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THE PARLIAMENT OF THE COMMONWEALTH OF AUSTRALIA

HOUSE OF REPRESENTATIVES

INTELLECTUAL PROPERTY LAWS AMENDMENT BILL 2014

EXPLANATORY MEMORANDUM

(Circulated by authority of the Minister for Industry,
the Honourable Ian Macfarlane MP)

INTELLECTUAL PROPERTY LAWS AMENDMENT BILL 2014

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 introduce a range of improvements across Australia's intellectual property system, making refinements to existing arrangements and implementing new initiatives aimed at increasing efficiency and effectiveness.

The Bill's amendments to the *Patents Act 1990, Trade Marks Act 1995, Designs Act 2003* and the *Plant Breeder's Rights Act 1994* are divided into five schedules:

- Schedule 1—TRIPS Protocol interim waiver
- Schedule 2—TRIPS Protocol: later commencing amendments
- Schedule 3—Plant Breeder's Rights Act 1994: Federal Circuit Court
- Schedule 4—Australia New Zealand Single Economic Market
- Schedule 5—Other Amendments

Schedule 1 and Schedule 2: TRIPS Protocol interim waiver and TRIPS Protocol: later commencing amendments

The Australian public benefits through having access to the latest technology, products and services. Many least-developed and developing countries have difficulty manufacturing or accessing patented pharmaceuticals, and so are unable to respond effectively to public health problems. This Bill will amend the Patents Act to allow Australian pharmaceutical manufacturers to supply these countries with the patented medicines they need.

The amendments will deliver on the Australian Government's commitment to implement the Protocol amending the World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property (the TRIPS Protocol). Under the new scheme, Australian laboratories will be able to apply to the Federal Court for a compulsory licence to manufacture generic versions of patented medicines under specific conditions, and export these medicines to developing countries. Adequate compensation for the patent holder will be negotiated, to ensure that they are not disadvantaged by the arrangements.

The scheme is designed to be as easy to use as possible and is open to all developing countries provided they meet specified criteria.

Schedule 3: Plant Breeder's Rights Act 1994: Federal Circuit Court

To be effective, IP rights must be enforceable by the IP right owner. The Federal Circuit Court is designed to deal with less complex matters more quickly and informally than the Federal Court. This Bill will amend the Plant Breeder's Rights Act to give the owners of plant breeder's rights the option of taking action in the Federal Circuit Court against alleged infringers.

Schedule 4: Australia New Zealand Single Economic Market

This Bill will allow the streamlining of the processes for applying for patents in Australia and New Zealand, and for the examination of common applications. Single patent application and examination processes for Australia and New Zealand aim to reduce duplication, making it easier for businesses to protect their IP in both countries.

Under this single examination model, if separate patent applications for the same invention are filed in both Australia and New Zealand, then both applications may be examined by a single examiner in either country. The regime will take account of the separate national laws, and would lead to separate patents being granted in Australia and New Zealand. A single patent examination process is part of a suite of IP initiatives proposed under the trans-Tasman Single Economic Market agenda, agreed to by the Australian and New Zealand Prime Ministers in August 2009.

Patent attorneys are a class of IP professionals who assist businesses by drafting applications for the grant of patents and prosecuting those applications before patent offices. Currently, Australia and New Zealand each have their own longstanding systems of regulation for patent attorneys, governing their accreditation, registration and discipline.

This Bill will implement a bilateral arrangement between the Australian and New Zealand governments for the trans-Tasman regulation of patent attorneys in both Australia and New Zealand. This arrangement was signed by the relevant Ministers in Australia and New Zealand in March 2013.

The arrangement provides for a single trans-Tasman register of patent attorneys, with registration giving a person the right to practise as a patent attorney in both countries. It also establishes a single set of qualifications for registration, a single trans-Tasman IP Attorneys Board and a single trans-Tasman IP Attorneys Disciplinary Tribunal. This will provide efficiencies in the registration and regulation of patent attorneys, and will improve the consistency of patent attorney services provided in Australia and New Zealand.

Schedule 5: Other amendments

Part 1 of Schedule 5 will make minor administrative changes to the Patents, Trade Marks and the Designs Acts to repeal unnecessary document retention provisions. These provisions currently require IP Australia to physically retain patent, trade marks and designs documents for an extended period of time. The retention and disposal of these documents is already comprehensively governed by the *Archives Act 1983* and the records disposal authorities issued by the National Archives of Australia.

Part 2 of Schedule 5 will make a number of technical amendments to the Patents Act primarily to address minor oversights in the drafting of the *Intellectual Property Laws Amendment (Raising the Bar) Act 2012*. The Raising the Bar Act introduced a wide range of intellectual property reforms designed to help Australian businesses and researchers, and entered into full effect on 15 April 2013.

FINANCIAL IMPACT STATEMENT

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

REGULATION IMPACT STATEMENT

Export of Patented Pharmaceuticals to Countries Experiencing a Health Crisis

BACKGROUND

Intellectual property and access to medicines

1. Intellectual property rights provide businesses with the incentive to invest in new technologies, products and services because they enable them to prevent others from copying their ideas. Consumers benefit by having access to new products, services and trusted brands. The patent system is a key element in the intellectual property system. It encourages business to invest in innovation by providing innovators with exclusive right to commercialise their inventions, or authorise another person to do so.

2. The patent system is particularly important for encouraging innovation in the pharmaceutical sector, as the development of new pharmaceutical products involves high costs and risks. Without patent protection, many vital new pharmaceuticals would not be made available to the public. However, the basic costs of production and the need for innovators to obtain a return on their investment can limit access to these products in the developing world due to their high costs.

3. Much of the world's population is suffering from treatable diseases, with over 100 countries currently experiencing one or more serious epidemics.[1] In 2011, an estimated 262 million people were infected with malaria, HIV/AIDS or tuberculosis, causing 3.8 million deaths.[2]

4. Many of the countries that are suffering such epidemics are developing or least-developed countries with limited resources and manufacturing capabilities. Such countries have difficulty obtaining and distributing the necessary medicines. The United Nations estimates that nearly two billion people lack access to essential medicines.[3]

5. There are a number of mechanisms to help developing and least-developed countries obtain affordable medicines. For example:

[1] 'World Health Statistics 2012', World Health Organization, 2012, Part III Global Health Indicators, Table 3.
[2] 'World Malaria Report 2012', World Health Organization, 2012; 'UNAIDS Report on the Global AIDS Epidemic 2012', UNAIDS, 2012; 'Global Tuberculosis Report 2012', World Health Organization, 2012.
[3] 'Human Rights Guidelines for Pharmaceutical Companies in relation to Access to Medicines', published in the report to the General Assembly of the United Nations 'Special Rapporteur on the right to the highest attainable standard of health', United Nations document A/63/263, 11 August 2008.

- Some pharmaceutical companies provide essential medicines at low or not-for-profit prices (price differentiation), or grant voluntary licences to other manufacturers to produce generic versions. Sectors of the biotechnology industry have committed to exploring further strategies for expanding access to medicines in the developing world.[4] For example, ViiV Healthcare, an HIV/AIDS pharmaceutical company set up by GlaxoSmithKline and Pfizer, provides manufacturers of generic pharmaceuticals with a royalty-free voluntary licence to all its current and future healthcare products, for supply to a wide range of countries.[5]

- UNITAID is an international medicine purchasing facility administered by the World Health Organization. It provides funding for the purchase of medicines and for research and development relevant to diseases that disproportionately affect people in developing countries. UNITAID has also established the Medicines Patent Pool to obtain licences from multiple patent owners to encourage innovation and lower costs for key HIV/AIDS treatments.[6]

- The Global Fund to Fight AIDS, Tuberculosis and Malaria is a major public/private partnership that raises and disburses funds to prevent and treat these diseases. Australia is a Global Fund Board member and has pledged $210 million to the fund.[7]

- The William J. Clinton Foundation provides funding for the treatment of HIV/AIDS, malaria and tuberculosis. Under a partnership with the Foundation, Australia has provided a total of $25 million over the last four years to improve the delivery of HIV/AIDS treatment and care in the Asia Pacific region.[8]

- Humanitarian organisations such as the International Red Cross Red Crescent Movement, Medecins sans Frontieres and UNICEF source and administer vital medicines to countries in need.

TRIPS Agreement

6. Another mechanism for helping countries access vital medicines is provided under the patent system. The World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (the TRIPS Agreement) sets out the minimum requirements for intellectual property protection for WTO Member states. Australia is a signatory to the TRIPS Agreement and complies with its provisions.

7. Article 31 of the TRIPS Agreement enables a country that is experiencing a serious epidemic to ensure that its population is supplied with a patented treatment. It

[4] 'Options for Increasing Access to Medicines in the Developing World', Biotechnology Industry Organization, policy statement May 2010.
[5] 'ViiV Healthcare announces a voluntary licence agreement with the Medicines Patent Pool to increase access to HIV medicines for children', ViiV Healthcare media release, 27 February 2013.
[6] 'The Medicines Patent Pool Initiative', viewed 11 September 2013 at < http://www.medicinespatentpool.org/ >.
[7] 'Australia's Global HIV/AIDS Initiative', AusAID, viewed 11 September 2013 at < http://www.ausaid.gov.au/aidissues/health/Pages/initiative-globalfund.aspx >
[8] 'AusAID-Clinton Foundation Partnership', AusAID, viewed 11 September 2013 at < http://www.ausaid.gov.au/aidissues/health/hivaids/Pages/foundation.aspx >.

provides that a patented product may be used without the authorisation of the patent owner, but only under certain conditions. These conditions include the following:

> (b) such use may only be permitted if, prior to such use, the proposed user has made prior efforts to obtain authorisation from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. This requirement may be waived by the Member in the case of a national emergency or other circumstances of extreme urgency.
> ...
> (f) any such use shall be authorised predominantly for the supply of the domestic market of the Member authorising such use;
> …
> (h) the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorisation.

8. Under this provision, a court may order a patent owner to grant to a third party a compulsory licence to manufacture and supply a pharmaceutical and ensure that the patent owner is compensated accordingly.

Doha Declaration

9. Prior to 2001, there was uncertainty over the interpretation of Article 31. In particular, paragraph (f) prevents products that are produced without the authorisation of the patent owner from being exported in significant quantities. This has the potential to prevent WTO Members that lack the capability to manufacture pharmaceuticals themselves from importing vital medicines from other Members. There are 49[9] least-developed countries and potentially 100[10] developing countries that could fall into this category. Around 28 of these are in the Asia-Pacific region.

10. In November 2001, the Fourth WTO Ministerial Conference in Doha, Qatar, adopted the Declaration on the TRIPS Agreement and Public Health (the Doha Declaration).[11] The Declaration recognised the following:

- The gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics.

- WTO Members have the right to use the provisions of the TRIPS Agreement to support public health by promoting access to medicines for all.

- WTO Members with insufficient manufacturing capacities in the pharmaceutical sector could find it difficult to use the compulsory licensing provisions under the TRIPS Agreement, and a solution to this problem was needed.

[9] 'Least Developed Countries – Country Profiles', United Nations Office of the High Representative for the Least Developed Countries, Landlocked Developing Countries and the Small Island Developing States (UN-OHRLLS), viewed 12 September 2013 at < http://www.unohrlls.org/en/ldc/25/>.
[10] 'World Economic Outlook', International Monetary Fund, April 2013, Table A4 'Emerging and Developing Economies'.
[11] 'Declaration on the TRIPS Agreement and public health', WT/MIN(01)/DEC/2, 20 November 2001.

TRIPS Protocol

11. In 2003, the General Council for TRIPS agreed to an interim waiver of paragraphs (f) and (h) of Article 31 so as to enable pharmaceuticals to be exported under compulsory licence. In 2005, the TRIPS Protocol[12] was drafted to give permanent effect to the waiver. The main features of the TRIPS Protocol are as follows:

- Only pharmaceutical products that are needed to address the public health problems afflicting many developing and least-developed countries are included.

- Products may be imported by any least-developed country Member, and any other Member that has notified of its intention to use the system as an importer. Before products may be obtained, the importing country must notify the TRIPS Council of the details of the shipment and confirm that the country has insufficient manufacturing capacity for the product(s) in question.

- The proposed licensee must have made prior efforts to obtain authorisation from the patent owner and such efforts have not been successful within a reasonable period of time. This requirement may be waived in circumstances of extreme urgency or 'public non-commercial use'. Public non-commercial use primarily means use by a government.

- Certain conditions must be placed on licences granted under the TRIPS Protocol, primarily to reduce the risk of pharmaceuticals being diverted from their intended recipients.

- Where a licence is granted, adequate remuneration must be paid to the patent owner.

12. The aim of the protocol is to encourage patent owners to either practice price differentiation, and provide medicines to least developed and developing countries in need at affordable prices, or to issue voluntary licenses to generic manufactures to provide medicines at affordable prices. If a patent owner is unwilling to do this, then the protocol provides a mechanism to force the patent owner to issue a compulsory licence.

13. Several jurisdictions around the world have amended their legislation to permit the export of pharmaceutical products under the system. To date, only one licence has been granted under the system. This was in Canada in 2007. Some of the suggested reasons for the low level of use are as follows:[13]

- Implementation of the system has been too complicated and places too high a burden on applicants for a licence and importing countries. For example, Canada's largest manufacturer of generic medicines, Apotex, has indicated it would make a lower cost version of a key AIDS medicine for export if Canada's

[12] 'Amendment of the TRIPS Agreement', WT/L/641, 8 December 2005.
[13] 'Report 86: Treaties tabled on 27 March and 9 May 2007', Joint Standing Committee on Treaties, Chapter 9 Protocol amending the TRIPS Agreement (Geneva, 6 December 2005), August 2007; 'Report on the Statutory Review of Sections 21.01 to 21.09 of the *Patents Act*', Industry Canada, 2007; 'Canada's Access to Medicines Regime', Canadian HIV/AIDS Legal Network, viewed 5 August 2011 at < http://www.aidslaw.ca/EN/camr/index.htm>.

law were streamlined, such as by only requiring a single licence for a product, regardless of the quantity of medicine required over time.

- Least developed-countries are not bound by the TRIPS Agreement to protect patents until 2016 and so have no need to use the TRIPS Protocol.

- Developing and least-developed countries lack awareness of the TRIPS Protocol, and the knowledge and resources necessary to use it.

Australia's acceptance of the TRIPS Protocol

14. In 2006 and 2007, the Department of Foreign Affairs and Trade (DFAT) consulted with the general public and other government agencies on Australia accepting the TRIPS Protocol. In 2007 the Joint Standing Committee on Treaties (JSCOT) conducted an inquiry into Australia accepting the Protocol. JSCOT supported the Protocol and recommended that binding treaty action be taken. It urged the government to actively support the provision of patented medicines to least-developed and developing countries and supported any necessary amendments to the *Patents Act 1990* to allow for compulsory licensing to enable the export of cheaper versions of patented medicines. JSCOT encouraged IP Australia to coordinate the consultation process on implementing the Protocol.[14]

15. The Government accepted JSCOT's recommendation and Australia accepted the terms of the Protocol on 12 September 2007. IP Australia commenced consultations on implementing the Protocol in 2009. Accepting the Protocol means that Australia accepts the additional flexibility in the TRIPS Agreement and that countries have the legal right to use the system if they choose to do so. It does mean that Australia is required to implement the TRIPS Protocol through its own laws.

PROBLEM

16. As outlined above, problems exist in ensuring that vital medicines are made available at affordable prices to people in least-developed and developing countries. In particular, issues arise where medicines are under patent, as some patent owners have shown themselves unwilling to practice price differentiation or to issue voluntary licenses to generic manufacturers to the necessary extent.

17. In particular problems exist because the TRIPS Agreement as it stands does not enable WTO Members such as Australia to export pharmaceuticals under compulsory licence to another country. As a result member countries with the capacity to manufacture vital medicines are unable to export them to developing and least-developing countries that lack the capacity to manufacture these medicines. The TRIPS Protocol was designed to address this problem by enabling WTO Members to export medicines under compulsory licence.

18. The development of the TRIPS Protocol was prompted by a situation in South Africa which demonstrated the need for a mechanism to ensure that patented essential

[14] 'Report 86: Treaties tabled on 27 March and 9 May 2007', Joint Standing Committee on Treaties, Chapter 9 Protocol amending the TRIPS Agreement (Geneva, 6 December 2005), August 2007.

medicines can be made affordable to people in least-developed and developing countries.

19. In the late 1990s, around 20% of adults in South Africa were infected with HIV; however few could afford the prices charged by the patent owners for treatment. In 1997, the South African Government attempted to make use of exemptions in the TRIPS Agreement, including compulsory licensing, by introducing legislation to over-ride patents on pharmaceuticals and enable the importation of generic versions. The US Government threatened sanctions against South Africa and in 1998 the Pharmaceutical Manufacturers Association and 40 international pharmaceutical companies took legal action against the South African Government, arguing that the legislation did not conform to international agreements.[15]

20. In March 2001, Cipla Ltd., an Indian manufacturer of generic medicines, applied to the South African Government for a compulsory licence to import HIV/AIDS medicines into South Africa. Cipla stated that it could sell the medicines to the government for 40% of the price offered by the patent owners.[16] Other Indian manufacturers made similar offers. As a consequence, patent owners Merck & Co., Bristol-Myers Squibb Co. and GlaxoSmithKline (GSK) significantly reduced their prices.[17] Due to pressure from the World Health Organization and other non-government organisations, in April 2001 the pharmaceutical companies withdrew their legal action. The Doha Declaration was adopted in November 2001 to clarify that governments are free under the TRIPS Agreement to ensure access to medicines.

21. However, the price of pharmaceuticals in South Africa continued to be too high. In 2003, the South African Competition Commission ruled that GSK and Boehringer Ingelheim breached the Competition Act 1998 by refusing to licence their patents to generic manufacturers in return for a reasonable royalty. The Commission threatened to issue compulsory licences and so the patent owners agreed to grant voluntary licences and offered not-for-profit prices on HIV medicines in the country.[18] Patent owners' continuing unwillingness to practice price differentiation without further encouragement is also demonstrated in a study commissioned by the World Health Organisation and Health Action International. The 2010 study shows that the continuing high price of medicines is having catastrophic effects on poor people.[19] In the countries studied,

[15] Rourmet, Rachel, 'Access to patented anti-HIV/AIDS medicine: the South African experience', European Intellectual Property Review, Vol. 32 No. 3, 2010, pp 137-141; Varella, Marcelo Dias, 'The WTO, intellectual property and aids: case studies from Brazil and South Africa', Journal of World Intellectual Property, Vol. 7 No. 4, July 2004, pp. 523-547.

[16] Swarn, Rachel, 'AIDS Drug Battle Deepens in Africa', The New York Times, 8 March 2001, viewed on 12 September 2013 at <http://www.nytimes.com/2001/03/08/health/08AIDS.html>.

[17] Schoofs, Mark et al., 'Price War Breaks Out Over AIDS Drugs in Africa as Generics Present Challenge', Wall Street Journal, 7 March 2001, viewed on 12 September 2013 at <http://lists.essential.org/pipermail/pharm-policy/2001-March/000753.html>.

