in all the circumstances, it is appropriate to do so, for example where there is no person who is correctly entitled to grant of the patent.

Item 79 below gives the Commissioner the power to amend the Register to correct an error or omission or to correct ownership details.

Taken together these changes improve the mechanisms for correcting ownership details.

Items 32 and 33: 'Grace period'

[s 24(1)]

These items amend section 24 of the Act to provide that, for the purposes of deciding whether or not an invention is novel, or involves an inventive or innovative step, any information made publicly available in the prescribed circumstances by, or with the consent of the patentee is to be disregarded. It also clarifies, for all circumstances covered by subsection 24(1) that a complete patent application must be made within the prescribed period.

Subsection 24(1) relates to a number of circumstances where information made publicly available is to be disregarded, including the 'grace period'. The grace period allows for public disclosure of information relating to an invention (under certain conditions) without that information affecting the tests for novelty, inventive step (for a standard patent) or innovative step (for an innovation patent) of a patent claiming the invention. The conditions are that a complete patent application for the invention is made within 12 months of the public disclosure and that the disclosure is made by, or with the consent of the patentee.

The purpose of the grace period is to cover circumstances where an inventor has inadvertently disclosed their invention prior to seeking patent protection. It gives the applicant 12 months grace to file a complete application. The grace period is also a requirement of the Australia-United States Free Trade Agreement.[147]

The first problem with the current provision is that it only applies to publication or use of the invention. This means that the grace period could be taken only to apply to information that could deprive an invention of novelty, not to information that could deprive an invention of an inventive or innovative step. For example, the grace period would not apply in a circumstance where the patentee disclosed the work they had done, or a prototype that led directly to their invention.

Item 32 addresses this problem by replacing the existing reference to 'information made publicly available, through any publication or use of the invention' in paragraph 24(1)(a) with a reference only to 'information made publicly available'. This will allow circumstances to be prescribed to align the grace period with similar periods of one form or another that apply in the United States, Japan and Canada.

[147] Article 17.9.9 – Each Party shall disregard information contained in public disclosures used to determine if an invention is novel or has an inventive step if the public disclosure (a) was made or authorised by, or derived from, the patent applicant, and (b) occurs within 12 months prior to the date of filing of the application n the territory of the Party.

However, the regulations will ensure that the specific treatment of disclosures associated with international exhibitions, learned societies and the public working of the invention remain unchanged.

A second problem is that section 24 refers to 'a patent application'. This has led to confusion as to whether the benefits of the provision apply to the filing of either a provisional or a complete application. (Provisional applications are discussed in item 7 of Schedule 1.) The intention is to clarify that to benefit from the provision a complete application must be made in the prescribed period. This will allow regulations to be simplified so that the circumstances and periods relevant to section 24 can be defined in a clear and consistent way.

However, there is no intention for this clarification to alter the benefit that may be obtained by section 24 in the various other circumstances prescribed.

Item 33 addresses this ambiguity by clarifying that section 24(1) only applies where a complete application is filed in the prescribed period.

Item 34: Making PCT and Convention applications

[ss 29A and 29B]

A number of different types of complete patent application may be made under the Patents Act. These include standard applications, Convention applications (applications claiming an earlier priority date from an application filed in another Convention Country[148]) and PCT applications (applications made under the *Patent Cooperation Treaty 1970*).

Currently the provisions dealing with these different types of application are located in different parts of the Act and are unnecessarily complicated and difficult to navigate.

First, the Patent Regulations govern many of the administrative and procedural requirements for PCT applications. However, the existence of such regulations is not well signposted in the Act and a reader of the Act may inadvertently miss a procedural requirement imposed in the regulations.

Secondly, paragraph 228(2)(t) provides that the Patent Regulations may modify the operation of the Act (a 'Henry VIII' provision). Where this occurs it is not obvious to the reader of the Act that a particular provision in the Act has been displaced by the regulations and is no longer operative. There are now a substantial number of instances where this occurs with respect to the procedural requirements for the different types of complete applications.

Thirdly, many similar processes for standard, Convention and PCT applications are dealt with in separate parts of the Act. This makes little sense and unnecessarily complicates navigation in the Act.

[148] Convention countries are countries that are signatories to the Paris Convention for the Protection of Industrial Property 1883 or the Agreement on Trade Related Aspects of Intellectual Property Rights.

The amendments in items 30, 34, 34, 42, 46, 47, 56, 57, 58, 59, 67, 75, 76, 78, 80, 85, 86, 90, 93, 97 and 100 are intended to address these issues and restructure the existing substantive requirements for complete applications into a more coherent, user-friendly package. The benefit of this will be clearer and more transparent legislation that is easier for users to navigate.

This item re-enacts the existing provisions for making PCT and Convention applications to co-locate them with the provisions for making standard applications.

PCT and Convention applications

New section 29A does the following:

- clarifies that a PCT application is to be treated as a complete application for a standard patent;

- clarifies the description, drawings and claims in a PCT application are the component parts of the complete specification;

- allows for regulations to be made in respect of how amendments of a PCT application are to be treated under the Patents Act;

- clarifies that compliance with the specific requirements for PCT applications, as set out in section 29A must not be taken as compliance with other requirements under the Patents Act; and

- allows for regulations to be made prescribing requirements for when translations of PCT applications must be filed.

New section 29B similarly re-enacts the existing provisions for making convention applications closer to the provisions for making standard applications.

Definition of 'convention country'

The new section 29B also amends the definition to define a 'Convention country' as prescribed in the regulations.

The Act currently requires the regulations to list each 'Convention country' (a member of the Paris Union or the World Trade Organization) individually. This imposes costs on government in amending the regulations each time membership changes. This is unnecessary when the updated information is readily available on the official World Intellectual Property Organization (WIPO) website. [149]

The amendments will permit the regulations to define a 'Convention country' by reference to parties to the Paris Convention or the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS Agreement), as they may be in force from time to time. The regulations will also refer readers to an internet site where a list of Convention countries can be found.

[149] www.wipo.int

The provision is not intended to change either the substantive domestic law or Australia's treaty obligations.

Item 35: Filing date of PCT and Convention applications

[s 30]

This item amends section 30 to clarify that the filing date for a PCT application is as determined by the regulations.

Existing section 88, which ostensibly deals with the filing date of PCT applications has been modified by regulation 8.3(5)(a Henry VIII provision). Consistent with the principles described in item 34 above, this amendment clearly flags that the filing date of a PCT application is governed by the regulations.

Item 67 below repeals Chapter 8, which includes section 88.

Items 36 to 41: Resolving ownership disputes

[ss 32 and 36]

These items improve the operation of sections 32 and 36. These sections deal with the procedures for settling disputes in respect of patent applications, including entitlement disputes. Both provisions give the Commissioner the power to consider ownership disputes between parties but operate in different circumstances, with different remedies and different appeal rights.

This creates complexity for parties seeking to resolve an ownership dispute, who are unclear as to which is the most appropriate provision to use in their particular circumstances. In particular, problems can arise where a party seeks to use section 32 to solve an ownership dispute but the application that is the subject of the dispute has lapsed or lapses before a decision is been made. For example, a dispute may relate to ownership of a provisional or priority application, which even as a lapsed application can provide a priority date for a later filed complete application.[150] Currently it is not clear that the Commissioner can make a direction in respect of a lapsed application.

The amendments address these problems by removing the overlap between the two sections and clarifying how the sections operate.

Items 36 to 39 confine section 32 to disputes between joint applicants, leaving section 36 for disputes between applicants and other interested parties.