[18] Boseley, Sarah, 'Ruling opens the door for cut-price HIV drugs', The Guardian, 17 October 2003, viewed on 12 September 2013 at <http://www.guardian.co.uk/world/2003/oct/17/southafrica.sciencenews>; Riviere, Philippe, 'At last, generic anti-AIDS medicine for sub-Saharan Africa', Le Monde Diplomatique, December 2003, viewed on 12 September 2013 at ,<http://mondediplo.com/2003/12/19aids>.

[19] Niens, Laurens et al., 'Quantifying the Impoverishing Effects of Purchasing Medicines: A Cross-Country Comparison of the Affordability of Medicines in the Developing World', Public Library of Science (PLOS) Medicine, 31 August 2010, viewed on 12 September 2013 at <http://www.plosmedicine.org/article/info%3Adoi%2F10.1371%2Fjournal.pmed.1000333>.

purchasing four commonly used medicines at current prices would push large portions of the population (up to 86%) below the poverty levels of US$1.25 or US$2.00 per day. Originator brand products (products still under patent) were significantly less affordable than the lowest-priced generic equivalents. The report's recommendations include that the use of low-cost generic medicines be actively promoted and pharmaceutical companies be encouraged to differentially price medicines according to markets.

22. The World Health Organization has stated that price is the most important barrier to the poor having access to medicines and that the availability of generic products is a major contributor to reducing the cost of medicines. For example, the prices of 'first line' antiretroviral medicines for HIV/AIDS have been reduced from over US$10,000 per patient per year in 2002 to US$140 in 2013 due to competition from generics. This has enabled a 12-fold increase in poor patients receiving treatment.[20]

23. Health Action International identified the flexibilities provided by the TRIPS Agreement, including the TRIPS Protocol, as an important strategy for bringing the price of vital medicines down and improving the availability and affordability of essential medicines.[21]

24. The problem is also likely to become more acute as the number of countries implementing the TRIPS Agreement increases. Many countries have not implemented the TRIPS Agreement in part or in full, or have done so only recently, and so have not provided patent protection for pharmaceuticals. Some of these, such as India, have traditionally been important producers of generic essential medicines for export to other countries. The implementation of the TRIPS Agreement in such countries is leading to the patenting of new medicines. As a result, generic versions of the new medicines may only become available after the patent has expired. This would significantly reduce the availability of affordable essential medicines.

25. As a means of addressing this issue, the United Nation's Millennium Development Goals Report 2009 recommended that countries with manufacturing capacity should facilitate the export of generic medicines to countries in need, in line with flexibilities contained in the TRIPS Agreement (including the Protocol).[22] Countries that implement the TRIPS Protocol are able to export patented medicines under compulsory licence to countries in need.

Government regulation

26. Compulsory licences to work a patented invention are currently provided for under Chapter 12 of the *Patents Act 1990*. These provisions are designed to address the needs of the Australian public. There is no existing government regulation in Australia to

[20] 'Generic competition pushing down HIV drug prices, but patents keep newer drugs unaffordable', MSF, 2 July 2013, viewed 12 September 2013 at <http://www.msfaccess.org/about-us/media-room/press-releases/generic-competition-pushing-down-hiv-drug-prices-patents-keep >; 'Little-used 'Par.6' system will have its day, WHO tells intellectual property and health review', WTO, 27 October 2010, viewed 12 September 2013 at <http://www.wto.org/english/news_e/news10_e/trip_26oct10_e.htm>.

[21] Ewen, Margaret, 'Medicine prices, availability, affordability and price components', Health Action International, WHO, WIPO and WTO Joint Technical Symposium, 16 July 2010.

[22] 'Millennium Development Goals Report 2009', MDG 8 – Strengthening the Global Partnership for Development in a Time of Crisis – Target 8e, United Nations.

allow patented pharmaceuticals to be exported under compulsory licence to meet the needs of another country.

27. Under the current provisions, the Federal Court may order a patent owner to grant a person a licence if is satisfied that:

- all of the following conditions exist:
  - the patentee has failed to exploit the patent and provided no satisfactory reason for this;
  - the 'reasonable requirements of the public' have not been met; and
  - the applicant for the licence has tried for a reasonable period to obtain authorisation to work the invention on reasonable terms;

  OR

- the patent owner has contravened Part IV of the *Competition and Consumer Act 2010* (relating to restrictive trade practices) or an application law in connection with the patent.

28. The reasonable requirements of the public are not satisfied if an existing or emerging trade or industry in Australia is unfairly prejudiced, or the demand for the invention is not reasonably met, because of the patent owner's failure to supply the invention in a reasonable way.

OBJECTIVE OF GOVERNMENT ACTION

29. The key objectives are to:

- ensure that developing and least-developed countries that are experiencing a health crisis are able to obtain supply of vital medicines in a timely manner on reasonable terms.
- support and encourage innovation, investment and international competitiveness.
- maintain existing budget expenditure on foreign aid.

OPTIONS THAT MAY ACHIEVE THE OBJECTIVE

30. Options may be broadly grouped as follows:

- Option 1: No change.

  Under this option, no action would be taken and developing countries that need to obtain vital medicines would source them from countries that have implemented the TRIPS Protocol, or some other means.

- Option 2: Amend the *Patents Act 1990* to enable the Federal Court to grant and amend licences under the TRIPS Protocol.

  Under this option, the current compulsory licence provisions in the Act would be amended to enable the Federal Court to grant and amend licences to export patented pharmaceuticals in accordance with the TRIPS Protocol. Eligible

developing countries would then be able to source affordable medicines from a manufacturer of generic pharmaceuticals in Australia.

- Option 3: Amend the *Patents Act 1990* to enable the Commissioner of Patents to grant and amend licences under the TRIPS Protocol.

  This option is similar to Option 2, except that the Commissioner of Patents would be given the power to grant and amend licences in accordance with the TRIPS Protocol.

- Option 4: Increase funding for aid programs that involve the delivery of pharmaceuticals to developing countries.

  Under this option, Australia's current funding of programs that include the provision of pharmaceuticals to other countries would be increased.

31. There a number of possible ways that the TRIPS Protocol may be implemented. Options 2 and 3 have been determined to be the two most appropriate options for implementing it in Australia. This has been based on consultation with stakeholders and analysis of the systems implemented in other countries. Some of the variations that are available are discussed below.

Power to grant licences

32. As shown in Options 2 and 3, the power to grant licences may lie with a government official, such as the Commissioner of Patents, or with the courts. The potential advantage of a government official having the power is that it may provide a cheaper and more informal application process. The experience of countries such as Canada[23] and India[24] that have given the power to a government official is that it does not ensure a less onerous and bureaucratic process. The main potential advantage of the courts having the power is a more streamlined system that builds on existing processes and expertise. The Government has been actively considering both options.

Limitations on licences

33. Licences may be limited to a maximum duration and a set amount of product, so that if further time or medicines are needed a new application must be lodged. The main advantage of this is that it provides certainty to patent owners. However, jurisdictions that have implemented this approach have been heavily criticised for the extra costs and delays it places on generic manufacturers and countries in need.[25] Alternatively, the authority with the power to grant licences may have the power to amend existing licences so as to accommodate changing circumstances. The Government prefers the latter approach for Options 2 and 3 as this better meets the humanitarian objectives of the system, while protecting the rights of patent owners.

[23] Rimmer, Matthew, 'A Submission to the Joint Standing Committee on Treaties', May 2007, viewed on 5 August 2011 at <http://www.aph.gov.au/house/committee/jsct/9may2007/subs.htm>.
[24] Matthews, Duncan, 'From the August 30, 2003 WTO Decision to the December 6, 2005 agreement on an amendment to TRIPS: improving access to medicines in developing countries?', Intellectual Property Quarterly, No.2, 2006, pp 121-122.
[25] 'Canada's Access to Medicines Regime', Canadian HIV/AIDS Legal Network, viewed 5 August 2011 at < http://www.aidslaw.ca/EN/camr/index.htm>.

Prior negotiation

34. A requirement for the grant of a licence may be that prior efforts have been made to seek a voluntary licence from the patent owner on reasonable terms and conditions, and that such efforts have not been successful within a reasonable or specified period. This approach has been strongly criticised by non-government organisations and the generic pharmaceutical industry as one of the greatest obstacles to the uptake of the system by developing countries.[26] An alternative is to waive the requirement in the case of national emergency or circumstances of extreme urgency in the importing country. The Government prefers the latter alternative for Options 2 and 3 as it ensures that the system is better able to address urgent circumstances. Attempts to seek a voluntary licence would still be required in non-urgent situations, such as where the health situation is not expected to escalate with serious consequences in the near future.

Eligible products and importers

35. The pharmaceutical products eligible to be imported under the system, and the countries eligible to import the products, may be predetermined and set out in the implementing legislation. This approach has been supported by the innovative pharmaceuticals sector due to the certainty it provides, but criticised by non-government organisations and generic manufacturers as too inflexible.[27] An alternative approach is for eligibility to be determined on a case-by-case basis. The Government prefers the latter approach for Options 2 and 3 because it is better able to adapt to the needs of developing countries.

IMPACT ASSESSMENT

Who would be affected by each option?

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

- Developing and least-developed countries
- Owners of Australian patents for pharmaceutical products
- Australian manufacturers of generic pharmaceutical products
- Government

What would be the effects of each option?

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

Option 1: No change

38. This option maintains the *status quo*. Australia would not implement the TRIPS Protocol, despite accepting it in 2007. Countries in need would have to source affordable pharmaceuticals from other countries that have implemented the TRIPS Protocol or by

[26] 'Report on the Statutory Review of Sections 21.01 to 21.09 of the *Patents Act*', Industry Canada, 2007, pp.14-15.
[27] 'Report on the Statutory Review of Sections 21.01 to 21.09 of the *Patents Act*', Industry Canada, 2007, pp.7-11.

other means. As outlined above, this includes humanitarian organisations and pharmaceutical companies that make their products available and affordable through the use of price discrimination.

Costs

39. WTO Members that have implemented the TRIPS Protocol comprise the European Union, Norway, The Netherlands, Switzerland, Canada, China, India, Philippines, Singapore, Albania, Croatia, Jordan and the Republic of Korea. As noted above, the implementation of the TRIPS Protocol in some of these countries have been criticised as being too burdensome on applicants and importing countries. Few developing countries have sought to use these systems and this is likely to continue. Also, as demonstrated above, patent owners are not making their products sufficiently affordable to those in need. As a consequence, the main burden would fall on humanitarian organisations and there would be no increase in the supply of pharmaceuticals. Also, developing countries that have an established aid relationship with Australia, particularly those in the Asia-Pacific region, would not be able to take advantage of this relationship when seeking to use the TRIPS Protocol. Examples include Timor-Leste, Papua New Guinea, Indonesia, Solomon Islands, Bangladesh and Burma.

40. The *status quo* involves no direct costs to the Australian Government or the public. However, the absence of another avenue for supplying pharmaceuticals to developing countries in the Asia-Pacific region may lead to an increase in infection and death rates in those countries and indirect costs to Australia. Also, the government could be criticised for accepting, but not implementing, the TRIPS Protocol.

Benefits

41. This option avoids the potential for patent rights to be infringed by pharmaceuticals being diverted from their intended recipients and sold illegally in developed countries.

Option 2: Amend the *Patents Act 1990* to enable the Federal Court to grant licences under the TRIPS Protocol

42. Under this option, the Federal Court's current powers under the Patents Act to grant compulsory licenses would be extended so as to implement the TRIPS Protocol in a simple and effective manner. The Court would have the power to grant and amend TRIPS Protocol licences. Court hearings and decisions would be progressed quickly in urgent cases. The Court would determine whether a licence should be granted, the conditions on the licence and, where the applicant and the patent owner cannot reach agreement, remuneration. Licences may be granted in respect of patents owned by domestic or foreign entities.

43. This option would enable the export of pharmaceuticals from Australia to countries that are experiencing a health crisis and that lack the capacity to manufacture the pharmaceuticals themselves. Also, as evidenced by the experience in South Africa and other countries, the threat of a compulsory licence being granted would encourage patent owners to agree to a voluntary licence. Option 2 would be consistent with Australia's foreign aid objective of assisting developing countries to reduce poverty and

achieve sustainable development.[28] It would also be consistent with Australia's increased focus on aid effectiveness and mutual accountability, rather than simple increases in aid funding. This involves country-owned and country-led aid responses, and use of local systems.[29]

44. A number of Australian pharmaceutical companies have the potential to manufacture generic medicines for export under the TRIPS Protocol or to have a licence granted in respect of a patent they own. For example there are:

- approximately 52 originator companies (most of these are subsidiaries of multi-national companies)[30]; and
- approximately 11 generic companies[31].

45. The broader industry has a total annual turnover of over $22 billion and employs over 40,000 people, with one third in the manufacturing sector. It sells around $10 billion worth of medicines domestically each year and over $4 billion in exports, making medical and pharmaceutical products Australia's largest manufactured export. In 2010-11, over $700 million was spent on research and development on human use pharmaceuticals.[32]

46. The 40 originator companies are responsible for almost 80% of all domestic sales and around two-thirds of exports, with the majority of the remainder from the manufacturers of generic medicines. The export destinations include Asia, South Africa, Europe, Canada, New Zealand and South America.[33]

Costs

47. The system implemented in Australia would be designed to be simpler and easier to use than some foreign systems. However, as the TRIPS Protocol system has only been used once worldwide in 2007, it is expected that only a small number of applications for a licence would be made in Australia. Implementation of the TRIPS Protocol provides an additional avenue for those who wish to address a public health problem in a developing country – it is an entirely voluntary option.

48. As the system is voluntary, it is expected that an applicant would not incur the costs of using the system if they did not think the benefit would outweigh the cost, as such, it is reasonable to expect that there would be a net positive outcome. for an applicant granted a license under the TRIPS Protocol.

[28] 'Annual Report 11/12', Australian Agency for International Development (AusAID) 2012.
[29] 'Annual Thematic Performance Report: Health 2008-09', AusAID, June 2010.
[30] There are 52 firm members of Medicines Australia, which represents originator pharmaceutical companies operating in Australia, viewed 4 December 2013 at <http://medicinesaustralia.com.au/about-us/our-members/>
[31] There are 11 members of the Generic Medicines Industry Association, viewed at 4 December 2013 at <http://www.gmia.com.au/about-gmia/gmia-members/>
[32] Medicines Australia 'Facts Book Third Edition', March 2013.
[33] 'The Australia Pharmaceuticals Industry: Winds of Change. Report of the 2009 Medicines Australia Member Economic Survey', Medicines Australia, 2010, pages 5-6;

49. The potential costs of this option could be considered in two separate categories: business as usual costs for an entity seeking to export a patented pharmaceutical overseas, and costs directly attributed to implementing this regulatory option.

50. There are standard steps (business-as-usual activities and costs) that an entity would need to take in seeking to manufacture a patented pharmaceutical for export. These steps occur regardless of whether the applicant is successful in privately negotiating the terms of a licence with the patentee, or whether they use the system proposed under this option. The cost of these activities is a not a direct result of regulation. These potential costs are as follows:

For an entity seeking to export a patented pharmaceutical product:

- Time take to ascertain which patent(s) are necessary to make the pharmaceutical product.
- Time taken to attempt to negotiate voluntary licences with patentee(s).
- Time taken to acquire familiarity with the new legislation.
- Remuneration to be paid to the patentee(s).
- Time taken to apply for regulatory approval from Therapeutic Goods Administration to permit export of the pharmaceutical products.
- Manufacture of the pharmaceutical and quality control.
- Packaging and labelling of the pharmaceutical.
- Export of the pharmaceutical.

For the owner of the patented pharmaceutical product:

- Time taken to consider the request for a voluntary licence, negotiation and issuing a response.
- Time taken to acquire familiarity with the new legislation.
- Monitoring compliance with any licences granted.

51. If an entity was unsuccessful in privately negotiating a voluntary licence with the patent owner, they could apply for a compulsory licence to exploit the patent under the TRIPS Protocol arrangements proposed by this option. The potential costs directly related to implementing this option are in addition to the costs outlined at paragraph 50 above, and are only applicable if an entity chooses to make an application for a compulsory licence:

For the applicant:

- Time taken to apply to the Federal Court for a licence - including obtaining written statements by, or on behalf of, the eligible importing country and the importer.
- Legal costs if the applicant opts to have legal representation in the Federal Court.

- Reporting and notification requirements – including time taken to notify the Commissioner of Patents of required information e.g. intention to use the system, shipment information and any variations to the licence, as well as time and costs associated with the applicant posting shipment information on a website for a set period of time.

For the owner of the patented pharmaceutical product:

- Legal representation in the Federal Court.

52. The total estimated annual costs for the activities outlined in paragraph 51 are outlined in the table below (based on the probability of the TRIPS Protocol system being used over a ten year period). These costs may be incurred, only if the proposed system is used. The costs are offset by a proposal to allow Plant Breeder's Rights holders to take matters to the Federal Circuit Court, rather than the Federal Court. The offset offers IP rights holders with a quicker and more cost effective option for enforcing their rights. See **Calculation** section below for a detailed explanation on these approximate costs.

Average Annual Change in Compliance Costs (from BAU)				
Sector/Cost Categories	**Business**	**Not-for-profit**	**Individuals**	**Total by cost category**
Administrative Costs	$1378.30	$0	$0	$1378.30
Substantive Compliance Costs	$106.00	$0	$0	$106.00
Delay Costs	$0	$0	$0	$0
Total by Sector	$1,484.30	$0	$0	**$1,484.30**
Annual Cost Offset				
	Agency	**Within portfolio**	**Outside portfolio**	**Total**
Business	$3,673			$3,673
Not-for-profit				
Individuals				
Total	$3,673			**$3,673.00**
Proposal is cost neutral? yes **Proposal is deregulatory no** **Balance of cost offsets to be banked $_2188.70_____**				

53. The full impact of Option 2 is uncertain; however there is no evidence of any perverse outcomes from this option, such as pharmaceutical developers deciding against entering the Australian market. Patents would remain an effective way for pharmaceutical developers to obtain a return on their investment because:

- the number of licences that would be granted is expected to be small;
- patent owners would be compensated for any licences granted; and
- measures would be taken to minimise products produced under licence being diverted to other markets.

54. The cost to government of this option would be the cost of amending and administering the new legislative provision and resolving any legal disputes that may arise. There would be no direct costs to the Australian public. However, the threat of compulsory licences may encourage patent owners to agree to voluntary licences, thereby creating inefficiency in the transactions of medicines where the TRIPS Protocol is relevant.

Benefits

55. The main benefit of this option to developing and least-developed countries is an opportunity to purchase generic pharmaceuticals from Australia, and in a simpler and more efficient manner than in other jurisdictions which have adopted the TRIPS Protocol. Pharmaceuticals obtained in this way would supplement those provided through other means. This could save them valuable time and money, however the amount is heavily dependent on specific circumstances and difficult to quantify.

56. The main benefit of this option to Australian manufacturers of generic pharmaceuticals is the opportunity to meet the immediate needs of developing and least-developed countries. Again, the amount would depend on specific circumstances.

57. This option would have no direct benefits to government or the Australian public. However, an increase in the supply of vital pharmaceuticals to developing countries, particularly those in the Asia-Pacific region, would be in Australia's national interest.

58. The total benefits of Option 2 are expected to be limited as the number of applications is expected to be low.

Option 3: Amend the *Patents Act 1990* to enable the Commissioner of Patents to grant licences under the TRIPS Protocol

59. Under this option, the Commissioner of Patents would be provided with the power to grant and amend licences under the TRIPS Protocol. The aim of this option would be to provide a quicker and simpler process than that provided by the Federal Court in order to minimise the administrative and financial burden on developing countries. However, the Commissioner's decision would be appealable to the Administrative Appeal Tribunal (AAT), in accordance with similar decisions under the Patents Act. IP Australia does not have the expertise to decide on remuneration, so where the parties cannot reach agreement the issue would be determined by the Federal Court.

Costs

60. The costs of this option to developing countries and manufacturers of generic medicines would be similar to those for option 2. It is expected that applicants would still use legal representation when making an application, however the fees charges by IP Australia and the AAT would probably be lower than those charged by the Federal Court.[34] An extra cost under this option would be the potential cost and delay of an appeal to the AAT and then to the Federal Court. This could be complicated by two actions occurring concurrently – one to the AAT regarding the Commissioner's decision to grant a licence and one to the Federal Court regarding remuneration.

[34] *Patents Act 1990*, Schedule 7 Fees; *Administrative Appeals Tribunal Regulations 1976*, Regulation 19.

61. Under this option, the costs to patent owners would be similar to those for option 2. However, if the grant of a licence is contentious, it is likely that patent owners would appeal the Commissioner's decision in the AAT or the Federal Court, increasing costs and also delaying the process. It is expected that patent owners would use legal representation when making an appeal in either fora.

62. The costs to Government would be similar to those under option 2, with the additional cost of IP Australia developing and maintaining the processes and expertise necessary to administer the system. There would be no direct costs to the public.

Benefits

63. The benefits of this option to developing countries and manufacturers of generic medicines are similar to those of option 2 (refer above). However, the process of applying to the Commissioner of Patents would be simpler and easier than applying to the Federal Court. Both applicants and patent owners would have the option of appealing to the AAT. This option would have no direct benefits to the government or the Australian public.

Option 4: Increase funding for aid programs that involve the delivery of pharmaceuticals to developing countries

64. Under this option, Australia would not implement the TRIPS Protocol, despite accepting it in 2007. Instead, the Government's funding for aid programs such as the Global Fund, Three Diseases Fund for Burma and William J. Clinton Foundation would be increased. As discussed in 1.1 above, these programs currently receive significant Australian support and include funding for treatments for HIV/AIDS, malaria and tuberculosis. Using existing programs such as these would be most appropriate way to increase funding because, due to Australia's comparative advantage and strategic priorities, Australia does not normally provide direct assistance for treatment and care.[35]

65. In 2011-12, Australia spent over $645 million of the aid budget on the health sector. Priority areas include tackling regional threats such as HIV, malaria and emerging infectious diseases.[36] Option 4 would involve increasing the level of funding and would be consistent with current priorities.

Costs

66. This option would involve no costs to developing countries, patent owners or manufacturers of generic pharmaceuticals. However, there could be significant costs to the Government and the Australian public, depending on the degree of increase in funding. This would not meet the objective of maintaining current budget expenditure on foreign aid. Also, not all of the funding would be targeted towards the supply of pharmaceuticals, as aid programs usually cover a range of activities, leading to inefficiencies. The Government could also be criticised for accepting, but not implementing, the TRIPS Protocol.

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[35] For example, see 'AusAID Ministerial Statement – Australia's International Development Assistance Program 2012-2013', AusAID, 2012,

[36] 'Aid issues: health', AusAID, viewed 13 September 2013 at <http://www.ausaid.gov.au/aidissues/health/Pages/home.aspx>

Benefits

67. Under this option, developing countries benefit from an increased supply of pharmaceuticals. Patent owners may benefit through a reduced risk of pharmaceuticals being diverted from the intended recipients. The Government and the Australian public would indirectly benefit because a more stable and healthy region is in the national interest.

CONSULTATION

The consultation process

68. There has been extensive consultation on the proposal to implement the TRIPS Protocol. In 2009 and 2010, IP Australia consulted a number of government agencies on proposed models. This included the then Department of Innovation, Industry, Science and Research, the Attorney-General's Department, the Federal Court of Australia, the Department of Health and Ageing, the Department of Foreign Affairs and Trade, and the Therapeutic Goods Administration.

69. In April 2010, IP Australia released a public consultation paper seeking stakeholder views on implementing the TRIPS Protocol. The paper was made available on the IP Australia website for a period of six weeks and was also circulated via email or post to a wide range of stakeholders, including the innovator pharmaceutical sector, generic medicine manufacturers, the biotechnology sector, aid organisations, the legal / attorney profession and academia. IP Australia received 14 submissions in response to this consultation process.

70. The comments received from the 2010 consultation process helped form an exposure draft of the proposed legislation to implement the Protocol. In August 2012, IP Australia released the exposure draft for public comment on the IP Australia website for a period of six weeks. The exposure draft was also circulated to a range of key stakeholder groups via email or post. IP Australia received six submissions from a range of stakeholders in response to this consultation process.

71. Stakeholder feedback was considered and a number of amendments were made to the draft legislation. Relevant agencies were again invited to comment on the revised draft legislation.

Views expressed by stakeholders

72. Submissions in response to the 2010 public consultation paper were received from:

- Medicines Australia, representing the innovative pharmaceuticals sector and patent owners;
- Australian Manufacturers' Patents, Industrial Designs, Copyright and Trade Mark Association (AMPICTA), representing patent owners;
- Generic Medicines Industry Association of Australia (GMiA), representing the generic medicines industry;

- Institute of Patent and Trademark Attorneys (IPTA), International Federation of Intellectual Property Attorneys – Australia (FICPI) and the International Association for the Protection of Intellectual Property – Australia (AIPPI), representing the patent attorney profession and patent owners;

- Law Council of Australia - Business Law Section, representing legal professionals;

- Individual legal professionals, and

- Individual academics.

73. A similar range of stakeholder groups responded to the 2012 exposure draft, including academics, patent attorney representative bodies, and innovative and generic pharmaceutical sector peak bodies.

74. Across all sectors there was strong support, during both consultation rounds, for introducing regulation to implement the TRIPS Protocol in Australia in order to provide another avenue for developing countries to obtain vital medicines. Academics have publicly expressed support for the exposure draft.[37] There was general support for the approach proposed by IP Australia, although concerns were raised about some aspects (see paragraphs 75 and 76).

75. The main concerns of Medicines Australia and legal / patent professionals were:

- the Federal Court of Australia, rather than the Commissioner of Patents, should have the power to grant, amend and revoke licences under the system. It was submitted that IP Australia lacked sufficient expertise and experience to assess and decide on whether compulsory licences should be granted and the conditions of any such licence. Submissions noted that the cost and complexity of the application for the licence is likely to be similar whether heard by the Commissioner or the Federal Court as the parties are likely to be represented regardless of where the application is made, the preparation of material will be the same and the length of the hearing would be similar. It was submitted by a number of stakeholders that remuneration will not be agreed upon in the majority of cases, and it would be cumbersome for the matter first be considered by the Commissioner and then referred to the Federal Court. Submissions also noted that the Federal Court should be able to grant, amend and determine adequate remuneration for the Protocol licences because it already has such powers under the current framework for compulsory licensing of patents and it makes similar determinations in other areas, such as trade practices;

- 'Public non-commercial use' of the pharmaceutical should not be grounds for waiving the requirement for prior negotiation between the applicant and the patent owner. It was submitted that this would be contrary to the public health aims of the Protocol, that the expression 'public non-commercial use' was too

[37] Nicol, D and Owoeye, O, 'Using TRIPS flexibilities to facilitate access to medicines', Bulletin of the World Health Organisation, July 2013, 1:91(7), 533-539, viewed 13 September 2013 at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3699798>; Rimmer, M., 'A crowning glory: patent law and public health', viewed 13 September 2013 at <http://theconversation.com/a-crowning-glory-patent-law-and-public-health-15259>

broad in this respect, and the requirement for prior negotiation should only be waived in urgent circumstances;

- measures to prevent the diversion of pharmaceuticals from the intended recipients need to be robust to reduce the risk of diversion of the pharmaceutical products from their intended location;

- dependent patent provisions are not applicable to TRIPS Protocol licenses and therefore should not form part of the scheme; and

- extension of the regime to include non-WTO countries is beyond the scope of the TRIPS Protocol. There was some concern that extending the scheme to non-WTO members may present as a higher risk of products being diverted away from the intended participants.

76. The generic medicines industry expressed no major concerns with the proposal. The main concerns of academics were:

- the system needed to be kept simple, quick and free from opportunities for delaying tactics by innovator companies;

- the legislation should clarify that vaccines are eligible products under the system;

- non-WTO members should be eligible to use the scheme, and that these countries should not be subject to extra requirements, such as additional anti-diversion measures, as this would be an unfair burden.

Key changes to draft legislation in light of stakeholder feedback

77. In light of the above stakeholder views, IP Australia proposes to revise the approach to implementation. The key changes proposed are as follows:

- The Federal Court of Australia, rather than the Commissioner of Patents, would have the power to grant, amend and revoke licences and determine remuneration. Many stakeholders preferred this option given the Federal Court's expertise in similar matters. IP Australia considered all submissions and concurred that this would be the most appropriate approach, for the reasons given in paragraph 75. This addresses concerns raised by Medicines Australia and legal / patent professionals.

- The initial model waived the requirement to attempt to negotiate a voluntary license in all circumstances of public non-commercial use. However, following consideration of stakeholder feedback (paragraph 75), this approach has been revised to limit the waiver to urgent circumstances. This approach is to ensure that the patent holder is not disadvantaged and would mean that prior negotiation is required in all circumstances, except where the Federal Court considers it to be urgent. This addresses concerns raised by Medicines Australia and legal / patent professionals.

- Anti-diversionary measures are to be strengthened to address concerns raised by Medicines Australia and legal / patent professionals, particularly in regard to third party importers. IP Australia considered anti-diversionary measures and

safeguards in detail to ascertain the correct balance between protecting the patent holder, preventing diversion of the products and ensuring that the requirements are not so onerous on the applicant that it could deter anyone from using the system. Under the proposed approach, the Federal Court can only grant a compulsory licence if it is satisfied that the applicant, the importing country and the importer will take reasonable measures to prevent diversion of the product. In doing so, the Federal Court will consider statements made by the eligible importing country and any importer. In addition to this requirement, it is proposed that other safeguards would apply, including that:

- all of the medicine must be exported to the eligible importing country;
- the medicine must be labelled and marked to distinguish the product as being manufactured and exported under the Protocol system; and
- information must be published online by the licensee before shipping the medicine to the developing country, including quantity, destination and distinguishing features of the medicine.

- Dependent patent provisions will not be included. IP Australia was initially of the view that these provisions might assist in streamlining the application process. However, on consideration of stakeholder comments, IP Australia agrees that they could cause unintended complexity. As these provisions are not required, the proposed approach has been revised. This addresses concerns raised by legal / patent professionals.

- The proposed approach to allow non-WTO members to be eligible to use the system was not revised, as while it was raised as a concern by some stakeholders, it was also supported by others. IP Australia considered these submissions in detail, and continued with the proposed approach to extend the scheme to non-WTO members as it is consistent with the humanitarian principles of the TRIPS Protocol and with the approach successfully taken by several other WTO members including Canada, Norway and Switzerland. Excluding non-WTO countries from the Australian system could deny assistance to countries that need it most, for example Timor-Leste.

- Some stakeholders submitted that vaccines should be considered eligible products under the Australian system. IP Australia agrees with this approach which is consistent with the TRIPS Agreement. The intention for the scheme to include vaccines will be clarified in explanatory material to the implementing legislation. This addresses concerns raised by academics.

- Stakeholders did not specifically comment on the differences between the proposed approach to implementing the Protocol in Australia and implementation of the Protocol by other exporting countries. However, as the regime implemented by Canada has been criticised for being too complex (see paragraph 13), IP Australia has made the proposed system less complex than the Canadian system. For example, the proposed approach allows the term of the licence to be amended by the Federal Court, whereas the Canadian regime has

enforced a maximum duration of two years[38]. Academics did note in their submissions that the system should be as easy to use as possible; IP Australia has taken this into consideration when developing the system.

CONCLUSION AND PREFERRED OPTION

78. Option 2, which proposes amending the Patents Act to enable the Federal Court to grant licences under the TRIPS Protocol, is the preferred option. This option utilises the fast track court processes to provide developing and least-developed countries with an affordable and efficient way to obtain vital medicines from Australia. This option also ensures that the rights of patent owners are respected and there is no increase to the foreign aid budget. This option was also generally supported by stakeholders in response to two public consultation processes. Stakeholder views have been taken into consideration in formulating the detailed approach to implementing option 2.

79. In contrast, option 1 does not provide developing and least-developed countries with improved access to vital medicines, particularly those countries in the Asia-Pacific region with whom Australia has an established relationship. Option 3 provides a system for improved access, but one that is overly complex and more costly if the decision is appealed. Option 4 increases the supply of pharmaceuticals for developing countries, but in a non-targeted fashion and with an increase in the foreign aid budget. Also, under options 1 and 4, Australia's acceptance of the TRIPS Protocol in 2007 may be criticised as a hollow gesture because the system is not being implemented in Australia.

80. It is therefore recommended that option 2 be endorsed. However, the implementation of the TRIPS Protocol will by no means fully address the problem of affordability of medicines for those suffering chronic poverty or for those living under ineffective government regimes. Continued maintenance of government aid funding is therefore justified.

IMPLEMENTATION AND REVIEW

81. Amendments to the *Patents Act 1990* would be required to implement the preferred option for implementing the TRIPS Protocol. A provision in the Act would enable applications for a compulsory licence to be made to the Federal Court. The Court would consider them in a manner similar to that for the existing compulsory licence provisions. Applications for a licence under the provision would be available from the date of commencement.

82. The operation of a provision in the Patents Act will not require IP Australia to take or cease to take any decision and therefore will have minimal impact on the current role of IP Australia. IP Australia intends to publish the details of the grant, amendment and/or revocation of a licence, as informed by the Federal Court or the licensee.

83. The Council for TRIPS is required to review annually the functioning of the TRIPS Protocol system with a view to ensuring its effective operation, and to report on its operation to the TRIPS General Council.[39] In Australia, review of the provision

[38] Canada's Access to Medicines Regime, viewed 4 December 2013 at <http://www.aidslaw.ca/publications/interfaces/downloadFile.php?ref=2081>
[39] Annex to the TRIPS Agreement, paragraph 7.

would be in accordance with the government's review requirements,[40] or if specific issues were raised through use of the system or by reviews conducted by the Council for TRIPS. No specific arrangements would be necessary.

STATEMENT OF COMPLIANCE

84. IP Australia has prepared a single-stage Regulatory Impact Statement (RIS), and as no decision has been previously announced since the commencement of the new Regulatory Impact Analysis process on 8 July 2013, an options-stage RIS is not required.

85. A RIS for implementation of the TRIPS Protocol was previously assessed as adequate by the Office of Best Practice Regulation in August 2011. This RIS has been updated in accordance with the new Regulatory Impact Analysis process.

86. As required by paragraph 7.86 of the Best Practice Regulation Handbook (July 2013), included below is a checklist for assessing an options-stage RIS:

- Does the options-stage RIS include a minimum of three elements—the problem, objective and options? No option-stage RIS was required.
- Does the options-stage RIS include at least three options (including a regulatory option, a non-regulatory or light-handed regulatory option, and a do-nothing option)? No option-stage RIS was required.
- Has the options-stage RIS been certified at the secretary or deputy secretary level and provided to the OBPR before consideration by the decision-maker? No option-stage RIS was required.
- Has the options-stage RIS been published following the public announcement of an initial decision to regulate? No option-stage RIS was required.

87. As outlined above, proposed changes to the Patents Act to implement the TRIPS Protocol have been subject to extensive consultation with the general public, key stakeholders and government agencies. This included:

- consultations with relevant agencies over the period 2007 to end of 2013;
- a first round of public consultation on a consultation paper to implement the TRIPS Protocol over a six week period commencing in April 2010;
- a second round of public consultation on an exposure draft of the proposed legislative changes (based on feedback from the first round of consultations) over a six week period commencing in August 2012; and
- a third and final round of public consultation on refinements to the proposed legislative changes is planned for January 2014, to address further feedback from stakeholders in May 2013.

[40] See the Office of Best Practice Regulation's *Best Practice Regulation Handbook*, July 2013, Chapter 6. See <http://www.finance.gov.au/obpr/about/index.html>.

88. IP Australia considers that this single-stage RIS, and the process leading to this RIS, fully meets all the requirements of the new Regulatory Impact Analysis process.

CALCULATION – Regulatory cost and offset

There are three categories of costs associated with the new legislation. These are:

1. The cost to legal professionals of familiarising themselves with the law.
2. The cost of using the application procedure for both the applicant and defendant.
3. The cost to a successful applicant of notifying the commissioner of patents and the public of a successful application.

The off-set for these costs are found in legislation that affects IP right holders, in particular the savings associated with allowing Plant Breeder's Right cases to be heard in the lower Federal Circuit Court as opposed to the Federal Court.

Table 1 summarises the regulatory costs and off-sets, and each value is discussed in detail below.

Table 1: Central estimate of Costs and Benefits of Proposal, in nominal dollars

$	Yr 0	Yr 1	Yr 2	Yr 3	Yr 4	Yr 5	Yr 6	Yr 7	Yr 8	Yr 9
Familiarisation with law	13,783	0	0	0	0	0	0	0	0	0
Using the Procedure	105	105	105	105	105	105	105	105	105	105
Notification requirements	1	1	1	1	1	1	1	1	1	1
Total Regulatory Cost	13,889	106	106	106	106	106	106	106	106	106
Off-set: Access to Justice	3,673	3,673	3,673	3,673	3,673	3,673	3,673	3,673	3,673	3,673

The Office of Best Practice Regulation report via its Business Cost Calculator provides the following break-down for the start-up costs per business and the total for all businesses.

Option 1		
Option name		Implement TRIPS protocol
Option description		Implement the application procedure for firms wishing to export patented pharmaceuticals
Businesses affected		186
	Cost per business	**Total cost for all businesses**
Start up cost	$74.10	$13,782.60
Ongoing compliance cost per year	$0.57	$105.56

Cost of familiarisation with the law

There would be regulatory costs associated with the time taken for the private sector to become familiar with the new legislation. This would be a one-off cost for practitioners

currently in the field, where-after it would be business as usual for any new entrant as the law would be established.