Under the amended section 32, one or more of joint applicants may ask the Commissioner to resolve an ownership dispute and issue a declaration as to who is the correctly entitled applicant, and in whose name the application should proceed. The Commissioner can make a declaration whether or not the application is lapsed. The Commissioner cannot make a direction without giving each joint applicant a reasonably opportunity to be heard.

[150] Provisional applications are priority dates are discussed in items 6, 10 and 11 of Schedule 1

Section 32 will also continue allow joint applicants to resolve other types of disputes about how the application is to proceed.

Section 36 will continue to apply where a party, other than the patent applicant, seeks a declaration from the Commissioner that the party (or another party with an interest in the application) is entitled to be an applicant, either in addition to the existing applicant, or in place of the existing applicant.

Item 40 ensures that section 36 can apply at any time until grant. This permits the resolution of entitlement issues without forcing parties to opposition. It also decreases the likelihood that a patent is granted to non-entitled persons.

The only change that item 41 makes to section 36 is to give the Commissioner the discretionary power to direct in whose name, or names, the application is to proceed. This will give the Commissioner, in appropriate circumstances, the flexibility to efficiently resolve disputes without necessarily requiring a new application to be filed as provided for in subsection 36(4).

The result will be one section (section 32) specifically for settling disputes, including ownership disputes, between joint applicants, and another section (section 36) for settling ownership disputes between parties who are not currently listed as applicants or inventors, and those who are.

Item 42: Period for making a Convention application

[s 38]

This item inserts subsection 38(1A) to provide that the time within which a Convention application must be made is prescribed in the regulations.

This requirement is currently provided by section 94. Consistent with the objective discussed in item 34 the amendment co-locates the provision relating to the time period for filing a Convention application with the provision relating to the time period for filing a complete application.

Item 67 below repeals Chapter 8, which includes section 94.

Item 43: Omnibus claims

[s 40(3A)]

This item amends section 40 to require that claims must not rely on references to the description or drawing except when absolutely necessary to define the invention.

The amendment relates to restricting the use of omnibus' claims, which define an invention by reference to the whole or part of the specification. For example, a claim may define an invention by reference to drawings or examples in the specification.

Unlike most other countries,[151] Australia has generally permitted omnibus claims. This gives rise to certain problems, where defining the claims in a general and non-specific way leads to a lack of clarity as to the exact scope of the monopoly. As far as possible, it is desirable that a claim should be free-standing, so that any person reading the claim will be able to ascertain the exact scope of the monopoly from the face of the claim.

The amendment prevents the use of omnibus claims except where the invention can only be defined by reference to a specific detail in the specification - for example, where reference to a spectroscopic profile or reference to specific feature in a figure or drawing is the only way of defining a chemical composition or apparatus.

Other jurisdictions permit omnibus claims only where it is 'absolutely necessary' to concisely and clearly define the invention.[152] The amendments implement a similar restriction in Australia.

Item 44: Disregarding earlier PCT and Convention applications

[s 43]

As a member of the Paris Convention, Australia allows applicants for a complete application to rely on an earlier application filed in another Convention country for priority, provided that the complete application is filed within 12 months of the earlier application, and the earlier application is the first application made for the invention in a Convention country.

Sometimes an applicant will file multiple earlier applications, some of which may have been filed more than 12 months prior to filing the complete application. Where multiple earlier application are filed, and one or more of the applications have been withdrawn, abandoned or refused, without being published (becoming open for public inspection) and without being used as the basis for claiming priority, the applicant can request that the Commissioner disregard the withdrawn, lapsed or abandoned application(s). Section 96 currently provides for this.

If the Commissioner could not disregard the applications the applicant would not be able to rely on any of the earlier applications as a basis for claiming priority for their complete application, because the first application made for the invention was filed more than 12 months before the complete application. Once published, the earlier application would likely also deprive the complete application of novelty.

Australia's requirements for disregarding earlier applications differ from the requirements in Europe and the United Kingdom. These jurisdictions automatically disregard an earlier application where the application has been withdrawn, abandoned or refused without becoming open for public inspection and without leaving any rights outstanding or serving as a basis for claiming priority. They also allow an earlier application to be disregarded where the earlier application is filed in a different Convention country to the application that they wish to use as the basis for claiming

[151] See eg *Ex parte Fressola*, 27 USPQ2d 1608 (Bd. Pat. App. & Inter. 1993) for why Omnibus claims are not acceptable in the USA.
[152] See Rule 29 (6), *Implementing Regulations to the Convention on the Grant of European Patents 1973*;

priority. In contrast, in Australia an earlier application will only be disregarded if filed in the same Convention country as the priority application.

Australia's requirements are more onerous and restrictive than requirements elsewhere. There is also the risk that an applicant who is unaware of the difference between Australia's requirements and those elsewhere will not realise that they have to make an explicit request of the Commissioner to disregard an earlier application, will not make the request and consequently invalidate their complete application.

The amendments make Australian requirements less complex and more consistent with requirements elsewhere. They provide that an earlier application made in another Convention country must be disregarded if it was made in the prescribed period and has been withdrawn, abandoned or refused, without becoming open for public inspection or serving as a basis for claiming priority. The prescribed period will be the period more than 12 months before the filing date of the Convention or PCT application. The note to the provision will clarify that the application from which the applicant wishes to claim priority need not have been made in the same Convention country as the earlier disregarded application.

The item inserts the provision as section 43, which places it in the section dealing with priority. Existing section 43 is repealed (see discussion in item 10 of Schedule 1).

The item clarifies that the provision also applies to PCT applications.

Item 45: Digital Access Service

[s 43AA]

This item inserts section 43AA to clarify the requirements for making basic applications available to the Commissioner and the circumstances in which the Commissioner will give account to the disclosures in these documents.

A basic application is an application made in a Convention country. A basic application can serve as a priority document for a later application; as long as certain requirements are met (Item 10 in schedule 1 discusses priority).

Normally it is not necessary for the Commissioner to require the filing of a basic document, a translation or other associated documents because, if it is necessary to confirm the priority date for the invention, it will be publicly available online from the patent office of the Convention country in which it was filed or from the WIPO. In some cases however the relevant documents are not readily available when required and the Commissioner needs to request that they are made available. The amendments ensure that the requirements for making basic and related documents available are sufficiently flexible to account for modern electronic means for filing and accessing documents.

In particular the amendments give the flexibility to meet the requirements of the Commissioner by making the relevant documents available through the WIPO Digital Access Service (DAS), or other like facilities. DAS is a centralised repository through which an applicant can make their priority documents available to all Patent Offices

that require them. Where a country requires access to the priority document, in respect of a complete application associated with the priority document filed in that country, the country need only access DAS. If not already available, the applicant can meet a request for the documents by ensuring the documents become available to the country in DAS. Prior to DAS, the country would have had to request that the applicant provide a copy of the document, imposing costs on the applicant and delays for the office.

First, the amendments give the Commissioner the power to require that a prescribed document relating to a basic application be made available to the Commissioner by the prescribed means and within the prescribed time.

Prescribed documents will include specifications and other documents, and, if the specification or other document is not in English, a translation into English. The prescribed means will include electronic means such as through the DAS or other means as appropriate.

Non-compliance with the Commissioner's requirement to make the document available within the prescribed time means that Commissioner cannot give account to the disclosure in the document in determining the priority date of the later application.

However, it is not necessary for the Commissioner to require that a document be made available by the prescribed means in order for the disclosure in the document to be taken into account. This ensures that the document is taken into account even if the Commissioner has not requested it.

Finally, the amendment clarifies that the Commissioner may require that the same document be made available more than once. This accounts for circumstances where a document may have initially been made available, for example in relation to examination of the later application, the document is subsequently removed from the DAS, but is then later required again by the Commissioner in respect of a further matter.

The amendments give flexibility to both applicants and the patent office in accessing basic applications. They also reduce cost and complexity for the applicant, who only need file their basic document once electronically with WIPO.

Items 46 and 47: Examination

[s 45]

These items amend the provision relating to examination of complete specifications to permit the Commissioner not to report on a PCT application where the prescribed requirements are not met.

Existing section 45 is modified by the regulations 8.3(1AA) to (1AF). Consistent with the principles set out in item 34 the amendments in this item more clearly flag the existence of relevant regulations to a reader of the Act.

Item 48: Informing the Commissioner of search results – standard patents

[s 45]

This item repeals the provisions in section 45 which previously required patent applicants to inform the Commissioner of certain patentability searches.

The requirement that applicants provide the Commissioner with detail of patentability, in particular for novelty and inventive steps, searches done by other patent offices was introduced to ensure that patent examiners had access to important information about the patentability of inventions during examination. This information supplemented their own search and examination information, contributing to the quality of examination decisions.

At the time the requirement was introduced this information was not readily available, and the best option was to request that applicant provide it. However, most major offices now publish this information on their websites. The Commissioner can now access the information via the internet and there is no need to put the applicant to the expense of providing the searches. Accordingly, the existing provisions are no longer required.

Items 49 and 50: Modified examination

[ss 46, 47 and 48]

These items repeal sections 47 and 48, which provide for modified examination, and section 46 which provides for deferral of examination.

Modified examination was introduced as an option for applicants to streamline examination and save costs by avoiding rework by patent examiners. Where a recognised foreign office has granted a patent on an equivalent application an applicant can request modified examination of their Australian application.

Under modified examination the Australian examiner does not examine for section 40 issues (full description and fair basis – these requirements, and proposed changes to them, are discussed in items 8 and 9 of Schedule 1). The examiner relies on the examination done by the foreign office in respect of these issues. However, the examiner does consider the remaining grounds (novelty, inventive step, manner of manufacture and whether the invention is for a human being or process for generating a human being). In practice, examiners give substantial weight to the novelty and inventive step assessments made by the foreign office.

This approach strikes a balance between relying on some of the work done by another office, while maintaining the option of doing further examination work where the examiner believes it is necessary.

Despite the advantages that modified examination can deliver to applicants it is not extensively used. Differences between patentability standards and requirements and minimal cost savings are cited by the attorney profession and applicants as reasons for the low use of modified examination.

Item 50 repeals the modified examination provisions in recognition of the fact that the provision is rarely used, and in the interests of reducing the complexity of the patents legislation.

Item 49 is consequential upon repeal of modified examination. Item 49 repeals section 46, which allows an applicant to request deferment of examination because they are waiting for examination of an equivalent foreign application to be completed, with the intention of then requesting modified examination on the equivalent Australian application.

Items 51 and 53: Postponing acceptance

[ss 49 (3) – (4) and 49A]

These items amend section 49 to change the way in which postponement of acceptance operates.

Currently the Commissioner must postpone acceptance of an application under subsection 49(3) if requested to do so by the applicant. Acceptance is postponed until a day specified by the applicant.

There are two problems with the current scheme. Firstly, it may not be in the public interest to delay acceptance. The public may be looking for early certainty about where there is freedom to operate. Delaying acceptance leaves the public, and third party competitors, in limbo during the postponement period.

Secondly, allowing the applicant to specify a particular end date for postponement adds administrative complexity. It requires that IP Australia record the date and obliges the Commissioner to accept the application on that date.

The changes address these problems by giving the Commissioner the discretion of whether to allow a request to postpone acceptance or not.

Item 51 repeals the existing provisions governing postponement. Item 53 introduces a new scheme which will operate as follows:

- Where the Commissioner is aware of a particular interest in early resolution of the application, for example where a third party has requested examination of the application, the Commissioner is unlikely to accept a request to postpone acceptance. Where the Commissioner is not aware of any particular interest in early resolution, she is likely to accept the request to postpone.

- If a request to postpone acceptance is granted, the Commissioner has the discretion of whether or not to set an end date for the postponement. Generally the Commissioner will elect not to set an end date. That being the case, the application will only be accepted if the applicant requests removal of the postponement, as long as the applicant's request is received early enough to allow the Commissioner to remove the postponement and accept the application before the application lapses at the end of the acceptance period.

However, it is envisaged that in the future the Commissioner may wish to restrict the duration of postponement of acceptance for applications. In these circumstances the Commissioner would specify a shorter time period for all postponements of acceptance. This would retain some flexibility for applicants to delay acceptance, but balance this with the public and competitors' interests in reducing delays and in having certainty about whether a patent will be granted. Where the Commissioner specified the time period, the application would be automatically accepted once the time period expired.

The Commissioner will also have the discretion to postpone acceptance, even if the applicant has not requested it. For example, there may be circumstances where there is a dispute about ownership of a patent application underway, and it is appropriate to postpone acceptance and then grant the patent to the correctly entitled person, once the dispute is resolved.

The amended scheme provides flexibility to balance the interests of applicants in having extra time to resolve issues before acceptance with the interests of the public in early resolution of applications. It also reduces the complexity and administrative burden of postponement.

Item 52: Modified examination – consequential amendments

[s 49(6)]

This item repeals subsection 49(6) consequential upon repeal of modified examination (see items 49 and 50).

Item 54: Revocation of acceptance – standard patents

[s 50A]

This item amends the Patents Act to permit the Commissioner to revoke acceptance of a patent application if she is satisfied, on the balance of probabilities, that the application should not have been accepted, and if it is reasonable to revoke acceptance in all the circumstances.

Administrative errors can occur during the process of accepting a patent application. Some of these can, if not remedied, lead to incorrect patent grants and low quality or invalid patents. General administrative law remedies provide a solution in some cases, but often applicants bear some cost or at least inconvenience in rectifying errors or omissions.

In contrast, when applications for trade marks are accepted following an administrative error or omission, the Registrar of Trade Marks has the power to revoke the decision to accept the application—section 38 of the *Trade Marks Act 1995*.

The amendments are intended to provide a similar power in respect of patent applications. This will provide an inexpensive and straightforward process for the Commissioner to rectify administrative errors in accepted applications.

The amendment gives the Commissioner a discretionary power to revoke acceptance of an application where an administrative error has resulted in acceptance of an application that should not have been accepted. The Commissioner will not be obliged to revoke acceptance on request of an applicant or other party. If questions arise about the substantive quality of an accepted application these are to be dealt with through re-examination or opposition.

The amendment is cast broadly to provide the Commissioner with sufficient flexibility to address a wide variety of circumstances in which an administrative error may be made, and take into account all relevant interests. This wording is consistent with the power to revoke acceptance of a trade mark application.[153]

If the power is exercised, the application is taken to have never been accepted. The Commissioner will remedy the error and recommence examination. If, on recommencing examination the Commissioner is satisfied that the application meets the requirements of section 49 the application will be accepted. Acceptance will be re-advertised under subsection 49(5) and be subject to the usual processes for accepted applications.

If there are outstanding issues the Commissioner will issue a further examination report.

Where acceptance is revoked, the normal period for accepting the application will be extended, as set out in the regulations. This ensures that the applicant has sufficient time to resolve any outstanding issues raised by the Commissioner.