The central estimate of this one-off cost is $13,783, with a low estimate of $11,160 and a high of $17,242. This cost would be incurred in the first year only.

Table 2: Ten year cost

	Yr 0	Yr 1	Yr 2	Yr 3	Yr 4	Yr 5	Yr 6	Yr 7	Yr 8	Yr 9
Best	$13,783	$0	$0	$0	$0	$0	$0	$0	$0	$0
Low	$11,160	$0	$0	$0	$0	$0	$0	$0	$0	$0
High	$17,242	$0	$0	$0	$0	$0	$0	$0	$0	$0

Number of affected individuals

There are two groups of legal professionals who will want to familiarise themselves with the new legislation: in-house counsel of pharmaceutical companies; and IP attorneys.

1. The new legislation could affect all firms in the pharmaceutical industry and it is reasonable to expect the 63 firms registered with pharmaceutical interest groups operating in Australia will want to familiarise themselves with the new law.[41] We expect each firm will have a legal section where one person will be tasked with familiarising themselves with the new law. Our best estimate is that this will affect 63 legal professionals.

2. The second group of legal professionals would be patent attorneys. There are no lists available for the number of patent attorneys who focus on pharmaceutical issues.[42] Instead we use the number of firms available on the search facility on the Institute of Patent and Trade Mark Attorneys' website, and assume that each firm will have an interest in any change in legislation, and so one attorney per firm will be required to familiarise themselves with the law. This assumption will over-state the number of firms slightly as firms who are represented in several states may be over-counted, and one could expect that individual firms will have a lead attorney across state boundaries. This leads to a figure of 123 legal professionals reading the legislation.[43]

This provides our estimate of 186 legal professionals who will want to familiarise themselves with the law once it is enacted.

[41] There are 52 firm members of Medicines Australia, which represents originator pharmaceutical companies operating in Australia, viewed at 4 December 2013 at <http://medicinesaustralia.com.au/about-us/our-members/> and the Generic Medicines Industry Association which has 11 members, viewed at 4 December 2013 at <http://www.gmia.com.au/about-gmia/gmia-members/.

[42] One could take a proportion of the 752 members of the Institute of Patent and Trade Mark Attorneys and assume they are interested in pharmaceutical patents, but this seems too arbitrary. Not all members of the Institute are patent attorneys, and not all patent attorneys deal with pharmaceutical matters. We do not however have fixed numbers on specialisation, nor on the number of members who do not practice patent law, but focus on trade marks, copyright or design rights only. (See http://ipta.org.au/about-ipta/ for number of members)

[43] http://ipta.org.au/find-an-attorney/ has a search capability where one can get an approximate number per state for firms. The individual state counts as of November 2013 was: ACT 2, NSW 42, QLD 21, SA 8, TAS 1, WA 12, VIC 37: Total 123.

Cost of labour estimates

To calculate the cost to effected businesses from familiarising themselves with changes to legislation we calculate the gross hourly cost of legal professionals as reported in the Australian Bureau of Statistics (ABS) *Employee Earnings and Hours Survey*.[44] We apply a loading of 50 per cent to cover over-head costs which is a standard practice to fairly reflect overheads such as building costs, equipment, consumables, IT & other support services, administrative support and corporate overheads.[45]

The ABS *Employee Earnings and Hours Survey* reports average earnings for a range of legal professionals.[46] As summarised in table 3, intellectual property lawyers,[47] such as patent and trade mark attorneys earn approximately $50 per hour on average. To provide a range of likely costs we also report the earnings for junior solicitors who earn $40 an hour,[48] and barristers,[49] who earn approximately $62 an hour. After adding overhead costs the labour costs are between $60 and $93 an hour.

The cost of an IP lawyer represents our best estimate of the hourly cost accruing to effected businesses from introduction of new legislation, so we treat that as our central estimate. The hourly cost of employing a junior solicitor represents the low cost bound, and a barrister, the high cost bound.

Table 3: Average cost of employing legal professionals ($ per hour)[50]

	Low (Jun. Solicitor)	Central (IP Attorney)	High (Barrister)
Average hourly cash earnings	40	49.4	61.8
Overhead costs (50 per cent)	20	24.7	30.9
Total cost	**60**	**74.1**	**92.7**

[44] See Australian Bureau of Statistics (ABS). 2012. 6306.0 - Employee Earnings and Hours, Australia, May 2012. Before tax and other items such as superannuation are deducted: <http://www.abs.gov.au/AUSSTATS/abs@.nsf/Latestproducts/6306.0Glossary1May%202012?opendocument&tabname=Notes&prodno=6306.0&issue=May%202012&num=&view=>.

[45] See for example The Victorian Competition and Efficiency Commission 2007, "Suggested default methodology and values for staff time in BIA/RIS analysis" viewed at <http://www.vcec.vic.gov.au/CA256EAF001C7B21/WebObj/FINALGuidanceNoteonvaluingstafftime-April2007/$File/FINAL%20Guidance%20Note%20on%20valuing%20staff%20time%20-%20April%202007.pdf>.

[46] <http://www.abs.gov.au/ausstats/abs@.nsf/Lookup/3A10D1544AFF972ACA257B9500131063?opendocument>

[47] <http://www.abs.gov.au/ausstats/abs@.nsf/Lookup/4A75F516516A69FACA257B9500131122?opendocument>

[48] <http://www.abs.gov.au/ausstats/abs@.nsf/Lookup/3A10D1544AFF972ACA257B9500131063?opendocument>

[49] <http://www.abs.gov.au/ausstats/abs@.nsf/Lookup/1167755F7F313871CA257B9500131145?opendocument>

[50] Charge out rates for legal professionals can range from $120 per hour to $800 per hour or more, viewed on 4 December 2013 at <http://www.legallawyers.com.au/legal-topics/law-firm-sydney/solicitor-prices/>. These costs do not reflect the opportunity cost of labour. We do not have information about the breakdown of these costs and hence we defer to the ABS earnings survey.

Total cost

The new legislation is fourteen pages long with associated regulations and it is expected that a practitioner in the area would take no more than 1 hour to familiarise themselves with the new text. Table 4 summarises the total costs.

Table 4: Fixed cost of familiarisation with the law

Professional	Estimate	cost per hour	hours	people		Total
IP Attorneys	best	$ 74	1	123	$	9,114
In-house counsel	best	$ 74	1	63	$	4,668
Total Cost					$	13,783
IP Attorneys	low	$ 60	1	123	$	7,380
In-house counsel	low	$ 60	1	63	$	3,780
Total Cost					$	11,160
IP Attorneys	high	$ 93	1	123	$	11,402
In-house counsel	high	$ 93	1	63	$	5,840
Total Cost					$	17,242

The central estimate of the fixed costs is $13,783 with a low cost estimate of $11,160 and a high of $17,242. These costs would all be incurred within 1 year of the legislation passing.

Cost to business of using court procedure

If firms wish to manufacture drugs for export under the proposed approach they would have to make an application to the Federal Court. Standard economic theory would suggest that no rational firm would voluntarily invoke court action if they did not think the benefit outweighed the cost. Being a voluntary system, this type of action would be expected to have a net positive outcome for the applicant. The owner of the patent being asked to provide a licence (the defendant in the case being brought), will have expenses associated with the action, and it is not certain that they will always enjoy a net benefit from the resulting outcome.

We focus only on the costs of such cases and estimate the probability that a case will be brought to the courts in any given year. The probability of a case happening multiplied by the expected cost of a case for both parties gives the expected annual cost.

Probability of a case being brought to the courts

The probability of court action being invoked in any given year can best be estimated by looking at the number of cases brought forward in countries that have implemented the same legislation derived from the Protocol amending the WTO Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS Protocol).

At present there are 40 countries that have provisions to allow for exports of pharmaceuticals under similar provisions to what is being proposed in Australia. Norway was the first to implement this legislation in 2004, with the latest being the Russian Federation in 2012. That means that in Norway, there have been nine years of observations where someone could have used the procedure, while in Russia only one year. To get the probability that a case will happen in any given year, we add up all the years where a case could have been brought in any country. Appendix 1 provides the data for each country, and the total is 265 years' worth of observations.

Over that time there has only been one case where this procedure has been acted upon, in Canada in 2007.[51] Therefore the expected probability that a case will occur in any given year, is estimated as 1 in 265 or 0.38%.

Cost of a case to applicant and defendant

Applicant costs

The applicant would bear the fixed federal court fees for making an application and for setting down a hearing. The total cost of this would be $12,590.[52]

There are additional daily expenses related to applications in front of the court including the court's own daily fee of $3,135, plus the legal costs relating to lawyers. The Federal Courts' *National Guide to Counsel Fees* suggests two ranges for fees on briefing and appearance at the first day of a hearing: between $1,275 and $5,100 for junior counsel, and $2,100 to $7,650 for senior counsel.[53] These are similar to the reference prices cited by Lawyers and Legal Services Australia, so we use the Federal Court numbers to approximate the cost of representation at the courts.[54]

We expect that applicants for the Federal Court would use a senior counsel, so we apply the $2,100 - $7,650 daily rates to estimate the cost of making an application. For our central estimate we take the average of this daily rate which is $5,925.

The central cost estimate is therefore $21,650 for a single application at the high court.[55] The low cost estimate is $17,825 and the high is $23,375.

[51] http://www.ip-watch.org/2010/03/01/efficacy-of-trips-public-health-amendment-in-question-at-wto/
[52] Federal Court fixed fees: Application to the Federal Court (item no. 101 of FC fees) $4,720; Setting down for a hearing a proceeding (item no. 116 of FC fees) $7,870. [$4,720 + $7,870 = $12,590]
[53] http://www.fedcourt.gov.au/forms-and-fees/legal-costs/national-guide-counsel-fees
[54] See http://www.legallawyers.com.au/legal-topics/law-firm-sydney/solicitor-prices/ where daily court fees are estimated at QC/SC: 8,000.00 per day; Senior Barrister: 5,000 per day; Junior Barrister: 3,000 per day
[55] [Fixed fees of $12,590 + 1 days court fees of $3,135 + 1 days senior counsel at $5,925]

Defendant costs

The entity who owns the patent would, if it wished to appear for the hearing, incur similar legal costs to the applicant. The central estimate relies on the above figures from the Federal Court and is $5,925 for a days' representation by senior counsel. The low and high are $2,100 and $7,650.

Total Cost

The central estimate of the cost of an application, based on the above is summarised in the table below, and is estimated at $27,575 for both parties.

Table 5: Total cost estimates

	Low	High	Central
Applicant fixed fees	$ 12,590	$ 12,590	$ 12,590
Applicant court fees (1 day)	$ 3,135	$ 3,135	$ 3,135
Applicant legal cost (1 day)	$ 2,100	$ 7,650	$ 5,925
Defendant legal cost (1 day)	$ 2,100	$ 7,650	$ 5,925
Total	$ 19,925	$ 31,025	$ 27,575

Given the cost estimates and the probability of an application being made we can estimate the expected annual cost of applications being made. The probability of an application being made is 0.38% and the cost of the application to all parties will be $27,575 then the expected cost per annum would be $105 [0.38% × $27,575]. The low and high cost estimates would be $75 and $117 per annum.

Table 6: Ten year cost

	Yr 0	Yr 1	Yr 2	Yr 3	Yr 4	Yr 5	Yr 6	Yr 7	Yr 8	Yr 9
Best	$105	$105	$105	$105	$105	$105	$105	$105	$105	$105
Low	$75	$75	$75	$75	$75	$75	$75	$75	$75	$75
High	$117	$117	$117	$117	$117	$117	$117	$117	$117	$117

Cost of Reporting and notifying for the applicant

There are a number of administrative tasks required of the applicant. They will be required to notify the commissioner of patents that they intend to use the system, and if their application to the Federal Court is successful, they will need to notify the commissioner of the shipping and patent information, and post the shipping information to their own website.

These relate to the costs of a legal professional acting after a successful outcome, so would only take place after an application. These costs are therefore likely to occur at

any given time, and we assume that they occur with the same probability as that of an application being made of 0.38%.[56]

The information requirements would most likely require one hour's work to notify the commissioner of patents in writing that the applicant intends to use the system, including the shipping information, and an additional hour's work to post the same information to the internet.

Using the costs estimated in table 3 for the average cost of an in-house counsel/legal professional, the central cost estimate is $148 [2 hours × $74.10 per hour], while the low and high estimates are $120 and $185.

Given the low probability of a case being brought, the expected annual cost is less than a dollar per year. [$0.56 = 0.38% x $148]

Table 7: Ten year costs

	Yr 0	Yr 1	Yr 2	Yr 3	Yr 4	Yr 5	Yr 6	Yr 7	Yr 8	Yr 9
Best	$1	$1	$1	$1	$1	$1	$1	$1	$1	$1
Low	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0
High	$1	$1	$1	$1	$1	$1	$1	$1	$1	$1

OFF-SET: Saving to IP Right holders from better access to justice

The off-set savings relate to other IP right holders, mainly Plant Breeder's Right (PBR) owners, and the changes to accessing justice. Under the proposed legislation PBR disputes could be taken to the Federal Circuit Court instead of the higher Federal Court and this will mean lower costs to both parties in a dispute.

This benefit is under-estimated as we expect cases in the Federal Circuit Court to take less time than Federal Court cases, and so there should be a saving both on the daily fees and the legal representation cost. We were however unable to find a reliable estimate of the time an average case takes in these courts, so restrict ourselves to the fixed cost of appearing in court.

Lower court fees

The Federal Court's fixed fees for a hearing is $12,590 while the Federal Circuit Court charges $4,115 for the same procedures as noted in table 8. This means that each case will be cheaper by $8,475, which will be a saving to the private sector.

[56] Strictly speaking the probability of this event is conditional on the event occurring and the application being successful. This would be a lower probability, but given the small numbers it seemed acceptable to apply the same probability as that of an application being made.

Table 8: Court Fees[57]

	Federal Court	Federal Circuit Court	Saving
Application to the Court	$ 4,720	$ 1,870	$ 2,850
Setting down for a hearing	$ 7,870	$ 2,245	$ 5,625
Total	$ 12,590	$ 4,115	$ 8,475

Cost of court representation

Both courts charge a daily appearance fee, and the Federal Circuit Court fee is lower by $890 per day.[58] There is also a chance that parties appearing in the lower court would utilise the legal services of a more junior counsel than in the Federal Court, so there could be potentially more savings from this change. We were however unable to get a reliable estimate of the average duration of cases after enquiring with the courts, and the only case information we have are from two PBR cases in the higher court that lasted 5 and 19 days respectively, but no information on the lower court.[59]

Without the comparison it is not possible to reliably estimate the savings, so we do not include them in this off-set, but note that there are potentially several thousand dollars a day saved for parties involved in a case.

Number of cases

The Advisory Council on Intellectual Property reported on PBR enforcement in 2009 and noted that there had been 13 cases and 2 appeals in the 15 years since the existing PBR act was introduced in 1994. This suggests that in any given year the probability of a new case at the Federal court is 87% [13 cases divided by 15 years].

It is not certain that under the new system all cases filed with the Federal Court would be filed with the lower Federal Circuit Court, so one could adjust the proportion of expected cases down by some factor. Having no evidence to suggest what proportion of cases could be heard in a lower court we assume that anywhere between zero and all the cases could be heard in a lower court, and use the mid-point of 50% as the central estimate.

So the probability that a case substituted out of the higher court occurs in any given year would be 43.5% [87% chance of case in higher court × 50% chance of substitution], with a range from 0% to 87%.

[57] Source: Federal Court fee schedule. See fee items 101 and 116 for Federal Court fees, and fee items 201 and 215 of Federal Circuit Court fees, viewed at < http://www.fedcourt.gov.au/forms-and-fees/court-fees/fees> < http://www.federalcircuitcourt.gov.au/pubs/docs/costsgfl_11Oct.pdf>

[58] Federal Court appearance fee is $3,135 (fee item no. 117) while the Federal Circuit Court fee is $2,245 (fee item no. 216). The difference is $890 [$3,135-$2,245].

[59] See the ACIP review of PBR enforcement, page 86, footnote 104, viewed at <http://www.acip.gov.au/pdfs/ACIP_Final_Report_Review_of_Enforcement_of_PBR_Archived.pdf>

On the other hand, it is also worth considering that the high costs of the Federal Court is likely to dissuade some potential litigants and so it is likely that more cases could be brought in a cheaper lower court, so the probability of a case being brought may be higher, but these would be new cases, not cases substituted out.

Expected Benefits

With an average saving of $8,475 per case, and a 43.5% probability that a case being substituted out of the Federal Court will appear in the Federal Circuit Court in a given year, the expected benefits will be $3,673 per annum.[60]

The low and high benefit estimates will range from $0 per annum (where no cases are substituted out of the Federal Court) to $7,345 per annum.[61]

Table 9: Ten year benefits

	Yr 0	Yr 1	Yr 2	Yr 3	Yr 4	Yr 5	Yr 6	Yr 7	Yr 8	Yr 9
Best	$3673	$3673	$3673	$3673	$3673	$3673	$3673	$3673	$3673	$3673
Low	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0
High	$7345	$7345	$7345	$7345	$7345	$7345	$7345	$7345	$7345	$7345

[60] [$8,745 savings × 87% probability of a case occurring in the Federal Court × 50% probability of a case being substituted out to the Federal Circuit Court]
[61] [$8,745 savings × 87% probability of a case occurring in the Federal Court × 100% probability of a case being substituted out to the Federal Circuit Court]

Appendix 1: Countries who have already implemented TRIPS procedure

Country	Earliest date country could have used system as exporting member	Years from earliest date to 2013
Norway	1/06/2004	9
Canada	14/05/2005	8
Korea, Republic of	1/09/2005	8
India	2005	8
Austria	29/06/2006	7
Belgium	29/06/2006	7
Bulgaria	29/06/2006	7
Cyprus	29/06/2006	7
Czech Republic	29/06/2006	7
Denmark	29/06/2006	7
Estonia	29/06/2006	7
European Union	29/06/2006	7
Finland	29/06/2006	7
France	29/06/2006	7
Germany	29/06/2006	7
Greece	29/06/2006	7
Hungary	29/06/2006	7
Ireland	29/06/2006	7
Italy	29/06/2006	7
Latvia	29/06/2006	7
Lithuania	29/06/2006	7
Luxembourg	29/06/2006	7
Malta	29/06/2006	7
Netherlands	29/06/2006	7
Poland	29/06/2006	7
Portugal	29/06/2006	7
Slovakia	29/06/2006	7
Slovenia	29/06/2006	7
Spain	29/06/2006	7
Sweden	29/06/2006	7
United Kingdom	29/06/2006	7
Hong Kong, China	2007	6
Iceland	2007	6
Romania	2007	6
Croatia	31/07/2007	6
Switzerland	1/07/2008	5
Albania	7/07/2008	5
Former Yugoslav Republic of Macedonia	12/02/2009	4
China	1/10/2009	4
Russian Federation	22/08/2012	1
Total		265

STATEMENT OF COMPATIBILITY WITH HUMAN RIGHTS

Prepared in accordance with Part 3 of the Human Rights (Parliamentary Scrutiny) Act 2011

Intellectual Property Laws Amendment Bill 2014

This Bill is compatible with the human rights and freedoms recognised or declared in the international instruments listed in section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*.

Overview of the Bill

The Intellectual Property Laws Amendment Bill 2014 makes amendments to several areas of Australia's intellectual property legislative framework comprising of the *Patents Act 1990* (the Patents Act), *Trade Marks Act 1995* (the Trade Marks Act), *Designs Act 2003* (the Designs Act) and *Plant Breeder's Rights Act 1994* (the Plant Breeder's Rights Act).

The Bill makes the following amendments:

- Schedules 1 and 2 amend the Patents Act to implement the Protocol amending the World Trade Organization Agreement on Trade-Related aspects of Intellectual Property (TRIPS Protocol) to assist with the treatment of serious health problems in developing countries. The Bill enables Australian generic medicine producers to manufacture and export patented pharmaceuticals to countries experiencing health crises, under a compulsory license from the Federal Court. Australia accepted the TRIPS Protocol in September 2007.
- Schedule 3 amends the Plant Breeder's Rights Act to provide these rights owners with a quicker and cheaper alternative to enforcing their rights in the Federal Court. Schedule 3 of the Bill enables Plant Breeder's Rights actions to be heard in the Federal Circuit Court.
- Schedule 4 amends the Patents Act to provide for single application and examination processes for trans-Tasman patents. A single pathway to patent protection across countries will remove unnecessary administrative processes and create a more streamlined process for inventors in Australia and New Zealand. Schedule 4 will also allow for a single trans-Tasman patent attorney regime which will include common qualifications for registration as a patent attorney, a single trans-Tasman IP Attorneys Board and a single trans-Tasman IP Attorneys Disciplinary Tribunal.
- Schedule 5 makes minor administrative changes to the Patents Act, Trade Marks Act and Designs Act to repeal unnecessary document retention provisions which are already adequately governed by the *Archives Act 1983*; and makes minor technical amendments to the Patents Act to address oversights in the drafting of the *Intellectual Property Laws Amendment (Raising the Bar) Act 2012*.

Human rights implications

The Bill does not negatively affect any of the applicable rights or freedoms.

Right to health

Article 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR) recognises the right of everyone to enjoy the highest attainable standard of physical and mental health. The ICESCR provides that as part of achieving the full realisation of this right, States Parties shall take necessary steps to prevent, treat and control epidemic, endemic, occupational and other diseases.

Article 24 of the Convention on the Rights of the Child (CRC) highlights the right of a child to enjoy the highest attainable standard of health. Article 24(4) of the CRC provides that in achieving this right, countries that are party to the CRC shall undertake the promotion and encouragement of international co-operation having particular consideration for the needs of developing countries.

The amendments to the Patents Act under Schedules 1 and 2 to the Bill, enable the export of generic versions of patented medicines to developing countries that are experiencing serious public health issues and that have no capacity to manufacture the medicines or purchase them in the normal manner. The amendments will advance the human right to health for everyone, including children, in developing countries by assisting with the treatment of serious health problems such as HIV/AIDS, malaria and tuberculosis.

While the amendments will enable manufacturers of generic pharmaceuticals to apply to the Federal Court for a compulsory licence, patent owners of affected pharmaceutical product will be compensated. In that case the Bill will not impact on the human rights of patent owners or the human rights outlined in Article 15 of the ICESCR[62].

Right to privacy

Article 17 of the International Covenant on Civil and Political Rights (ICCPR) recognises the right to privacy. Under Schedule 4, the Bill will allow for the disclosure of information to New Zealand officials, however, safeguards will be in place to ensure that the right to privacy is not impacted by the amendments.

The type of information to be disclosed to New Zealand officials would be patent specifications, which would include details of the invention, and name and contact details of applicants and/or their agents.

The individuals that the Bill would allow information to be disclosed to are New Zealand public servants. Such individuals are bound by privacy legislation in New Zealand in the form of the Privacy Act 1993 (NZ). New Zealand's law also provides for criminal sanctions in the event of its public servants disclosing private or confidential information they have obtained in the course of their duties, similar to the provisions of

[62]UN Economic and Social Council, General Comment No.17, viewed at <www.unhchr.ch/tbs/doc.nsf/898586b1dc7b4043c1256a450044f331/03902145edbbe797c125711500584ea8/$FILE/G0640060.pdf>

the Australian Crimes Act 1914. Information provided by Australian officials to New Zealand officials would therefore be protected under New Zealand law, to an appropriate standard.

Further, New Zealand delegates of the Australian Commissioner of Patents will, as a condition of conferring any delegation, be required to sign binding confidentiality agreements in respect of private and confidential information the Commissioner releases to them.

The disclosure of personal information to New Zealand officials will be consistent with Article 17 of the ICCPR because it will lead to neither an arbitrary nor unlawful interference with privacy. Proposed new subsections 183(3) to (6) will permit the Commissioner of Patents and the Designated Manager to disclose to specified New Zealand officials specified information, which could include personal information.

The power to disclose information to a New Zealand delegate of the Commissioner of Patents may sometimes be necessary to ensure that a New Zealand delegate has access to the same information that the Australian delegate would have when examining an Australian patent application, to ensure that the application can be examined. It would be neither arbitrary nor unlawful for the Commissioner to make this information available to the New Zealand delegate, since the delegate has been authorised to examine the application and to correspond with the applicant.

In addition, in the course of administering the patent attorney regime, the Designated Manager (currently the Director General of IP Australia who is charged with administering the system of registering patent attorneys) may obtain information relating to an incorporated patent attorney that would be relevant to the Registrar of Companies' functions under the Companies Act 1993 (NZ). The information that can be disclosed is limited to information relevant to the functions conferred on the New Zealand Registrar by or under the Companies Act 1993 of New Zealand, which was obtained by the Designated Manager as a result of the Designated Manager's responsibility for regulating incorporated patent attorneys. The disclosure of personal information to New Zealand Registrar of Companies will be consistent with Article 17 of the ICCPR because it will lead to neither an arbitrary nor unlawful interference with privacy.

Schedules 3 and 5 do not raise any human rights issues.

Conclusion

The Bill is compatible with human rights because it advances the protection of human rights.

The Hon Ian MacFarlane MP, Minister Industry

Preliminary Matters

Notes on clauses

Clause 1: Short title

Upon enactment, the Bill will be known as the *Intellectual Property Laws Amendment Act 2014*.

Clause 2: Commencement

A number of provisions in the Bill will commence 6 months after the day the Bill receives the Royal Assent. This will enable the necessary regulation changes and amendments to the Federal Court Rules to be made before commencement.

Schedule 1 will commence 6 months after the Bill receives the Royal Assent. This schedule implements the interim waiver of paragraphs 31(f) and (h) of the TRIPS Agreement agreed to by the General Council of the World Trade Organization (WTO) on 30 August 2003. This will enable the export of pharmaceuticals under compulsory licence to countries in need, until the TRIPS Protocol agreed to by the General Council of the WTO on 6 December 2005 comes into force. The TRIPS Protocol will come into force when two-thirds of WTO members accept it. The interim waiver will terminate as soon as the TRIPS Protocol takes effect.

Schedule 2 will amend the Patents Act to correctly refer to the TRIPS Agreement as it will be when amended by the TRIPS Protocol. It will commence at the later of:

(a) 6 months after the day the Bill receives the Royal Assent; and

(b) the day the TRIPS Protocol enters into force.

It is appropriate for Schedule 2 to commence as soon as is convenient after the TRIPS Protocol commences, to ensure that the Patents Act correctly refers to the provisions of the TRIPS Agreement as amended by the TRIPS Protocol. It would be undesirable to delay making these amendments until after the TRIPS Protocol comes into force; in that time the Patents Act would incorrectly refer to the then-terminated interim waiver.

Schedule 3 extends the jurisdiction of the Federal Circuit Court to plant breeder's rights matters, and will commence 6 months after the Bill receives the Royal Assent.

Schedule 4 amends the *Designs Act 2003*, the *Patents Act 1990*, the *Plant Breeder's Rights Act 1994* and the *Trade Marks Act 1995* to implement single trans-Tasman patent application and examination processes as well as a bilateral arrangement between the Australian and New Zealand governments for the trans-Tasman regulation of patent attorneys. This arrangement will come into effect once both countries are able to give effect to it. Accordingly, sufficient time is required for each country to make the necessary amendments to its legislation.

To allow for this, Schedule 4 will commence on a single date to be fixed by Proclamation. The Proclamation may specify a day up to the last day of the period of 24 months beginning on the day that the Bill receives the Royal Assent. If the schedule does not commence in that period, it will be automatically repealed on the day after the end of that period (i.e. on the second anniversary of the Bill receiving the Royal Assent).

Schedule 5 makes a number of other amendments:

- Part 1 repeals unnecessary document retention provisions, and is due to commence the day after the Bill receives the Royal Assent.
- Part 2 makes minor technical amendments, primarily to address oversights in the drafting of the *Intellectual Property Laws Amendment (Raising the Bar) Act 2012* (the Raising the Bar Act). Items 7 to 15 and 17 to 19 are due to commence 6 months after the Bill receives the Royal Assent, unless proclaimed into effect earlier.

Items 6 and 16 of Schedule 5 will commence retrospectively on 15 April 2013, in line with the commencement of item 32 of Schedule 6 to the Raising the Bar Act. These items correct drafting oversights made in preparing the Raising the Bar Act and seek to clarify existing law only.

Item 6 is a minor amendment to ensure that the heading of section 24 of the Patents Act accurately reflects amendments made to section 24 by item 32 of Schedule 6 to the Raising the Bar Act. This minor amendment will not make a substantive change to existing law.

Item 16 amends paragraph 119(3)(b) of the Patents Act to correct an inadvertently-created inconsistency between that paragraph and the related provisions of paragraph 24(1)(a) of the Patents Act. Item 32 of Schedule 6 to the Raising the Bar Act amended paragraph 24(1)(a) of the Patents Act by omitting the words 'through the publication or use of the invention'. However, due to an oversight, the same words appearing in the related paragraph 119(3)(b) of the Patents Act were not omitted. There is however, very little difference between the two meanings: the invention being made publicly available by publication or use (current provision); and information about the invention being made publicly available (proposed change).

Item 16 corrects the oversight, ensuring that the long-standing provisions of section 24 and section 119 continue to be aligned. The commencement of item 16 is highly unlikely to have an effect on individual rights, liberties or obligations. The likelihood of a person’s rights being adversely affected is so low that it is difficult to conceive of a situation where this might occur. Retrospective effect will ensure consistency of legislation, clarity for users, and put the matter beyond legal doubt so that competitors of a patentee are not disadvantaged in relation to conduct before a patent application was filed.

Item 20 provides for the different application of the amendments made by items under Part 2 of Schedule 5. It will commence on the day that the Bill receives the Royal Assent.

Clause 3: Schedules

The Patents Act, Trade Marks Act, Designs Act and the Plant Breeder’s Rights Act are to be amended as set out in Schedules 1 to 5 of the Bill.

Schedule 1—TRIPS Protocol interim waiver

Introduction

Many least-developed and developing countries do not have the capacity to manufacture the medicines necessary to treat epidemics such as malaria, HIV/AIDS and tuberculosis. The interim waiver and the TRIPS Protocol agreed to by the General Council of the WTO provide a mechanism to provide such countries with the medicines they need to address health problems.

This schedule contains amendments to enable countries to source generic versions of patented pharmaceuticals from Australia in accordance with the WTO General Council's 2003 interim waiver and Australia's other international obligations. The approach aims to balance the interests of patent owners, importing countries and manufacturers of generic medicines. Schedule 2 contains amendments to implement the TRIPS Agreement as amended by the TRIPS Protocol, when it comes into effect.

An outline of the proposed process for obtaining and exercising a compulsory licence under the interim waiver / TRIPS Protocol is as follows:

1. **Identify a country's need for a pharmaceutical product and establish that the country has insufficient manufacturing capacity**

   A country identifies that it has a public health problem that can be addressed by the use of a particular pharmaceutical product. The country also establishes that it has insufficient or no manufacturing capacity to make the necessary product (this is not required for a least-developed country).

2. **Identify a suitable Australian manufacturer to make the product and identify the relevant patent(s)**

   The importing country finds an Australian pharmaceutical manufacturer with the technical capacity to make the product—whether from basic chemicals or from active ingredients sourced outside Australia. The importing country and the Australian pharmaceutical manufacturer then identify any relevant patents in Australia.

3. **Attempt to obtain authorisation**

   The Australian pharmaceutical manufacturer makes reasonable attempts to obtain authorisation from the innovator company (the patentee) to manufacture and export the product(s). This step may be omitted if the public health problem amounts to a national emergency or other circumstance of extreme urgency, in the importing country.

4. **Notify intent to use the system**

   If the Australian pharmaceutical manufacturer is unsuccessful in obtaining the innovator company's authorisation within 30 days of seeking it, or circumstances of national emergency or extreme urgency apply in the importing country, the importing country notifies its intent to use the Protocol system and other details. Importing countries that are WTO members must notify the Council for Trade-

Related Aspects of Intellectual Property Rights (TRIPS Council); those that are not WTO members must notify the Commissioner of Patents.

5. **Apply to the Federal Court for a compulsory licence**

   The Australian pharmaceutical manufacturer applies to the Federal Court for a compulsory licence to use the patent(s). The Court hears the application, using an expedited process in urgent cases.

6. **Notify grant of the compulsory licence**

   If the Federal Court grants the licence, the licensee must notify the Commissioner of Patents of the licence and of the address of the website where shipment information is to be posted (see no. 9 below). The Commissioner then provides this information to the TRIPS Council.

7. **Determine remuneration**

   If the Federal Court grants the compulsory licence, the Australian pharmaceutical manufacturer and the patentee can negotiate the remuneration due to the patentee for the use authorised by the licence. If they cannot agree, the Federal Court can determine the remuneration. This can occur when the court considers the application for the licence, or on a separate application later on.

   If the pharmaceutical product is to address a public health crisis in the importing country, then the Australian manufacturer can make and export the pharmaceutical product before the remuneration is determined. For other public non-commercial use of the pharmaceutical product by the importing country, the remuneration must be determined before the Australian manufacturer can make and export the pharmaceutical product.

8. **Manufacture and export of the patented pharmaceutical**

   The Australian pharmaceutical manufacturer makes and exports the patented pharmaceutical in accordance with the terms of the licence.

9. **Notify details of shipment**

   Before sending the pharmaceutical to the importing country, the Australian pharmaceutical manufacturer posts the quantities, destinations, labelling and markings of the product(s) on the website referred to at no.6.

10. **Take reasonable measures to prevent re-exportation**

    The importing country and anyone importing the pharmaceutical product on its behalf must take reasonable measures to prevent re-exportation of the pharmaceutical product. This is to ensure that the pharmaceutical product is used in the importing country for the intended public health purposes. The measures taken by the importing country must be proportionate to the country's administrative capacity and to the risk of the pharmaceutical product being diverted.

Items 1 to 10: List of definitions

[s 3]

Item 1 removes the expression 'compulsory licence' from the list of expressions defined in Schedule 1 to the Patents Act. That definition relates to general compulsory licences only and so is no longer suitable.

Items 2 to 10 insert into the list of defined expressions the following expressions:

- ***eligible importing country***, to refer to those countries eligible to import pharmaceutical products under the system (see the notes on item 27 below)
- ***patented pharmaceutical invention***, to refer to those inventions that are subject to the new compulsory licence provisions (see the notes on item 28 below)
- ***pharmaceutical product***, to refer to those products that may be manufactured and exported under the new provisions (see the notes on item 29 below)
- ***PPI***, to provide an abbreviation for patented pharmaceutical invention (see the notes on items 30 to 33 below)
- ***PPI compulsory licence***, to provide an abbreviation for the compulsory licence provided for in section 136C (see the notes on items 30 to 33 below)
- ***PPI order***, to provide an abbreviation for the court order provided for in section 136C to grant a PPI compulsory licence (see the notes on items 30 to 33 below)
- ***PPI order applicant***, to provide an abbreviation for the person applying under section 136C for an order to grant a compulsory licence (see the notes on items 30 to 33 below)
- ***TRIPS Agreement***, to refer succinctly to the international agreement that governs intellectual property rules in the multilateral trading system (see the notes on item 34 below)
- ***WTO General Council decision of 30 August 2003***, to refer to the interim waiver of paragraphs 31(f) and (h) of the TRIPS Agreement (see the notes on item 35 below).

Items 11, 12 and 13: Extensions of patent term

[s 70, s 71]

These items amend the Patents Act to ensure that obtaining regulatory approval for the export of pharmaceuticals to countries in need does not adversely affect a patent owner's subsequent application for an extension of the term of a patent.

Section 70 enables the term of a patent for a pharmaceutical invention to be extended to compensate patent owners for delays in obtaining marketing approval from the Therapeutic Goods Administration (TGA). An extension of term of up to five years is available if certain conditions are satisfied.

These conditions include that goods containing the pharmaceutical substance are included in the Australian Register of Therapeutic Goods (ARTG) and at least five years has passed from the filing date of the patent to the ***first regulatory approval date***. The first regulatory approval date is either:

- the date of commencement of the first inclusion in the ARTG of goods that contain the substance; or
- where ***pre-TGA marketing approval*** was given – the date of the first approval to market or import the substance or product containing it into Australia.

Under sections 71 and 77, the first regulatory approval date is also used to calculate the period within which an application for an extension of term must be made, and the actual extension period.

In some cases, pharmaceuticals to be exported in accordance with the objectives of the TRIPS Protocol may be exempt under section 18 of the *Therapeutic Goods Act 1989* from being included in the ARTG. However, ARTG listing of pharmaceuticals may still be sought.

It would not be appropriate for such an inclusion in the ARTG to adversely affect the patent owner's subsequent application for an extension of term. This is because the patent owner would be expected to obtain only limited remuneration for the export of the product to an eligible importing country. This should be the case whether the first inclusion is sought by the patent owner, by a manufacturer of generic medicines under a voluntary licence from the patent owner, or by a manufacturer of generic medicines under a TRIPS Protocol licence granted under the new provisions.

These items address this problem by providing that, when working out a pharmaceutical substance's first regulatory approval date, an inclusion in the ARTG is to be disregarded if it was sought for the sole purpose of exporting goods containing the pharmaceutical substance from Australia to be used in an eligible importing country in circumstances governed by the TRIPS Protocol. These circumstances are further discussed below in regards to item 19 and section 136D. This approach will ensure that a patent owner's application for an extension of term is not adversely affected by the export of pharmaceuticals to countries in need.