Item 55: Revocation of acceptance – consequential amendment

[s 51]

This item is consequential upon item 54. It clarifies that a decision to revoke acceptance under new section 50A is not appealable to the Federal Court.

A decision made by the Commissioner to accept or refuse an application following examination (including where examination has re-commenced following revocation of acceptance under section 50A) is appealable to the Federal Court. It is not necessary that the decision to revoke acceptance, prior to recommencing examination, also be appealable.

Item 56: Publication of information about PCT applications

[s 53]

This item amends section 53 to clarify that the existing requirement of section 53 that the Commissioner publish the prescribed information about the applicant and the application in the *Official Journal* does not apply to PCT applications. The item also permits regulations to be made concerning the publication of information relating to PCT applications.

[153] Section 38 (1) (b), Trade Marks Act.

The existing sections of the Act concerning publication of information in PCT applications are overridden by regulations 8.3(1A) and (1B). Consistent with the principles discussed in item 33 this item more clearly flags the existence of such regulations.

Items 57 and 58: Publication of PCT applications

[s 56A]

This item inserts new section 56A to permit regulations to be made in relation to PCT applications when they become open for public inspection (OPI).

The existing sections of the Act concerning publication of information in PCT applications are overridden by regulations 8.3(1C) to (1E). Consistent with the principles discussed in item 34 this item more clearly flags the existence of such regulations. It also co-locates the provisions relating to publication of PCT applications and standard applications.

Item 57 is consequential to item 58: it provides that the cross reference is to the new section 56A, instead of the previous section 90.

Item 59: Effect of publication for PCT complete specifications

[s 57]

This item amends section 57 to also deal with PCT applications. Section 57 deals with the effect of publication of an application. The item inserts a reference to section 56A to take account of the amendments made by item 58 above.

Consistent with the principles discussed in item 34, this item more clearly flags the existence of such regulations. It also co-locates the provisions relating to publication of PCT applications and standard applications.

Items 60 and 61: Grant of a standard patent

[s 61]

These items amend the Patent Act to replace the current process for sealing a standard patent with a process for entering the particulars of the grant into the Register of Patents.

Currently, a patent is granted by 'sealing' the patent: the Commissioner must physically affix a seal to the patent deed after it has been printed in its final form.

By contrast the registration of a trade mark only requires entry of certain particulars in the Register of Trade Marks[154] and the trade mark owner receives a certificate of the registration.[155] Administratively this is a simpler approach that is better aligned with today's electronic business environment.

[154] Section 69, Trade Marks Act.
[155] Section 71 (b), Trade Marks Act.

Item 60 implements a similar, more streamlined system for the grant of a patent. The sealing process is replaced with a process whereby the act of grant occurs via entry of the particulars of the patent in the Register.

Item 61 requires, as is currently the case, that the Commissioner notify the patentee of the grant. At present it is envisaged that this would be by providing an extract of the Register or a paper (but unsealed) certificate of grant. Further extracts of the Register can be obtained if particulars on the Register are amended.

Items 62 and 63: Grant of an innovation patent

[s 62]

These items amend the Patent Act to replace the current process for granting an innovation patent with a process for entering the particulars of the grant into the Register of Patents.

Currently, an innovation patent is granted by 'sealing' the patent: the Commissioner must physically affix a seal to the patent deed after it has been printed in its final form.

Items 62 and 63 implement an equivalent process for the granting of innovation patents as is discussed in items 60 and 61 above for the grant of standard patents.

The objective is to provide an administratively simpler approach better aligned with today's electronic business environment.

Items 64 to 66: Grant of patents – consequential amendments

[s 66]

Item 64 consequentially repeals section 66. As patents will no longer be required to be sealed, there is no need to have provision for sealing a duplicate patent.

Patentees may continue to seek an extract of the Register if they lose their original certificate or extract[156] or if particulars on the Register are corrected due to an error or omission by the Commissioner.

[s 79C and 81]

Item 65 is consequential upon item 62. It replaces the reference to "sealed" in subsection 79C(1) with 'granted'.

Item 66 is consequential upon item 60. It replaces the references to 'sealed' in subsection 81(3) with "granted".

Item 67: Repeal of Chapter 8

[Chapter 8]

[156] Section 197 (2), Patents Act.

This item repeals Chapter 8, which deals with requirements for PCT and Convention applications.

This item is consequential upon item 34 which moves the procedural and administrative requirements for PCT and Convention applications from Chapter 8 to co-locate them with the procedural and administrative requirements for standard applications in general.

The amendments are intended to restructure the existing substantive requirements for complete applications into a more coherent, user-friendly package. The benefit of this will be clearer and more transparent legislation that is easier for users to navigate.

Item 68: Informing the Commissioner of search results – innovation patents

[s 101D]

This item repeals the provisions which previously required innovation patentees to inform the Commissioner of certain patentability searches.

The policy rationale and intent behind the changes is the same as for the amendments for standard patents in item 48.

Item 69: Revocation of certificate of examination – innovation patents

[s 101EA]

This item amends the Patents Act to permit the Commissioner to revoke a decision to certify an innovation patent.

The policy intent of this amendment is the same as the amendments permitting the Commissioner to revoke acceptance of a standard patent application: that is to permit the Commissioner to easily rectify an administrative error (see item 54). The provisions are intended to operate in the same way, except that the revoked decision is the certification decision (which is analogous to the acceptance decision for standard patents, as innovation patents are not examined prior to grant).

Where certification of an innovation has been revoked the Commissioner will be able to amend the Register under new paragraph 191A(1)(c) to remove details of the patent from the register (see item 79).

Item 70: Informing the Commissioner of search results – consequential amendment

[s 102]

This item repeals subsection 102(2C) which provided a sanction for non-compliance with subsections 45(3) to (5) and section 101D. As these provisions are being repealed (see items 48 and 68), the sanction is being repealed.

Items 71 and 72: Grant of patents – consequential amendments

[s 105]

These items are consequential upon items 60 and 62. They remove references to 'the patent'.

The amendments are necessary as patents will no longer by physically 'sealed'. Accordingly, there will no longer by a physical document to amend under section 105. Instead the patent will be granted by entry of particulars into the Register. Amendments to the Register in court proceedings will be able to be made under section 192 instead.

Item 73: Non-infringement declarations

[ss 125 to 127]

This item amends the Patents Act to amend a number of aspects of the non-infringement declaration regime that have proven to be unsatisfactory.

A person (the applicant) is able to apply to a court for a declaration that the exploitation of an invention would not infringe the claims of a particular complete specification (owned by the respondent). This is known as a 'non-infringement declaration'. Non-infringement declarations assist manufacturers who are proposing to make an article or use a process, but who cannot obtain clear legal advice or an assurance from a patentee that their proposed activities would not infringe a patent. They are seldom sought in Australia.

Person seeking the declaration

The item amends section 125 to provide that the person seeking the declaration need not have sought or been granted a patent themselves in order to make use of the provision.

In a recent decision *Occupational and Medical Innovations v Retractable Technologies Inc*[157], the words 'exploit an invention' were interpreted as applying only when the applicant was themselves a patentee or patent applicant. This is contrary to the policy intent of the provisions, which are intended to protect all legitimate competitors, regardless of whether the competitor has themselves applied for a patent or not.

The reference to a person who wishes to "exploit the invention" is replaced with a reference to a person who "has done, is doing, or is intending to do an act".

Retrospective, current and prospective infringement

Specifying that a declaration can be sought by a person who "has done, is doing, or is intending to do an act" also clarifies that a declaration can apply to a present, current or past act.