Items 14 to 18: Compulsory licences (general)

[s 132A, s 133, s 134]

Item 14 inserts a new Part 1 into Chapter 12 setting out a simplified outline of the Chapter in new section 132A. It also places the existing provisions for compulsory licences in sections 133 and 134 into a new Part 2 of Chapter 12 to govern compulsory licences generally. This structure will clearly differentiate the existing compulsory licence provisions from the new provisions relating to the TRIPS Protocol. New section 132B provides a simplified outline of the new Part 2. Items 15 and 17 update the headings of sections 133 and 134 to clarify that they relate to general compulsory licensing of patents.

Item 16 inserts a note at the end of subsection 133(1) to clarify that a PPI compulsory licence, ordered in accordance with the TRIPS Protocol (under new Part 3), does not prevent a general compulsory licence from being ordered under new Part 2 of Chapter 12.

Item 18 amends subsection 134(1) to make it clear that the provisions in section 134 for revocation of compulsory licences only apply to the general type of compulsory licences. Separate provision is to be made for the revocation of compulsory licences governed by the new provisions.

Item 19: Patented pharmaceutical invention compulsory licences (for manufacture and export to eligible importing countries)

This item amends Chapter 12 to provide in a new Part 3 the provisions for the application, grant, amendment, remuneration and revocation of TRIPS Protocol licences. It also establishes a new Part 4 for the existing provisions relating to the surrender and revocation of patents generally.

Division 1—Introduction

[s 136B, s 136C]

This new division introduces the new Part 3 by providing a simplified outline of the Part (new section 136B). New section 136C explains that the new provisions relating to TRIPS Protocol licences for pharmaceutical inventions do not prevent a compulsory licence for a patented pharmaceutical invention being ordered under the general compulsory licence provisions in Part 2.

Division 2—Patented pharmaceutical invention compulsory licences

PPI compulsory licences—applications for orders

[s 136D(1)]

This subsection provides that a person may apply to the Federal Court for a PPI compulsory licence to exploit a patented pharmaceutical invention to the extent necessary for the purposes of manufacturing a pharmaceutical product in Australia for export to an eligible importing country. The term ‘exploit’ is defined in Schedule 1 to the Patents Act to include all the acts the PPI order applicant would need and ‘to the extent necessary’ is in line with wording of the TRIPS Protocol. The Federal Court is best placed to determine if a compulsory licence should be granted and is able to deal with applications quickly in urgent situations.

There may be situations where a person may need a PPI compulsory licence for more than one pharmaceutical invention. In the interests of efficiency, it is intended that a person may apply for an order requiring a patent owner to grant a single PPI compulsory licence in respect of more than one pharmaceutical invention.

The TRIPS Protocol enables the export of products only to certain countries in order to avoid misuse of the system. Paragraph 1(b) of the Annex to the TRIPS Agreement

defines those countries that are ‘eligible importing Members’ of the WTO. Subsection 136D(1) implements a modified version of this requirement by providing that the purpose of the licence must be to export to an eligible importing country. Item 28 amends Schedule 1 to define an eligible importing country and explanation of the definition is provided in relation to that item.

As clarified by Note 1 to the subsection, and the definition to be inserted by item 28, a patented pharmaceutical invention may be a patented product or a patented process. A PPI compulsory licence may be granted to exploit a patented process for manufacturing a pharmaceutical product so that it can be exported to an eligible importing country.

[s 136D(2)]

This subsection provides that a person cannot apply for an order in respect of an innovation patent unless the patent has been certified. This is because an innovation patent cannot be enforced until it has been examined and certified, and is also for consistency with subsection 133(1A) governing applications for general compulsory licences.

[s 136D(3)]

This subsection provides that an application for a PPI compulsory licence must include a statement to the effect that the eligible importing country will take reasonable measures to prevent re-exportation from its territory of a pharmaceutical product that is imported into its territory in accordance with a PPI compulsory licence.

The exportation of pharmaceuticals to least-developed and developing countries carries a risk of the pharmaceuticals being diverted from the intended recipients and being sold for profit in other countries. The requirement to provide a statement will help to reduce this risk, and is consistent with paragraph 3 of the Annex to the TRIPS Agreement.

[s 136D(4)]

This subsection provides that if the pharmaceutical product is to be imported on behalf of, and with the authorisation of, the importing country, an application must also include a statement made by the importer. The statement must be that the importer will take reasonable measures within its means to prevent the pharmaceutical product from being used other than in accordance with a PPI compulsory licence. This provision will help to prevent the pharmaceutical product from being diverted from the intended recipients in the importing country.

[s 136D(5)]

This subsection sets out the parties to proceedings on an application for a PPI compulsory licence. The eligible importing country has the option of being a party to such proceedings.

PPI compulsory licences—orders

[s 136E(1)]

This subsection provides that the Federal Court may make an order requiring the patentee to grant a PPI compulsory licence to the applicant, if the court is satisfied of a number of matters. These matters ensure that a licence is only granted in appropriate circumstances and consistently with Australia's international obligations.

Paragraph (a)—application made in good faith

It is possible that a person may inappropriately seek a PPI compulsory licence for a purpose other than to export a pharmaceutical product to a country in need. For example, the applicant may actually wish to prepare stocks of the product for commercial sale immediately upon the expiration of the patent. This requirement enables the court to determine whether the licence is being sought for its intended purpose. In accordance with the WTO General Council chairperson's statement of 6 December 2005 on the TRIPS Protocol, the system of PPI compulsory licenses is intended to be used in good faith to protect public health, and not as an instrument for pursuing industrial or commercial objectives.

Paragraph (b)—importation by or on behalf of the eligible importing country

As noted above in relation to subsection 136D(1), the TRIPS Protocol limits export to certain countries. Paragraph 136E(1)(b) implements this requirement, with some modifications. Item 27 amends Schedule 1 to the Patents Act to define the expression 'eligible importing country'. Also, in some circumstances it may be appropriate for the product to be imported by another country, regional group or non-government organisation on behalf of the eligible importing country. This may enable the product to be obtained or distributed more efficiently, and paragraph 136E(1)(b) enables this to occur. Importation on behalf of eligible importing countries is not provided for in the TRIPS Protocol. However, it provides such countries with some flexibility in obtaining the medicines they need.

Paragraph (c)—proposed use of pharmaceutical product

The TRIPS Protocol is intended to help address the public health problems afflicting many least-developed and developing countries. The requirement in this paragraph is to ensure that the proposed use of the pharmaceutical product is consistent with that intent, and with paragraph 1(a) of the Annex to the TRIPS Agreement.

Article 17.9.7(b) of the Australia-United States Free Trade Agreement provides that Australia shall not permit the use of the subject matter of a patent without the authorisation of the right holder except in cases of public non-commercial use, or of national emergency, or other circumstances of extreme urgency, provided that a number of conditions apply. The requirement in paragraph 136E(1)(c) is intended to ensure that a PPI compulsory licence would only be granted in one of those circumstances in the importing country. In circumstances of national emergency or extreme urgency in the importing country, it is expected that the applicant could provide evidence of this to the satisfaction of the court. Examples of public non-commercial use include use by a government or a non-profit non-government organisation.

Paragraph (d)—necessity of licence

It is possible that a licence could be sought to exploit an invention that is not necessary to enable the pharmaceutical product to be provided to the eligible importing country to address the public health problem. The requirement in this paragraph is to ensure that there is a direct link between the licence to exploit the invention (i.e. by manufacturing and exporting the patented pharmaceutical product) and the required purpose.

Paragraph (e)—authorisation by patentee

In circumstances of extreme urgency in an eligible importing country, including a national emergency, it is not reasonable to require the applicant to seek authorisation from the patentee before applying for a PPI compulsory licence. This could create delay with serious consequences for the people suffering the health problem.

However, if there are no circumstances of extreme urgency in the eligible importing country, it is appropriate that the applicant seek such authorisation, as voluntary licences between parties are preferable to compulsory licences ordered by the courts.
This is consistent with Article 31(b) of the TRIPS Agreement. The period of 30 days for trying to obtain authorisation is intended to provide certainty for all parties, and to reduce the scope for any party to deliberately delay an application for a PPI compulsory licence.

Paragraph (f)—notification requirements

Paragraph 2(a) of the Annex to the TRIPS Agreement provides that the eligible importing WTO Member must notify the Council for TRIPS of a number of matters. These comprise:

- the names and expected quantities of the product(s) needed;
- confirmation that the Member (if not a least-developed country) has insufficient manufacturing capacities for the product(s) in question;
- confirmation that, where a pharmaceutical product is patented in its territory, the Member has granted or intends to grant a compulsory licence to allow importing and use of the product.

This notification requirement is to help ensure that Protocol licences are granted in appropriate circumstances. Regulations made for the purposes of paragraph 136E(1)(f) would prescribe these requirements.

The countries to be prescribed as eligible importing countries under the new definition to be inserted by item 27 will include some countries that are not WTO Members. It is intended that the regulations would require non-WTO Members to notify the prescribed information to the Commissioner of Patents, not to the Council for TRIPS. Publication on the WTO or IP Australia websites of the prescribed information is to be accepted as evidence that the notification requirement has been complied with.

Paragraph (g)—measures against diversion

As noted above, there is a risk of the exported pharmaceuticals being diverted from the intended recipients. This requirement is to help ensure that this does not occur. The statements provided under subsection 136D(3) and 136D(4) (if applicable) are to constitute evidence for the court's consideration of this matter.

[s 136E(2)]

This subsection provides that the Court must take into account any matters prescribed in the regulations when deciding whether it is satisfied of a matter mentioned in subsection 136E(1). For example, the regulations may provide that, when determining whether the application has been made in good faith, the court must consider evidence of the previous activities of the applicant and the eligible importing country.

[s 136E(3)]

This subsection will allow the regulations to:

a) prescribe different notification requirements for eligible importing countries, referred to in subsection 136E(1)(f), depending on the kind of country (e.g. whether or not it is a Least Developed Country); and

b) establish the kinds of eligible importing countries by referring to lists of countries contained on the United Nations and WTO websites, as these are from time to time. These lists are freely available and readily accessible to the public. This will avoid the need to list all of the eligible importing countries and what kind they are in the regulations. Subsection 136E(3)(b) repeats the regulation-making power in new subsection 228(4) (to be inserted by item 25 below) to make it clear that the different kinds of countries is relevant to prescribing the notification requirements under 136D(1)(f).

PPI compulsory licences—terms

[s 136F(1)]

This subsection specifies the terms of any PPI compulsory licence that may be granted.

Paragraphs (a) and (b)—quantity of product manufactured and exported

In order to help ensure that the PPI licence is being used for its intended purpose, it is important that only the amount of pharmaceutical product necessary to meet the needs of the eligible importing country is manufactured, and that all of the product is exported to that country, whether directly or by way of another country. These terms are in accordance with paragraph 2(b)(i) of the Annex to the TRIPS Agreement. Should it become apparent that additional quantities are needed, an amendment to the licence can be sought under section 136G.

Paragraph (c)—labelling and marking

As mentioned above, there is a risk of the exported pharmaceuticals being diverted from the intended recipients. It is therefore appropriate that the pharmaceutical product be labelled and marked so that it is easily identified as being for the intended purpose, and not for sale in other markets.

The regulations will prescribe the labelling and marking requirements in accordance with paragraph 2(b)(ii) of the Annex to the TRIPS Agreement. This requires that products manufactured under licence be clearly identified through specific labelling or

marking. It also states that suppliers should distinguish such products through special packaging and/or special colouring/shaping of the products themselves, provided that such distinction is feasible and does not have a significant impact on price. The Attachment to the WTO General Council chairperson's statement of 6 December 2005 also discussed best practices for differentiating products.

Should it become apparent that some change is needed to the labelling and marking of a pharmaceutical product, an amendment to the licence can be sought under section 136G.

Paragraph (d)—publishing shipment information

In the interests of transparency, it is appropriate that information on the quantities being supplied to each destination and the distinguishing features of the products be made available on a website. The regulations will set out these requirements in accordance with paragraph 2(b)(iii) of the Annex to the TRIPS Agreement.

Paragraph (e)—duration

In order to help ensure that the PPI licence is being used for its intended purpose, it is appropriate that the duration of the licence be limited to that which is necessary to address the public health problem concerned. This provision implements this approach in accordance with Article 31(c) of the TRIPS Agreement. Should it become apparent that a change to the duration is necessary, an amendment to the licence can be sought under section 136G.

Paragraph (f)—no exclusive right

As the purpose of a PPI compulsory licence is to enable countries in need to access vital pharmaceuticals, it would not be appropriate for a PPI compulsory licence to give the licensee the exclusive right to exploit the patented pharmaceutical invention. The granting of other licences to enable the export of a pharmaceutical product to the same or other countries in need should be allowed, if not encouraged. This provision implements this approach and is consistent with paragraph 133(3)(a) of the Patents Act in regards to general compulsory licences.

Paragraph (g)—restricting assignment of licence

In order to help ensure that the PPI compulsory licence is used for its intended purpose, it is appropriate that the licence is to be assignable only in connection with an enterprise or goodwill in connection with which the licence is used. This provision is consistent with paragraph 133(3)(b) of the Patents Act in regards to general compulsory licences.

Paragraph (h)—giving information to the Commissioner

In the interests of transparency, it is appropriate that the Commissioner is provided with details about the licence granted, any subsequent amendment of the licence and the address of the website referred to in (d) above. This will enable the Commissioner to publish the information on the IP Australia website and to inform the Council for TRIPS as required by paragraph 2(c) of the Annex to the TRIPS Agreement.

[s 136F(2)]

This subsection provides the Court with the power to order that a licence include any other terms, including terms covering the labelling and marking of the product and the information provided by the licensee. It is difficult to foresee all the relevant issues that may need to be taken into account when determining the terms of a PPI compulsory licence in a given situation. For example, due to the circumstances in a particular eligible importing country, it may be necessary to further reduce the risk of the product being diverted to other markets. This could involve additional identification requirements for the pharmaceutical product, or the licensee providing information on how the product will be shipped and supplied to the intended recipients. This provision provides the Court with the flexibility to specify such terms where necessary and is consistent with subsection 133(3) of the Patents Act in regards to general compulsory licences.

[s 136F(3)]

This subsection provides that a term specified in a PPI order must not be inconsistent with any regulations prescribed for the purposes of labelling and marking of the pharmaceutical product, providing information on a website prior to shipment or providing information to the Commissioner.

PPI compulsory licence—amendment

[s 136G]

Any person may apply to the Federal Court for an order to amend any of a number of terms of a PPI compulsory licence. It may be difficult for the eligible importing country and the PPI compulsory licence applicant to predict the quantity of the pharmaceutical product and the duration of the licence required to address the health problem. Similarly, owing to changed circumstances, it may be appropriate to change the labelling and marking of the product, and the information to be provided by the licensee. This provision enables any person to seek an amendment to the PPI compulsory licence to account for such developments, and thereby potentially avoid the delay and expense of making a new application for a PPI compulsory licence. Enabling amendment of the PPI compulsory licence is not required by the TRIPS Protocol, but will provide a balanced and efficient means of dealing with changed circumstances.

The court may grant the order to amend the licence if it is satisfied that it is just to do so and the legitimate interests of the listed persons are not likely to be adversely affected by the amendment. This approach ensures that the court considers all the relevant effects of the proposed amendment before making a decision. The applicant for amendment only has legitimate interests to be considered if the applicant is one of the listed persons.

An amended term must not be inconsistent with any regulations prescribed for the purposes of labelling and marking of the pharmaceutical product, providing information on a website prior to shipment or providing information to the Commissioner.

Subsection 136G(4) sets out the parties to any proceedings for amendment of a PPI compulsory licence. The eligible importing country has the option of being a party at will.

PPI compulsory licences—revocation

[s 136H]

This section provides that any person may apply to the Federal Court to revoke a PPI compulsory licence. Only the court can revoke a compulsory licence, thereby ensuring that the legitimate interests of the licensee and the eligible importing country are considered. The court may revoke the licence if it is satisfied of a number of matters. These matters ensure compliance with Article 31(g) of the TRIPS Agreement and that the PPI compulsory licence may be revoked if it is no longer appropriate.

The court must first be satisfied of one or all of the following grounds when considering an application for revocation.

Ground 1—Change in circumstances justifying the licence

The first ground of revocation is that the substantive circumstances that justified the grant of the licence have ceased to exist and are unlikely to recur. For example, if the health problem in the eligible importing country has abated and the pharmaceutical product is no longer required for the foreseeable future, then it is appropriate that the licence may be revoked.

Only the substantive circumstances justifying the grant of the licence are relevant to this consideration. For example, this ground should not be made out merely because the applicant for the PPI compulsory licence had not complied with all of the notification requirements specified in the regulations for paragraph 136E(1)(f).

Ground 2—Non-compliance with terms of licence

An alternative ground is that the licensee has not complied with the terms of the licence. This is to help ensure that a licensee abides by the terms of the licence. This ground should not be made out for minor or trivial breaches that do not affect anyone's interests, but should be found for serious breaches with harmful consequences.

For example, this ground should be made out if the PPI compulsory licensee does not comply with the terms relating to marking and labelling of the product, thereby increasing the risk of the product being diverted to other markets. In contrast, this ground should not be made out if the PPI compulsory licensee inadvertently overproduces the patented pharmaceutical product and the excess is disposed of with the consent of the patentee.

Ground 3—Failure to pay remuneration within the time agreed or determined

Another ground for revocation is that the amount negotiated under section 136J has not been paid to the patent owner within the time agreed or determined. This ground is to ensure that the patent owner is compensated for the licence within the agreed time period.

The legitimate interests of the licensee or the eligible importing country

If any of the grounds for revocation is made out, the court may only revoke the licence if satisfied that that the legitimate interests of the licensee or the eligible importing country are not likely to be adversely affected by the revocation.

For example, the eligible importing country might not have appropriately authorised the pharmaceutical product to be imported on its behalf. Nevertheless, the country might wish to import the product to address the health problem. In such a case, it would not be appropriate for the PPI compulsory licence to be revoked.

The applicant for revocation has no legitimate interest to be considered if the applicant is not the licensee or the eligible importing country.

Subsection 136H(3) sets out the parties to any proceedings under this section. The eligible importing country has the option of being a party at will.

Enabling revocation of a PPI compulsory licence is not required under the TRIPS Protocol, however this provision will provide a balanced and efficient means of dealing with changed circumstances.

Division 3—Remuneration

[s 136J]

This section provides for the patentee to be remunerated for the use of the patented pharmaceutical invention authorised by the PPI compulsory licence and specifies how the remuneration amount is to be determined. These provisions are to ensure that appropriate remuneration is paid to the patentee in a manner consistent with the requirements of the TRIPS Protocol.

Subsection 136J(2) defines that use to be either the use authorised by the licence as granted and amended, or where the licence is no longer in force, the actual use of the invention while the licence was in force. This approach ensures that the remuneration to the patentee is not finally determined at the time the licence is granted, but can be adjusted to take into account any changed circumstances.

Subsection 136J(3) defines the remuneration amount to be either an amount agreed between parties or an amount determined by the Federal Court to be adequate remuneration, taking into account the economic value to the eligible importing country of the use authorised.