[157] [2008] FCA 1102; 77 IPR 570.

The current provision is phrased such that it arguably only applies to future acts ('wishes to exploit' and 'would not infringe a claim'). The equivalent provision of the *Patents Act 1977* (UK) has a broader wording: '… an act does not, or a proposed act would not, constitute an infringement of a patent …'.[158] To ensure that all aspects of the dispute are dealt with, it is desirable that the court be able to declare with respect to past, present and proposed conduct. Accordingly, the item introduces wording similar to the UK provisions.

Declarations before grant

The item amends section 125 to provide that a non-infringement declaration may not be sought until the respondent's standard patent has been granted, or innovation patent certified.

The *Occupational and Medical Innovations v Retractable Technologies Inc* decision held that a non-infringement declaration can be obtained even before the respondent's patent has been granted. This does not reflect the original policy intent, that non-infringement declarations be available for granted patents only. This is because an application may be substantially amended prior to grant, thereby rendering the declaration useless.

The reference to an application for a declaration being made "at any time after the complete specification becomes open for public inspection" is replaced with a reference to "at any time after the patent has been granted" (standard patent) and "at any time after the patent has been certified" (innovation patent).

The item also consequentially amends section 127 to remove the references to "nominated persons". Limiting the provisions to granted patents makes the reference redundant.

Challenges to validity

The item also repeals subsection 126(2) to permit an applicant for a non-infringement declaration to challenge the validity and seek revocation of the respondent's patent in the same proceedings.

Currently, subsection 126(2) prohibits the applicant from challenging the validity of a respondent's patent. This creates the situation where a non-infringement declaration could be refused because the applicant's exploitation would 'infringe' an invalid patent. This acts as a disincentive to a person seeking a non-infringement declaration, who would need to institute and run separate court proceedings to challenge invalidity. It also delays the final resolution of patent disputes and reduces public confidence in the validity of granted patents.

This item repeals the prohibition against challenging validity. An applicant for a non-infringement declaration may now also seek revocation under the existing section 138. The intention is that both matters may be heard by the same court as a single proceeding.

[158] Section 71.

The changes would provide a safeguard to prevent the patentee asserting an overly broad construction of their patent in order to establish infringement and prevent a declaration being made. It would also permit a court to resolve all aspects of the patent dispute more efficiently and with a greater degree of finality.

Legal costs

Finally, the item also amends subsection 126(3) to provide the court with the discretion to award costs in the usual manner.

Currently, subsection 126(3) provides that the person seeking the non-infringement declaration must pay the legal costs of all parties, unless the court orders otherwise. This is a disincentive for persons to use the non-infringement declaration provision, as the default position is that they will pay the patentee's legal costs even if they are successful in obtaining a non-infringement declaration. This also does not take account of the fact that subsection 126(1) makes it an explicit precondition for granting the declaration that the respondent has already refused an opportunity to settle the matter with the applicant.

The changes provide that the default position is that costs follow the event. It is intended that, consistent with most other civil litigation, the winning party would ordinarily be entitled to their costs, unless the court thinks fits to order otherwise.

Item 74: Grant of patents – consequential amendments

[s 135]

This item consequentially amends the Patents Act to replace the reference to 'seal' with a reference to 'grant'.

This amendment is necessary as patents will no longer by physically 'sealed' (see items 60 and 62.

Item 75: Revocation

[s 138]

This item amends section 138 to provide that a court must not revoke a patent for incorrect entitlement unless it is just and equitable to do so in all the circumstances.

This provision operates in conjunction with the amendments in item 31, which provides that a patent is not invalid merely because the patent was granted to incorrectly entitled persons. As explained above, it is often difficult to determine the persons correctly entitled to the patent and errors in entitlement are often no more than an honest mistake by the inventors and applicants. Revocation of the patent is often an unnecessarily harsh outcome.

This amendment is intended to provide that the default remedy for a defect in entitlement is not revocation of the patent. If the correctly entitled persons are available and willing to be recorded as inventors and have acted in good faith, the intention is that the patent would not be revoked. In such an instance a declaration of

who is correctly entitled to the patent and an order for the rectification of the Register under section 192 would be more appropriate.

However, there may be some instances where revocation is appropriate in all the circumstances. For instance, if none of the persons to whom the patent was granted are correctly entitled to the patent, revocation may be appropriate. Similarly, if the correctly entitled persons have not acted in good faith or have been grossly negligent in permitting the patent to be granted to incorrectly entitled persons, revocation may be appropriate. However, it is intended that revocation is the exception, rather than the rule.

Item 76: Withdrawal of PCT applications

[s 141]

This item amends section 141, which relates to withdrawal of applications, to flag the existence of regulations prescribing circumstances in which PCT applications are taken to be withdrawn. (Note a related proposal relating to withdrawal of applications in item 11 of Schedule 3.)

The existing sections of the Act concerning withdrawal of PCT applications are overridden by regulation 8.3(2). Consistent with the principles discussed in item 33 this item more clearly flags the existence of such regulations.

Item 77: Modified examination – consequential amendments

[s 142(2)(c)]

This item repeals paragraph 142(2)(c), which relates to the lapsing of applications where examination has been deferred. The amendment is consequential upon the repeal of modified examination and deferral of examination provisions (see items 49 and 50).

Item 78: Lapsing of PCT applications

[s 142(2)(f)]

This item inserts paragraph 142(2)(f) to flag the existence of regulations prescribing circumstances applying to the lapsing of PCT applications.

The existing sections of the Act concerning lapsing of PCT applications are overridden by regulation 8.3(3). Consistent with the principles discussed in item 34 this item more clearly flags the existence of such regulations.

Item 79: Rectification of the Register

[s 191A]

This item inserts new section 191A to give the Commissioner the power to declare who owns the patent and to amend the Register to correct an error or omission or to correct ownership details.

On grant of a patent, certain details of the patent, including ownership details are recorded in the Register. Currently, only the courts have the power to rectify details in the Register. This can make it onerous and costly for a patentee to seek to have the Register corrected where details of their patent are incorrect.

This item gives the Commissioner the power to declare who is the correct owner, or owners, of the patent and to rectify the Register where she is satisfied, on the balance of probabilities, that details on the Register are incorrect.

In particular, this gives the Commissioner the power to correct ownership details where she is satisfied that a patent was granted to the wrong person or persons. This issue is discussed further in item 30, which relates to correcting ownership details.

Where the Commissioner corrects the names of patentees on the Register, it is not intended that she also deal with any disputes that may arise about the status of licenses issued, or other rights granted by the original or new patentee. These matters are to be dealt with by the courts.

Existing section 189 deals with the situation, among others, where a third party has, in good faith, dealt with a patentee to whom the patent should not have been granted (for example a person who obtained a licence before the ownership error was rectified). This provision will continue to apply to situations where patent ownership is corrected under the new provisions.

The Commissioner must not correct the Register without first giving anyone affected by the correction the opportunity to be heard. The Commissioner also cannot correct the Register while relevant court proceedings are underway.

Where the Register is corrected, the Commissioner will publish details of the correction.

An appeal to the Commissioner's decision to correct the Register lies to the Federal Court.

Item 80: Evidence of matters arising under the PCT

[s 197AA]

This item inserts section 197AA to provide that a certificate signed by the Commissioner relating to things done or not done in respect of a PCT application is evidence of the matters set out in the certificate. This is currently dealt with in section 93 of the Act, which is modified by regulation 8.3(2).

Consistent with the principles discussed in item 33, this item more clearly flags the existence of such regulations and co-locates the provisions relating to evidence of things done or not done in relation to standard applications in the same provision.

Items 81 and 82: Sub-offices of the Patent Office

[s 205(2)]

Item 81 amends the Patents Act to replace the requirement that there is to be a sub-office of the Patent Office in each State with a provision that there 'may' be a sub-office in each State. The item also provides that the Commissioner may abolish any sub-office.

The background, issue and intended operation of this amendment is the same as the related amendments in relation to State sub-offices of the Designs Office (item 19) - in practice the Patent and Designs sub-offices are the same physical premises.

[s 214]

Item 82 amends the Act to clarify that section 214 does not implicitly require that there must be sub-offices of the Patent Office.

This item is consequential to the related amendments in item 80 to provide discretion to withdraw sub-office services in the future. The provision has been re-drafted so that a document may be filed at a State sub-office, only so long as sub-offices continue to exist, and with the Patent Office, regardless of whether or not there are sub-offices.

It also clarifies that the 'prescribed means' is not limited to filing only at a sub-office, but applies to filing in general, and to filing at the Patent Office.

Item 83: Correcting the Register upon the death of the patentee

[s 215(3)]

This item amends section 215. As a patent will be granted by entering the particulars in the Register instead of by sealing the patent (see items 60 to 63), the Commissioner will need to amend the Register instead of the patent if the patentee dies.

Item 84: Doing an act when the Patent Office reopens etc

[s 222A(1)]

This item consequentially amends section 222A, as item 81 contemplates that there may not always be a sub-office of the Patent Office in the future.

Item 85: Extension of time – PCT applications

[s 223]

This item amends section 223(1), which deals with extensions of time where there has been an error or omission by the Patent Office, to clarify that the subsection also applies to errors or admissions made in respect of PCT applications by the receiving office for PCT applications or the International Bureau of the WIPO.

Currently, this section of the Act is modified in respect of PCT applications by regulation 8.3(5). Consistent with the principles discussed in item 34 this item more clearly flags the existence of such regulations.

Item 86: Review of decisions - consequential amendment (grant of patents)

[s 224(1)(a)]

This item amends paragraph 224(1)(a) to provide for merits review by the Administrative Appeals Tribunal (AAT) for a decision of the Commissioner to grant or refuse inspection or production of documents that are not Open to Public Inspection (OPI).

Providing independent merits review is consistent with the policy of increasing the quality, openness and accountability of government decision making.[159] Providing AAT review will also improve access to a quick and less costly review mechanism for parties affected by a decision of the Commissioner.

The item also amends paragraph 224(1)(a) to remove the reference to section 66. This item is consequential upon repeal of section 66 (see item 64 above).

Item 87: OPI documents do not infringe copyright

[s 226]

This item repeals existing section 226, replacing it with a new section clarifying exemptions from copyright right infringement for certain documents in certain circumstances. The documents are provisional and complete specifications and other prescribed documents. The prescribed documents will include the documents normally associated with the case file of a patent application. Documents such as journal, book and other technical material that may have been submitted by the applicant during prosecution of the application will however be excluded. Normal rules of copyright will apply to these documents.

The copyright exemption will extend to reproduction of the documents in a two dimensional form and communicating the document to the public. This includes making the documents available via the internet. It will allow IP Australia to implement an e-dossier system; making patent application case files available to the public via the internet. It is intended that most, but not all of the documents associated with prosecution of an application, be made available.

The exemption is also intended to cover a translation, as the documents may include foreign language documents, such as search reports from foreign patent offices, which may need to be translated.

Subsection (3) provides that the supply or communication does not constitute a publication. This has two effects. First, it ensures that if the supply or communication would also otherwise constitute a publication it is exempt from copyright infringement. Secondly, it preserves the author's exclusive right to publish under the Copyright Act.

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[159] See eg Administrative Review Council, *What decisions should be subject to merits review?* (1999), at par 1.5 and 2.1 (http://www.ema.gov.au/agd/WWW/arcHome.nsf/Page/Publications_Reports_Downloads_What_decisions_should_be_subject_to_merit_review)

Item 87: Review of decisions - consequential amendment (grant of patents)

[s 227]

This item is consequential upon item 34**,** which moves the requirements for filing PCT applications from section 89 to new section 29A, co-locating them with the requirements for filing standard applications.

The item replaces the reference to subsection 89(3) in the note to subsection 227(3), which deals with failure to pay a fee, with a reference to subsection 29A(3).

Item 89: Regulation making power – correcting patents

[s 228(2)(f)]

This item repeals the paragraph consequentially. A patent will be granted by registration of particulars instead of sealing a patent (items 60 to 63), and the new section 191A will provide the Commissioner with power to amend those particulars (item 79). Accordingly, there is no need for the regulations to make provision for correcting sealed patents.

Item 90: Regulations providing for PCT applications

[s 228]

This item inserts new paragraph 228(2)(ha) to allow for regulations to be made providing for the requirements that must be met in respect of making a PCT application, giving the Commissioner the power to direct an applicant to do certain things necessary, in order for a PCT application to proceed as a standard application under the Patents Act and for the lapsing of the application if such a direction is not complied with.

This will enable the regulations to prescribe the requirements for the formalities checking process with respect to PCT applications.

Item 91: Treaty texts

[s 228]

This item repeals provisions requiring the full text of certain treaties to be set out in the Patents Regulations.

The requirement to set out the full text in the legislation dates back to a time when it was difficult to access authoritative texts of such treaties. However, with the advent of the internet, members of the public are able to access authoritative versions of treaties from other sources, such as the official website of the WIPO. Additionally, maintaining the text of the treaties in the legislation consumes government resources, as the regulations must be amended every time the treaty is changed. This use of resources is wasteful and provides no real advantage when members of the public can more easily access the treaty text from other sources.

The amendment addresses these issues by removing the requirement for the regulations to include the treaty texts. Instead, a note has been included in the Act which will refer the reader to the regulations, which will set out the internet address where the text may be viewed.

The provision is not intended to change the law either the substantive domestic law or Australia's treaty obligations.

Items 92 to 103: Schedule 1 - definitions

["Budapest Treaty"]

Item 92 provides a reference to the Budapest Treaty text, as available on the AustLII website. This is consequential to the amendments in item 91.

["Convention application"]

Item 93 replaces the reference to Part 2 of Chapter 8 with a reference to Part 1 of Chapter 3. This item is consequential upon the repeal of Chapter 8 (see item 67), and replacement of Part 2 of Chapter 8 with Part 1 of Chapter 3.

["Convention country"]

Item 94 directs readers of the Act to the new definition of the term in the new section 29B (see item 34).

["examination"]

Item 95 removes the reference to "modified examination" from the definition of "examination". This is consequential upon item 50, which repeals modified examination.

["foreign patent office"]

Item 96 repeals the definition of "foreign patent office" consequential upon item 50, which repeals modified examination.

["international filing date"]

Item 97 amends the definition of "international filing date" consequential upon item 34, which sets out the requirements for filing PCT applications.

["modified examination"]

Item 98 repeals the definition of "modified examination" consequential upon item 50, which repeals modified examination.

[" PCT"]

Item 99 provides a reference to the PCT text, as available on the AustLII website. This is consequential to the amendments in item 91.

Item 100 removes the reference to a PCT application being an application that has been given an international filing date. It is sufficient that a PCT application be defined as an international application in which Australia is specified as a designated State. Item 35 deals with the filing date for PCT applications.