Subsection 136J(4) provides that any person may apply to the court to make or amend such a determination. This approach provides the parties with an opportunity to reach agreement but, where this does not occur, enables the court to determine remuneration according to Article 31bis(2) of the Annex to the Protocol Amending the TRIPS Agreement. In most circumstances it would be appropriate for the court to determine the matter if agreement is not reached within 30 days of the PPI compulsory licence being granted or amended. Subsection 136J(5) sets out the parties to any proceedings under this section.

Subsection 136J(6) explains that a PPI compulsory licensee may only begin exploiting a PPI compulsory licence, whether or not remuneration is yet to be agreed or determined,

if the proposed use of the product is to address circumstances of national emergency or extreme urgency in the importing country. In such cases it would be inappropriate to delay provision of the product until remuneration had been determined, particularly as there may be a significant period of negotiation between the patentee and the licensee. This provision ensures that the licensee can commence the manufacture and export of the product as soon as the licence is granted, but that the patentee will receive appropriate remuneration.

Subsection 136J(7) provides that a PPI licensee must not exploit a PPI compulsory licence, other than to address circumstances of national emergency or extreme urgency, unless an amount has been agreed or determined. This is to avoid the licensee exploiting the patent and creating unreasonable delays in the determination of remuneration.

Subsection 136J(8) explains that a PPI compulsory licence may be revoked regardless of whether an amount has been agreed or determined.

Division 4—General

PPI compulsory licences—nature of orders

[s 136K**]**

This section provides that a court order to grant or amend a licence is equivalent to a deed executed by the patentee and all other necessary parties. This provision is consistent with subsection 133(4) in regards to general compulsory licences.

PPI compulsory licences—consistency of orders with international agreements

[s 136L**]**

This section ensures that a PPI order is not inconsistent with a treaty between the Commonwealth and a foreign country, including the Australia-United States Free Trade Agreement. This provision is consistent with section 136 in regards to general compulsory licences.

PPI compulsory licences—applications heard together

[s 136M**]**

This section explains that the Federal Court may deal with applications for different PPI compulsory licences together, or for the amendment or revocation of these orders. There is also nothing to prevent to the Federal Court from considering applications for determination of remuneration in relation to different PPI compulsory licences together, or for the amendment of such determinations. The court may consider it to be more efficient to hear applications together, thereby avoiding multiple proceedings.

Heading to new Part 4—surrender and revocation of patents and simplified outline of part

[s 136N]

Item 19 also inserts the heading to new Part 4 containing existing sections 137 and 138 relating to the surrender and revocation of compulsory licences generally, and inserts new section 136N providing a simplified outline to the Part.

Item 20: Revocation of patents (general)

[s 137]

This item clarifies that the Commissioner must not accept an offer to surrender a patent where a general compulsory licence is in force in relation to the patent. The Commissioner can, however, accept an offer to surrender a patent where a licence granted in relation to a patented pharmaceutical invention is in force in relation to the patent.

Item 21: New Heading and simplified outline of Part

This item provides a new heading (Part 5) for the existing provisions on parties to proceedings (section 139) and the giving of copies of orders to the Commissioner (section 140). The item also inserts section 138A providing a simplified outline of Part 5.

Items 22 and 23: Parties to proceedings

[s 139]

Item 22 inserts a note after subsection 139(1) to direct the reader to Part 3 for details of parties to proceedings relating to compulsory licences for patented pharmaceutical inventions.

Item 23 amends subsection 139(2) to provide that the applicant to any proceeding under Chapter 12 must serve a copy of the application on the Commissioner and that the Commissioner may appear and be heard in the proceedings.

Items 24 and 25: Regulation-making power

[s 228]

Item 24 amends subsection 228(1) to ensure that there is sufficient power to make the regulations necessary for carrying out or giving effect to the WTO General Council decision of 30 August 2003. Item 35 amends Schedule 1 to the Patents Act to define the expression ‘WTO General Council decision of 30 August 2003’, and the definition is explained below.

These regulations would govern a number of matters, including the information the Commissioner must give to the TRIPS Council so that Australia complies with its obligations as an exporting country under paragraph 2(c) of the Annex to the TRIPS Agreement.

Item 25 inserts new subsection 228(5) to ensure that there is sufficient regulation-making power to provide for different classes of countries by reference to lists of

countries on the United Nations website and the WTO website, that are updated from time to time. This will avoid the need to list (and update) the different countries included in each class in the regulations. The lists contained on these websites are freely available and readily accessible to the public.

Item 26: Definition of compulsory licence

[Schedule 1]

This item repeals the definition of compulsory licence, as it could not apply appropriately to compulsory licences under the TRIPS Protocol.

Item 27: Definition of eligible importing country

[Schedule 1]

This item inserts a definition of the expression 'eligible importing country', used in the new Part 2 in Chapter 12. As outlined above in relation to subsection 136C(1), paragraph 1(b) of the Annex to the TRIPS Agreement limits eligible importing members to least-developed country WTO Members and other WTO Members that have made a notification to the Council for TRIPS of their intention to use the TRIPS Protocol system as an importer. This does not enable export to non-WTO Member countries and so limits the potential benefits of the TRIPS Protocol system.

An eligible importing country will be prescribed by the regulations as a country in any of the following two classes:

(a) A foreign country recognised by the United Nations as a least-developed country. Not requiring the country to be a WTO Member increases the number of countries that are eligible to use the system. The United Nations maintains a list of least-developed countries which is available through its web portal.

(b) A foreign country that has notified the Council for TRIPS of its intention to use the 2003 interim waiver as an importer.

The regulations will refer to a list of least-developed countries contained on the United Nation's website, and a list of WTO members contained on the WTO's website (see item 25 above). The lists contained on these websites are freely available and readily accessible to the public. This will avoid the need to list (and update) the different countries included in each class in the regulations.

Item 28: Definition of patented pharmaceutical invention

[Schedule 1]

This item inserts a definition of 'patented pharmaceutical invention'. Under the new Part 3 of Chapter 12, a PPI compulsory licence may be obtained in relation to a patented pharmaceutical invention. The definition provides that a patented pharmaceutical invention can be a patented pharmaceutical product, or it can be a patented process for producing the pharmaceutical product. This enables a PPI compulsory licence to be obtained for the type of invention required to manufacture and export a pharmaceutical

product and is consistent with Article 31bis(1) of the Annex to the Protocol Amending the TRIPS Agreement.

Item 29: Definition of pharmaceutical product

[Schedule 1]

This item inserts a definition of 'pharmaceutical product'. Under new Part 3 in Chapter 12, a PPI compulsory licence may be obtained for the purposes of manufacturing and exporting a pharmaceutical product. The definition provides that a pharmaceutical product is any patented product, or product manufactured through a patented process, of the pharmaceutical sector. The definition and examples given are consistent with paragraph 1(a) of the Annex to the TRIPS Agreement and include a broad range of products including vaccines, provided that they fall within the pharmaceutical sector.

Items 30 to 33: PPI definitions

[Schedule 1]

Item 30 inserts a definition of 'PPI' as being an abbreviation for patented pharmaceutical invention. Items 31 to 33 insert definitions of various terms used in new Part 3 of Chapter 12, by reference to the sections where they are first used. These terms are to differentiate between general compulsory licences and the various licences relating to patented pharmaceutical inventions under the TRIPS Protocol system.

Items 34: TRIPS Agreement

[Schedule 1]

Item 34 inserts a definition of the expression 'TRIPS Agreement', as referred to in the definition of the expression 'WTO General Council decision of 30 August 2003' (see item 35 below).

Item 35: Definition of WTO General Council decision of 30 August 2003

[Schedule 1]

This item inserts a definition of the expression 'WTO General Council decision of 30 August 2003'. The 2003 decision implemented the interim waiver of Article 31(f) and (h) of the TRIPS Agreement to enable WTO Members to manufacture and export pharmaceutical products under compulsory licence. Schedule 2 of the Bill implements the 2003 interim waiver. As noted above, should the TRIPS Protocol come into force, item 3 of Schedule 2 would repeal this definition.

Part 2—Application

Item 36: Application of amendments

Sub-item (1) provides that PPI compulsory licences may be granted under the new Part 2 of Chapter 12 in respect of existing patents and patents for which the application was

filed before commencement of this Schedule. This is to allow the new provisions to be used immediately upon their commencement, rather than only in relation to later granted patents for pharmaceutical inventions. This is consistent with the intention of providing a mechanism to provide least-developed and developing countries with the medicines they need to address health problems.

Sub-item (2) provides that the amendments relating to the disregarding of an inclusion in the Australian Register of Therapeutic Goods only apply to applications for inclusion made on or after the commencement of this Schedule. Inclusions resulting from applications made before commencement cannot be disregarded for the purposes of working out the date of first inclusion. This is to prevent patentees from enjoying a windfall from applications for inclusions that were not made in reliance on the new compulsory licensing provisions.

Schedule 2—TRIPS Protocol: later commencing amendments

Introduction

This schedule contains amendments to implement the TRIPS Agreement as amended by the TRIPS Protocol, when it comes into effect. Schedule 1 contains amendments to enable countries to source generic versions of patented pharmaceuticals from Australia in accordance with the WTO General Council's 2003 interim waiver and Australia's other international obligations.

Items 1 and 2: Definitions

[s 3]

Item 1 removes the expression 'WTO General Council decision of 30 August 2003' from the list of defined terms. These amendments are consequential on the TRIPS Protocol coming into effect and superseding the 2003 General Council decision.

Item 2: Amendment of reference to 2003 General Council decision

[s 228]

This item amends subsection 228 (1)(f) so that the reference to the 2003 General Council decision is replaced by reference to the TRIPS Agreement. This will ensure that there is sufficient power to make the regulations necessary for carrying out, or giving effect to the TRIPS Agreement as amended by the TRIPS Protocol, if the TRIPS Protocol should come into effect.

Item 3: Definition of WTO General Council decision

[Schedule 1]

Item 3 repeals the definition of 'WTO General Council decision of 30 August 2003', consequential on the TRIPS Protocol coming into effect and superseding the 2003 General Council decision.

Schedule 3—Plant Breeder's Rights Act 1994: Federal Circuit Court

Introduction

This schedule is to make the amendments necessary to provide the owners of plant breeder's rights (PBR) in a plant variety with the option of taking action in the Federal Circuit Court against alleged infringers. The amendments address the need for a way to resolve disputes about the infringement of PBR in a plant variety that is quicker and less formal than taking action in the Federal Court. As most disputes over plant breeder's rights are less complex matters, and many of the parties involved are small businesses with limited resources, the Federal Circuit Court is well placed to hear such cases.

Items 1, 2 and 3: Definitions

[s 3]

These items:

- repeal the definition of the expression ***Court***, as the definition refers to the Federal Court only and so is no longer suitable (item 1)
- define the expression ***Federal Circuit Court*** as meaning the Federal Circuit Court of Australia (item 2)
- define the expression ***Federal Court*** as meaning the Federal Court of Australia (item 3).

Item 4: Subsection 39(5)

A decision of the Administrative Appeals Tribunal (AAT) can be appealed to the Federal Court. Under subsection 44A(2) of the *Administrative Appeals Tribunal Act 1975* (AAT Act), the Federal Court has the power to stay or otherwise affect the operation or implementation of the decision of the AAT or of the agency. The Federal Court can transfer an appeal to it to the Federal Circuit Court. In such cases the Federal Circuit Court can also make orders under subsection 44A(2) of the AAT Act. This item is a consequential amendment clarifying that these powers remain unaffected by section 39 of the PBR Act.

Item 5: Subsection 50(7)

This item is similar to item 4, in that it clarifies that section 50 of the PBR Act does not affect the powers of the Federal Court or of the Federal Circuit Court under section 44A(2) of the AAT Act.

Items 6 and 7: Actions for infringement

[s 54]

These items substitute references to 'Court' with references to the 'Federal Court or the Federal Circuit Court' or 'court'. These substitutions are to permit actions for infringement of PBR to be taken in the Federal Court or in the Federal Circuit Court. Currently, actions for infringement can be taken in the Federal Court only.

Items 8 and 9: Declarations of non-infringement

[s 55]

Items 6 and 7 substitute references to 'Court' with references to the 'Federal Court or the Federal Circuit Court' or 'court'. These substitutions are to permit persons proposing to do an act relating to PBR protected material to apply to the Federal Court or to the Federal Circuit Court for a declaration that the act does not infringe the PBR. Currently, such an application can be made to the Federal Court only.

Items 10 to 16: Jurisdiction of the Federal Court

[s 56]

These items amend section 56 – currently providing for the jurisdiction of the Federal Court – as a consequence of the extension of jurisdiction to the Federal Circuit Court.

Item 17: Correcting a typographical error

[s 56]

This item corrects a typographical error.

Item 18: New section 56A Jurisdiction of Federal Circuit Court

This item inserts a new section 56A providing for the jurisdiction of the Federal Circuit Court. Section 56A is modelled on section 56, which currently provides for the jurisdiction of the Federal Court under the Plant Breeder's Rights Act.

As with the Federal Court, the Federal Circuit Court is to have the jurisdiction conferred under Part 5 of the Plant Breeder's Rights Act – namely, in proceedings for infringement of PBR, or applications for declarations of non-infringement. See the notes above.

By analogy with the jurisdiction of the Federal Court, this jurisdiction is exclusive of the jurisdiction of all other courts – excepting the jurisdiction of the Federal Court under section 56, and the original jurisdiction of the High Court under the Commonwealth Constitution.

By analogy with the powers of the Federal Court in proceedings for infringement of PBR, the Federal Circuit Court is to be able to grant injunctions and either award damages or order an account of profits.

As with the Federal Court, the regulations are to be able to govern the practice and procedure of the Federal Circuit Court in actions under the Plant Breeder's Rights Act. Nevertheless, this conferral of regulation-making power is not to limit the power of the Federal Circuit Court to make its own Rules of Court for such actions, provided these Rules are consistent with any regulations made under the power.

Items 19 and 20: Innocent infringement

[s 57]

These items substitute references to 'the Court' with references to 'a court' and 'the court'. As the Federal Court is able to do now, the Federal Circuit Court is to be able to refuse to award damages, or order an account of profits, against an infringer if satisfied that the infringer was not aware of, and had no reasonable grounds to suspect the existence of PBR in a plant variety.

Item 21: Agents may act in matters relating to PBR

[s 72]

This item is to ensure that a general provision allowing one person to act for another under the Plant Breeder's Rights Act is clearly subject to the Rules of the Federal Circuit Court for any transactions before that court. The item is also to ensure that more standard reference is made to the Rules of Court of the High Court and to the Rules of Court of the Federal Court.

Schedule 4—Australia New Zealand Single Economic Market

Introduction

Single patent application and examination processes

Patents for inventions are territorial rights granted by sovereign states. Most patent applications filed in New Zealand are also filed in Australia. These applications are currently subject to a similar, but separate, examination process. Providing for single application and examination processes will reduce duplication, leading to increased efficiencies and potential cost savings for inventors and users of the patent system.

The process involves:

- either country accepting the filing of applications, correspondence and other documents and accepting the payment of fees, resulting in the filing of documents under each country's law
- an examiner in either country considering applications for grant of patents under both countries' laws—as a delegate of each country's Commissioner of Patents.

This new process will not create a single patent covering both Australia and New Zealand. Each country will grant patents under its own legislation.

A single Trans-Tasman patent attorney regime

The Patents Act creates and regulates a class of professionals called patent attorneys. Patent attorneys provide a valuable service to innovators and business by advising them how to protect their intellectual property. Patent attorneys must satisfy specific requirements, relating to their technical qualifications and character in order to be registered.

The Trans-Tasman Mutual Recognition Arrangement ('TTMRA'), signed in 1996, streamlines the reciprocal registration of members of occupations, including patent attorneys. The majority of Australian and New Zealand patent attorneys are already registered in both countries under the TTMRA, paying fees in both countries annually for the renewal of their registrations.

The TTMRA does not, however, require that an Australian or New Zealand patent attorney demonstrate their competence in the law and practice of the other country to obtain registration there under the TTMRA. Nor is it currently a requirement for domestic registration in Australia or in New Zealand that a person demonstrate such competence in both countries' law and practice, so that a person could successfully practise in both countries.

Australia and New Zealand have agreed to establish a single trans-Tasman regulatory regime for patent attorneys, under a bilateral arrangement. The arrangement was signed in March 2013 by the relevant Australian and New Zealand Ministers and is publicly

available on the IP Australia website[63].

The regime will achieve efficiencies in the regulation of patent attorneys through:

- a single trans-Tasman register of individual and incorporated patent attorneys
- common requirements for registration, appropriate to whether the person is an individual or a company
- a trans-Tasman code of conduct for patent attorneys
- a common disciplinary process
- common regulatory bodies—the Designated Manager, the Trans-Tasman IP Attorneys Board and the Trans-Tasman IP Attorneys Disciplinary Tribunal.

Australia will amend its patents legislation to provide for the trans-Tasman regulatory regime. This Schedule makes the necessary amendments to the Patents Act to implement the regime.

The Schedule also makes consequential amendments to the Trade Marks Act to allow the Trans-Tasman IP Attorneys Board to regulate Australian registered trade marks attorneys, continuing the current role of the Professional Standards Board for Patent and Trade Marks Attorneys. New Zealand does not currently have a trade mark attorney profession, but a number of patent attorneys practise as trade mark specialists.

The Schedule also amends the Australian patents, trade marks, designs and plant breeder's rights legislation to allow applicants for these IP rights to provide a single address for service in either Australia or New Zealand. This will mean that applicants for IP rights in both these countries will not need to nominate an address for service in each country. The Schedule will also provide the flexibility to allow service electronically in future.

Part 2 of the Schedule contains several transitional arrangements to ensure a smooth transition to the new regime. In overview:

- At commencement, all patent attorneys registered in New Zealand but not in Australia will be entered into the Australian Register of Patent Attorneys. This will then be the single trans-Tasman register of patent attorneys.
- New Zealand patent attorneys who are trade mark specialists will be able to apply in a 12-month transitional period to be registered as Australian trade marks attorneys, without obtaining further qualifications, so long as the Designated Manager is satisfied the patent attorney has a sufficient level of competency in trade marks law and practice.
- A person who passes one of the New Zealand patent attorney examinations before commencement can complete the rest of those examinations in a four-year transitional period, and seek registration as a patent attorney under the new regime within six months of passing the examinations, without obtaining further qualifications.
- An attorney who is the subject of disciplinary proceedings in New Zealand at commencement can be subsequently removed from the trans-Tasman register, if

[63] http://www.ipaustralia.gov.au/pdfs/13-04-02_Bilateral_Arrangement_Final_Version.pdf

a New Zealand court finds that the person should not practise as a patent attorney in New Zealand.

Once the Bill is enacted, IP Australia intends to seek the necessary amendments to the regulations. The commencement of the amending regulations would be conditional on the commencement of this Schedule (see notes on Clause 2 above).