'Whole of contents' citations

[subparagraphs (b)(ii)(B) and (b)(ii)(C) of the definition of "prior art base"]

Items 101 and 102 make two amendments to the definition of the prior art base for novelty in Schedule 1 of the Act. The first amendment clarifies that the specification of the 'whole of contents' citation was published on or after the priority date of the claims under consideration. The second amendment specifies that the information considered is the information in the 'whole of contents' citation as published.

As a general rule, prior art for the purpose of assessing novelty is restricted to information published, and public acts done, before the priority date of the claims under consideration. However, there are some exceptions. Complete specifications of patent applications filed in, or with effect in, Australia, with an earlier priority date but later publication date than the priority date of the claims under consideration, are one such exception. These are commonly called 'whole of contents' citations.

Earlier patent applications are taken into account to ensure that patent rights are only granted to the first person to file an application for the invention or where the invention will come into the public domain through the publication of the earlier application. This principle is common to patent systems around the world, with the UK, Europe and Japan having similar requirements to that applying in Australia.

However, in Australia, it is only information in the citation at both its filing and publication date that is taken into account. In contrast, in Europe it is information in the citation when it was filed that is considered.

The advantage of the European approach is that it reduces complexity, and is consistent with the principle that it is the information in the citation at its filing date that is important, not the information in the citation at a later date.

Other countries also specify that 'whole of contents' relates to citations published on or after the priority date of the claims under consideration. In contrast, the Australian definition only refers to citations published after the priority date. This results in an absurd situation where a citation filed before but published on the priority date must be disregarded as prior art because it does not meet the general rule for novelty and it does not meet the 'whole of contents' rule.

The clause amends the Australian requirement to make it consistent with the European requirement. For 'whole of contents' citations, only the information in the citation at its filing date is to be taken into account. Information that is either added or removed between filing and publication is to be disregarded.

The clause also corrects the oversight with respect to the publication date of 'whole of contents' citations. The clause clarifies that 'whole of contents' citations are

applications where the complete specification was published on or after the priority date of the claim under consideration.

["sealed"]

Item 103 repeals the definition of "sealed" consequential upon items 59 and 61, which replace sealing of a patent at grant with a process whereby the act of grant occurs via entry of the particulars of the patent in the Register.

Amendments to the Plant Breeder's Rights Act 1994

Items 104 to 108: Treaty texts

[s 3]

Item 104 amends the *Plant Breeder's Rights Act* (PBR Act) to refer to the International Convention for the Protection of New Varieties of Plants (UPOV Convention) as in force from time to time.

The PBR Act currently requires the regulations to include the text of the UPOV Convention. This imposes costs on government maintaining a schedule that simply repeats the text of the Convention, and updating the regulations if the Convention is amended. This is unnecessary when the information is readily available on the official UPOV website or on AustLII. [160]

The amendments will allow for repeal of the Schedule 1 of the PBR Act and will refer the reader directly to the AustLII website for the full text of the Convention.

[s 43]

Items 105 to 107 consequentially amend the PBR Act to ensure that the meaning of certain terms is interpreted consistently with the UPOV Convention.

As a matter of administrative practice, certain terms in the PBR Act should be interpreted consistently with the definition of those terms in the UPOV Conventions. The related amendment in item 104 removes the requirement to set out the text of the UPOV Convention in the legislation. The amendments in this provision clarify that the meaning of these terms is to continue to be interpreted consistently with the UPOV Convention.

[Schedule 1]

Item 108 repeals schedule 1 of the PBR Act.

This item is consequential to the amendment in item 103, which refers to the UPOV Convention as in force from time to time. This obviates the need to set out the full text of the treaty in the legislation.

[160] www.austlii.edu.au

Amendments to the Trade Marks Act 1995

Items 109 and 110: Convention countries

[s 6]

Item 109 amends the Trade Marks Act to define a 'Convention country' as prescribed in the regulations.

The Act currently requires the regulations to list each 'Convention country' (a member of the Paris Union or the World Trade Organization) individually. This imposes unnecessary costs on government in amending the regulations each time membership changes when the information is readily available on the official WIPO website. [161]

The amendments will permit the regulations to define a 'Convention country' by reference to parties to the Paris Convention of the Trade Related Aspects of Intellectual Property Agreement (TRIPS Agreement), as they may be in force from time to time. The regulations will also refer readers to an internet site where a list of Convention countries can be found.

The provision is not intended to change either the substantive domestic law or Australia's treaty obligations.

Item 110 is necessary to ensure that the definition can refer to other instruments, as in force from time to time.

Item 111: Trade marks sub-offices

[s 27]

This item relates to removing the requirement for sub-offices, and is consequential upon items 129 to 131 as discussed below.

Item 112: Federal Magistrates Court

[s 35]

This item relates to expanding the jurisdiction of the Federal Magistrates Court to hear Trade Mark matters. It is consequential upon items 114 to 128 as discussed below.

Item 113: Presumption of registrability

[s 41]

This item amends the Trade Marks Act to clarify that the presumption of registrability applies to section 41.

Under the previous *Trade Marks Act 1955* the applicant bore the onus of demonstrating to the Registrar that their mark was registrable. One of the policy

[161] www.wipo.int

objectives of the current Trade Marks Act was to reverse this. The intention was to introduce a 'presumption of registrability': that a trade mark ought to be registered unless there is a specific objection to it.[162]

This policy was intended to be implemented by paragraph 33(1)(b), which provides that the Registrar must accept an application unless satisfied that there are grounds for rejecting it. The effect of this was to shift the onus from the applicant to the Registrar.

While this has been effective in respect of most of the grounds on which an application may be rejected, this has not been effective in implementing a presumption of registrability in respect of section 41 (which deals with the capacity of the trade mark to distinguish the applicant's goods and services from others).

The decision in *Blount Inc v The Registrar of Trade Marks*[163] found that, if there were any doubt about whether a mark was inherently adapted to distinguish the applicant's goods, subsection 41(4) required the Registrar to resolve the doubt according to the decision-making process in subsections 41(5) and (6). The effect of this was that presumption of registrability in section 33 could not apply.

This is contrary to the intended policy of the new Act.

The changes are intended to clarify that the presumption of registrability, as provided for in section 33, does apply to section 41. This is achieved by removing the reference to the decision-making process in section 41, and instead focussing on the characteristics that a mark must possess for it to be capable of distinguishing. The intention is that, if the Registrar is equally unsure of whether the mark is or is not capable of distinguishing, that doubt should be resolved in the applicant's favour.

To ensure that the presumption of registrability applies, the criteria for the trade mark's capacity to distinguish are framed negatively by defining the circumstances in which a trade mark is *not* capable of distinguishing. Consistent with the presumption, this will focus the Registrar's enquiry on what must be wrong with the mark before the Registrar is entitled to reject it.

Note that while the amendment ensures that the onus rests with the Registrar during examination, it is not intended to require that the trade mark should clearly not be registered. Rather, as with other grounds it is intended that the delegate need only be satisfied that a ground exists on the balance of probabilities.

The amendments are not meant to alter the key concepts of 'inherently adapted to distinguish', 'capable of distinguishing', and 'does or will distinguish'. The judicial tests for these terms are settled and the amendments are not intended to change the legal concept of a trade mark distinguishing the applicant's good or services from others.

In particular, the amendments are intended to preserve the three existing categories of trade mark, based on the degree to which they are inherently adapted to distinguish:

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[162] Working Party to Review the Trade Marks Legislation, *Recommended Changes to the Australian Trade Marks Legislation* report, 1992, p 41-2 ('Working Party report').
[163] (1998) 40 IPR 498.

- Trade marks that are *sufficiently* inherently adapted to distinguish on their own would not fall within either the new subsection (3) or (4) and could not be rejected under section 41. Consistent with the existing subsection 41 (3), the Registrar would accept such marks without consideration of use, intended use or other circumstances, as these marks are capable of distinguishing due to their intrinsic characteristics.

- Trade marks that are *to some extent* inherently adapted to distinguish, but are not sufficiently inherently adapted to distinguish on their own will be rejected under the new subsection (4) if consideration of the combined criteria in subparagraphs (i) to (iii) shows that the mark does not or will not distinguish. Consistent with the existing subsection 41 (5), the combination of their (limited) inherent adaptation considered with the use, intended use or other circumstances may bring a mark outside the new subsection (4): the Registrar would then accept the mark.

- Trade marks that are *not to any extent* inherently adapted to distinguish will be rejected under new subsection (3) if the pre-filing date use of the mark (if any) does not show that the mark was in fact distinctive at the date of filing. Consistent with the existing s 41 (6), overwhelming pre-filing date use of the mark may show that it is factually distinctive at filing: the Registrar would then accept the mark.

It is intended that trade marks which have no inherent adaptation to distinguish will be dealt with exclusively in subsection 41 (3).

The amendments also make a minor change to move the existing subsection 41(1) to the end of the section. This subsection merely clarifies the meaning of 'use of a trade mark' elsewhere in the provision. For readability, the section has been re-ordered so the key test for capacity to distinguish is first and the ancillary definition is last. No change to the meaning of 'use of a trade mark' is intended.

Items 114 to 128: Federal Magistrates Court

[ss 56, 67, 83, 83A, 83D, 104, 190, 191, 192, 193, 194, 195, 196 and 197]

These items amend the Trade Marks Act to provide the Federal Magistrates Court (FMC) with jurisdiction to hear and decide trade mark matters.

The background, issue and intended operation of this amendment is the same as the related amendments in relation to extending the jurisdiction of the Federal Magistrates Court to hear design matters, discussed under items 3 and 5 to 19.

Items 129 to 131: Trade marks sub-offices

[ss 199, 213 and 223]

These items amend the Trade Marks Act to replace the requirement that there is to be a sub-office of the Trade Marks Office in each State with a provision that there 'may' be a sub-office in each State.

The background, issue and intended operation of this amendment is the same as the related amendments in relation to State sub-offices of the Patent Office (items 81 and 82) and the Designs Office (items 20 to 22) - in practice the Patent and Trade Marks sub-offices are the same physical premises.

Item 132: Consequential amendment – convention countries

[s 225]

This item repeals subsection 225 (1) and is consequential upon the changes to definition of 'convention countries' set out in items 109 and 110 above.

Part 2 – Application, savings and transitional provisions

Item 133: Application provisions

Sub-item (1): The amendments in item 29 relate to extending the grace period to encompass secret use. This change will apply to any secret use that occurs on or after commencement.

Sub-item (2): This item relates to amendments made by items 30, 34, 35, 42, 45, 47, 56, 57, 58, 59, 67, 76, 78, 80, 85, 88, 890, 93, 97 and 100 relating to PCT and Convention applications. The amendments apply to PCT and Convention applications made on or after the day the Schedule commences.

Sub-item (3): Items 31 and 79 relate to correcting ownership issues for granted patents. The amendments apply to patents granted before, on or after commencement.

Sub-item (4): The amendments in items 32 and 33 relate to the grace period. This change will apply so that the amendments will capture information published on or after the commencement day.

Sub-item (5): Items 36, 37, 38 and 39 relate to the Commissioner's power to resolve ownership disputes between joint applicants. They apply in relation to disputes arising on or after commencement.

Sub-item (6): Items 40 and 41 relate to the Commissioner's power to resolve ownership disputes between the applicant and a third party. They apply in relation to declarations made on or after commencement.

Sub-item (7): Item 43 involves changes narrowing the circumstances in which omnibus claims are permitted. Item 102 relates to what information is considered in assessing 'whole of contents' citations. These items clarify the standards to be met by patentees. Consistent with the general principles described in Schedule 1, Item 55 at sub-item (1), these changes are to apply in relation to the following:

- patents granted on applications made on or after commencement (paragraph a);

- standard patents for which the application was made before the day of commencement, but where the applicant has not asked for examination of the application relating to the patent on or before that day (paragraph b);

- innovation patents granted on or after commencement, if the application relating to the patent was made before that day (paragraph c);

- complete innovation and standard patent applications made on or after the day of commencement (paragraph d);

- standard patent applications made before the day commencement, but where the applicant has not requested examination before that day (paragraph e);

- innovation patent applications made before the day of commencement but not granted at that day (paragraph f); and

- innovation patents granted before the day of commencement, but where the Commissioner has not received a request to examine the patent or has not decided to examine the patent before that day (paragraph g).

Sub-item (8): This item relates to the amendments made by item 44 relating to disregarding earlier PCT and Convention applications. The amendments apply in relation to applications filed and patents granted before, on or after the day of commencement.

Sub-item (9): Items 60 to 64 relate to the new system where by a patent will be granted by entry of particulars in the Register, instead of physically sealing a patent. These changes will apply only to patents granted on or after commencement.

Sub-item (10): Items 71 and 72 relate to amendments to remove a consequential reference to amending the patent. The amendments apply to court proceedings initiated on or after the day of commencement.

Sub-item (11): Items 54 and 55 relate to the Commissioner's new power to revoke accepted applications for standard patents to correct an administrative error. The acceptance of an application will only be able to be revoked under the new provisions if the acceptance occurred on or after commencement.

Sub-item (12): Item 69 relates to the Commissioner's new power to revoke certification of innovation patents to correct an administrative error. A certificate will only be able to be revoked under the new provisions if the innovation patent was certified on or after commencement.

Sub-item (13): Item 73 relates to the amendments to the system for granting non-infringement declarations. It will apply only to applications for non-infringement declarations made on or after commencement.

Sub-item (14): Item 75 relates to a clarification that a court must only revoke an invalid patent if it is just and equitable to do so. The amendments apply to orders made on or after commencement.

Sub-item (15): Item 77 relates to lapsing deferred applications and is consequential on changes to repeal the deferment provisions in s 46. This item ensures that an application that was deferred before s 46 was repealed, can still be lapsed under the existing s 142 (2) (c) even where the prescribed time period for the applicant to request examination expires after the date of commencement.

Sub-item (16): Item 101 clarifies the prior art base for assessing novelty. These items clarify the standards to be met by patentees. Consistent with the general principles described in Schedule 1, Item 55 at sub-item (1), these changes are to apply in relation to the following:

- patents granted on applications made on or after commencement (paragraph a);
- standard patents for which the application was made before the day of commencement, but where the applicant has not asked for examination of the application relating to the patent on or before that day (paragraph b);
- innovation patents granted on or after commencement, if the application relating to the patent was made before that day (paragraph c);
- complete innovation and standard patent applications made on or after the day of commencement (paragraph d);
- standard patent applications made before the day commencement, but where the applicant has not requested examination before that day (paragraph e);
- innovation patent applications made before the day of commencement but not granted at that day (paragraph f); and
- innovation patents granted before the day of commencement, but where the Commissioner has not received a request to examine the patent or has not decided to examine the patent before that day (paragraph g).

Item 134: Savings provisions

This item saves the existing provisions governing modified examination. It applies where a modified examination has been requested, but not completed at commencement. The existing provisions will continue to apply to ensure that previously requested modified examinations may be completed.