It is expected that New Zealand will make complementary legislation to recognise the Australian regulatory regime, including the status of a New Zealand company registered as a patent attorney in Australia. Only an individual or company registered as a patent attorney in Australia would be permitted to practice as a patent attorney in New Zealand.

Expressions used frequently in these notes:

- The **Australian Commissioner** of Patents is the official principally responsible for the administration of the *Patents Act 1990.*
- The **Designated Manager** is an SES employee (currently the Director-General of IP Australia) charged with administering the system of registration and deregistration of patent attorneys.[64]
- The **Director-General of IP Australia** is the Chief Executive of IP Australia for the purposes of the *Financial Management and Accountability Act 1997*
- An **incorporated patent attorney** is a company registered as a patent attorney under new subsections 198(9) to (11) of the Patents Act, which came into effect on 15 April 2013.[65]
- **IP Australia** is a prescribed Agency for the purposes of the *Financial Management and Accountability Act 1997*. The Patent Office, Trade Marks Office, Designs Office and the Plant Breeder's Rights (PBR) Office operate within it.
- The **New Zealand Commissioner** of Patents is the official principally responsible for the administration of the Patents Act 1953 (NZ). See also the definition inserted by item 54 in Part 1 of this Schedule.
- A **New Zealand delegate** is a New Zealand patents official (see below) to whom the Australian Commissioner delegates powers and functions under the Patents Act. See the definition inserted by item 55 in Part 1 of this Schedule.
- A **New Zealand patents official** is a person employed in any part of the State services of New Zealand whose functions or duties relate to administering New Zealand patents law. See the definition inserted by item 57 in Part 1 of this Schedule.
- The **Professional Standards Board** for Patent and Trade Marks Attorneys is the body established by section 227A of the Patents Act. It has a central role in the accreditation of persons for registration as attorneys, and in the discipline of registered attorneys.

[64] See s 200A and, generally, Chapter 20, Patents Act

[65] Inserted by item 21 of Schedule 4 to the *Intellectual Property Laws Amendment (Raising the Bar) Act 2012* ('Raising the Bar Act')

Part 1—Amendments

Designs Act 2003

Items 1 to 4: Service of documents in Australia or New Zealand

[s 145]

These items broaden the allowable addresses for service of documents under the Designs Act, and provide flexibility in specifying the means of service.

Currently, an address for service under the Designs Act must be a physical or postal address in Australia, and the permitted means of service are by postal or personal delivery to that address (see also section 28A of the *Acts Interpretation Act 1901*).

Item 2 amends the Designs Act to allow an address in New Zealand to be an address for service of documents. As a result any person seeking design protection in Australia will be able to nominate an address in either Australia or New Zealand as their address for receiving notices from the Registrar of Designs.

Item 3 amends the Designs Act to allow a document to be served to an address for service in Australia or New Zealand by means prescribed in the regulations. Initially, the prescribed means would be those currently available, that is, by post.

In future, IP Australia proposes to develop electronic means for routinely and securely serving notices on electronic addresses in Australia or New Zealand. When appropriate means are available, these may be prescribed in the regulations.

There might be some uncertainty about whether an electronic address can be an address for service in Australia or in New Zealand. To put this beyond doubt, item 4 inserts new subsections 145(2) to (5) to allow an electronic address to be an address for service in Australia or in New Zealand. This will apply from a time specified in regulations, but not before those regulations are registered in the Register of Legislative Instruments under the *Legislative Instruments Act 2003.* The question of whether a particular electronic address is in Australia or in New Zealand is to be determined in accordance with the regulations.

These amendments do not affect the rules of courts or tribunals governing service. The courts and tribunals decide what constitutes effective service in proceedings before them, including service on persons outside Australia.

Neither Australia nor New Zealand registers specialist design protection professionals. In Australia, patent attorneys, trade marks attorneys or legal practitioners advise businesses on how to protect their designs. In New Zealand, registered patent attorneys or lawyers provide this advice.

Patents Act 1990

Items 5 to 13: Definitions

[s 3]

These items amend the list of defined terms to reflect the inclusion, amendment or repeal of definitions by items 49 to 59. These definitions allow the amended provisions of the Patents Act to be more concise.

Items 14 and 15: Protection of New Zealand delegates

[s 20]

These items amend the Patents Act to ensure that New Zealand delegates of the Australian Commissioner (see item 25) enjoy the same immunity from liability under section 20 as Australian officers and employees in the Patent Office. This immunity is limited to the exercise of powers or performance of functions delegated to the New Zealand delegate under the Australian patents legislation. It does not apply to their exercise of powers or performance of functions under the New Zealand patents legislation: when performing their duties as examiners of New Zealand patent applications. See item 55 for the definition of 'New Zealand delegate'.

Generally, Australian legislation is presumed to only apply in Australia. Paragraph 21(1)(b) of the *Acts Interpretation Act 1901* provides that references in any Act to localities and jurisdictions are to be read as references to those in and of the Commonwealth of Australia. Currently, section 12 extends the Patents Act and its regulations to Australia's continental shelf and its external territories, but not to any foreign nation.

Several of the amendments made by this Schedule insert provisions stating that, for the purpose of specified provisions, it is immaterial whether some act takes place in New Zealand, or whether some matter concerns something taking place in New Zealand. This ensures that the Australian legislation can apply to specified actions or circumstances taking place in New Zealand as necessary.[66]

Item 15 inserts new subsection 20(3) stating that it is immaterial for the purposes of section 20 whether the act was done in New Zealand. That is, the immunity from liability will be available for an act, even if it is done in New Zealand. For example, say a New Zealand delegate of the Australian Commissioner does not accept an application for grant of a patent when examining it, owing to a mistaken understanding of the invention being claimed. Later on, a Deputy Commissioner in Australia hears the applicant and accepts the application. The applicant is inconvenienced by the delay in the grant of the patent. It is immaterial that the New Zealand delegate's decision is made in New Zealand: the New Zealand delegate will have the same immunity in Australia as an Australian delegate.

[66] See items 16, 21, 23, 34, 35, 38, 45, 48 and 85

Item 16: Disclosure of information to New Zealand Registrar of Companies and to New Zealand delegates of the Commissioner

[s 183]

This item amends the Patents Act to permit the disclosure of information to the New Zealand Registrar of Companies ('Registrar of Companies') and to New Zealand delegates of the Australian Commissioner in New Zealand.

New subsections 183(3) and (4) make it clear that the Designated Manager can give information, including personal information, to the Registrar of Companies, where the Designated Manager obtains that information as a result of performing functions and duties, or exercising powers, in relation to incorporated patent attorneys. The substituted definition of 'company' (see item 50)—which includes a company registered under the Companies Act 1993 (NZ)—ensures that those powers and functions can apply to those New Zealand companies seeking registration or that are registered in Australia as incorporated patent attorneys.[67]

In the course of administering the patent attorney regime, the Designated Manager may obtain information relating to an incorporated patent attorney that would be relevant to the Registrar of Companies' functions under the Companies Act 1993 (NZ). For instance, the Designated Manager might obtain information indicating that the company is trading in New Zealand while insolvent. It is in the public interest that the Designated Manager be able to disclose such information to the Registrar of Companies. The new subsection is directly modelled on new subsection 183(2), which makes it clear that the Designated Manager can give information to the Australian Securities and Investments Commission ASIC.[68]

New subsections 183(5) and (6) make it clear that the Australian Commissioner can give information, including personal information, to a New Zealand delegate to assist the delegate in exercising their delegated powers and functions. This power is necessary to ensure that a New Zealand delegate has access to the same information that the Australian delegate would have when examining an Australian application. Item 25 inserts a new provision permitting the Australian Commissioner to delegate powers and functions to New Zealand patents officials.

Item 17: Repeal of an outdated offence provision

[s 185]

This item repeals an offence provision that is no longer required in the Patents Act. The provision imposes a penalty of 10 penalty units (currently $1,700) on officers and employees of the Patent Office who prepare documents relating to other persons' inventions or who search the records of the Patent Office unofficially. The provision for a special offence, applying only to officers and employees of the Patent Office, appears outdated. Such conduct would breach the APS Code of Conduct in the *Public Service Act 1999*, and could be dealt with appropriately under that Act.

[67] Under new subsections 198(9) to (11) inserted by item 21 of Schedule 4 to the Raising the Bar Act (with effect from 15 April 2013)
[68] Inserted by item 15 of Schedule 4 to the Raising the Bar Act (with effect from 15 April 2013)

Item 18: Repeal of residency requirement

[s 198]

This item repeals the requirement that an individual be ordinarily resident in Australia to be registered as a patent attorney. This requirement is inconsistent with the single trans-Tasman attorneys' regime.

An individual seeking registration as a patent attorney must:

- hold qualifications specified in, or ascertained in accordance with, the regulations
- have been employed as prescribed for not less than the prescribed period
- be of good fame, integrity and character
- not have been convicted of a prescribed offence during the previous five years
- not be under sentence of imprisonment for a prescribed offence
- meet any other requirements prescribed by the regulations.[69]

The Patents Regulations will continue to specify stringent requirements for the qualifications and employment of individuals seeking registration.[70] These appear sufficient to ensure the technical competence and good character of individuals registered as patent attorneys in Australia and New Zealand. No residency requirement will be prescribed in the regulations.

Item 19: Reference to the Professional Standards Board

[s 198]

This item amends section 198 to replace an occurrence of 'Professional Standards Board' with the more concise 'Board'. This is consequential on the amendment made by item 40, which continues the Professional Standards Board for Patent and Trade Marks Attorneys under its new title: 'the Trans-Tasman IP Attorneys Board'.

Items 20 and 21: Registration of patent attorneys

[s 198]

These items amend section 198 of the Patents Act to ensure that its provisions for registering individuals and companies[71] as patent attorneys can apply appropriately to the circumstances in New Zealand of an individual or company.

Item 20 repeals current subsection 198(7) of the Patents Act which provides how to work out if an individual is ordinarily resident in Australia. This provision is no longer required, as a consequence of the removal of the residency requirement (see item 18).

Item 20 also repeals existing subsection 198(8) and substitutes a new subsection 198(7) for it. Substitute 198(7) ensures that someone found guilty, but not convicted of an

[69] Inserted by item 17 of Schedule 4 to the Raising the Bar Act with effect from 15 April 2013
[70] See Part 2 of Chapter 20 of the *Patents Regulations 1991*
[71] See new subsections 198(9) to (11) inserted by item 21 of Schedule 4 to the Raising the Bar Act

offence in New Zealand is treated the same as someone found guilty, but not convicted of an offence in Australia.

Currently, a person who is the subject of an order under section 19B of the *Crimes Act 1914*—or its State or Territory equivalents—is taken to have been convicted of that offence for the purposes of section 198. Section 19B of the Crimes Act permits a court to find that a charge is proved, but to dismiss the charge or to discharge the person without conviction (e.g. on an order to be of good behaviour for some period).

An example of how the deeming provision in substituted subsection 198(7) works follows:

1. Existing paragraph 198(4)(e) of the Patents Act disqualifies someone from registration as a patent attorney if convicted of a prescribed offence during the previous five years.
2. The regulations made for the purpose of that paragraph currently prescribe offences against the Australian intellectual property legislation, including the *Patents Act 1990*.[72]
3. Those regulations would be amended to prescribe offences against the New Zealand intellectual property legislation, including the Patents Act 1953 (NZ). See notes on item 21 below.
4. An individual is found guilty in New Zealand of an offence against section 103 of the Patents Act 1953 (NZ)—for acting as a patent attorney in New Zealand without being registered there.
5. The New Zealand court discharges the individual without conviction under the New Zealand equivalent of section 19B of the Crimes Act.[73]
6. Owing to substituted subsection 198(7), that individual is taken to have been convicted of the offence for the purposes of paragraph 198(4)(e) of the Patents Act.
7. The individual is barred from registration as a patent attorney for five years from the date of being discharged by the New Zealand court.

Item 21 inserts new subsection 198(12) ensuring that the matters required for an individual or a company to register as a patent attorney can relate to Australia or to New Zealand as required[74]:

- The requirements for an individual to register as a patent attorney in paragraphs 198(4)(a) to (g) (see the list in item 18 above)—e.g. an individual is disqualified from being registered if convicted of a prescribed offence in Australia or New Zealand in the previous five years.
- The employment requirement prescribed under paragraph 198(4)(c) will specify that the relevant employment has been undertaken in Australia or New Zealand.

[72] Subregulation 20.12(2) of the Patents Regulations (at 1 October 2012).
[73] Sections 106 and 107 of the Sentencing Act 2002 (NZ) appear to correspond to section 19B of the *Crimes Act 1914* (at 18 September 2012)
[74] The new subsection follows new subsections 198(9) to (11) inserted by item 21 of Schedule 4 to the Raising the Bar Act (with effect from 15 April 2013)

- A qualification for registration can consist of examinations conducted by the Trans-Tasman IP Attorneys Board in Australia or New Zealand. This is in the unlikely event that the Board ever conducts examinations again. For some while individuals have qualified for registration by undertaking appropriate tertiary studies approved by the Board.
- A company incorporated in New Zealand seeking registration as a patent attorney in Australia ('New Zealand company') must have at least one director who is
  - — a registered patent attorney in Australia. See item 82 which ensures that all New Zealand patent attorneys become Australian patent attorneys at commencement
  - — a validly appointed director of the company under New Zealand company law.
- The New Zealand company must notify the Designated Manager of its intention to act as a patent attorney. It will not matter that it intends to practise in Australia, in New Zealand or in both countries.
- The New Zealand company must comply with any additional requirements prescribed in the regulations, whether these requirements concern something that happened in Australia or New Zealand. For example, the regulations would require that the company provide evidence that it has adequate and appropriate professional indemnity insurance for its practice as an incorporated patent attorney—whether this is in Australia, in New Zealand or in both countries.

Items 22 and 23: Deregistration of patent attorneys

[s 199]

These items amend section 199 of the Patents Act to make it plain that the prescribed grounds for deregistration of a patent attorney can concern something that happened in New Zealand. The Designated Manager can deregister persons (both individuals and companies) registered as patent attorneys.[75] The substituted definition of 'company' (see item 50)—which includes a company registered under the Companies Act 1993 (NZ)—ensures that New Zealand companies can be registered in Australia as incorporated patent attorneys.

The grounds and manner of deregistration of individuals are prescribed in the regulations.[76] For example, an individual may be deregistered for failing to meet the continuing professional education (CPE) requirement.[77] As a result of new subsection 199(2), it is immaterial that a person who fails to meet the CPE requirement resided in Australia or in New Zealand in the year. It is expected that sufficient CPE activities would be available in both countries.

Similarly, for any prescribed ground of deregistration of a company as an incorporated attorney (e.g. failing to maintain adequate and appropriate indemnity insurance would be

[75] From 15 April 2013, companies will be able to be registered as patent attorneys under new ss198(9) to (11) inserted by item 21 in Schedule 4 to the Raising the Bar Act
[76] For individuals, Part 6 of Chapter 20 of the Patents Regulations (at 1 October 2012)
[77] Regulations 20.24 and 20.28 of the Patents Regulations (at 1 October 2012)

prescribed), it would be immaterial whether the company is established in Australia or New Zealand.

Items 24 to 26: Delegation to New Zealand patents officials

[s 209]

These items amend the Patents Act to permit the Australian Commissioner to delegate all or any of the Australian Commissioner's powers and functions under the Patents Act and its regulations to a New Zealand patents official (see item 57).

This will allow the Australian Commissioner to delegate powers and functions to patent examiners in the Intellectual Property Office of New Zealand. It is not intended that the delegating powers be used otherwise. Similarly, it is proposed that the New Zealand Commissioner would delegate powers and functions under New Zealand's patents legislation to patent examiners in the Patent Office in Australia ('Patent Office'). A delegate of both the Australian and New Zealand Commissioners will be able to examine applications made in Australia and in New Zealand for the grant of patents in both countries.

The Australian and New Zealand Governments will enter into a bilateral arrangement setting out the powers and functions that each country's Commissioner will delegate to patents officials in the other country. This instrument will provide evidence of each country's consent to its patents officials exercising powers and functions delegated by the other country's Commissioner. It will be made publicly available once it is finalised.

New subsection 209(1B) puts it beyond doubt that the New Zealand delegate of the Australian Commissioner can exercise delegated powers or perform delegated functions in New Zealand. This ensures the legal effect in Australia of actions taken by a New Zealand delegate. See the notes for items 14 and 15 above.

As with Australian delegates, a New Zealand delegate must—if so required by the instrument of delegation—exercise a delegated power or perform a delegated function under the direction or supervision of the Commissioner or an employee in the Patent Office specified in the instrument of delegation (see subsection 209(2) of the Patents Act). This will ensure that New Zealand delegates can be given appropriate guidance by Australian patents officials. The New Zealand examiners' performance will be subject to the same quality review systems as Australian examiners. If New Zealand examiners do not maintain sufficient standards, then their delegated ability to examine under the Australian Patents Act will be revoked.

In respect of accountability and review mechanisms, the designation to a New Zealand examiner as a delegate of the Australian Commissioner provides that a decision made by that examiner would be deemed to be one that has been made by the Australian Commissioner.

As a result, any decision made by a New Zealand would be reviewable through the normal procedure in the Patents Act. In combination with schedule 4 item 38 (which provides that for the purposes of the *Administrative Appeals Tribunal Act 1975* and the *Administrative Decisions (Judicial Review) Act 1977*, it is immaterial whether a decision is taken in New Zealand), review by the Administrative Appeals Tribunal and the

Federal Court will be available to Australian applicants for decisions taken in New Zealand or by New Zealand officials.

In practical terms, where decisions of New Zealand examiners are subject to dispute by a patent applicant, the matter will be referred to supervising examiners and to the Deputy Commissioner of Patents at IP Australia. If the dispute continues, the usual procedure would be to request a hearing before a hearings delegate of the Australian Commissioner, who would be an officer of the Australian Public Service. It would be this decision, and not the decision of the New Zealand examiner, that would be appealed to a court.

With regards to transparency, because decisions by New Zealand examiners will be considered as decisions of the Australian Commissioner, applications under the *Freedom of Information Act 1982* (the FOI Act) would be capable of being made in respect of those decisions.

The vast majority of documents that are handled by patent examiners relating to patent applications become open to public inspection (OPI) 18 months after the application was filed. The OPI system under the Patents Act provides an exemption for access to such documents under the FOI Act. IP Australia publishes most OPI documents on its website; copies of other OPI documents are available from IP Australia on request. Documents relating to patent applications that are handled by New Zealand delegates of the Australian Commissioner will be subject to the same OPI provisions as Australian examiners, and will all be published by IP Australia.

Personal information supplied to one patent office as part of an application will be protected according to the law of the jurisdiction governing that office. A consistent application of privacy laws will apply to each jurisdiction by virtue of the revised *Privacy Act 1988* which, as of March 2014, will ensure that actions of Australian Government agencies in overseas territories will be regulated.

In addition, the jurisdiction of the *Ombudsman Act 1976* already has extraterritorial effect, and its application would apply to decisions made by a New Zealand examiner with the delegated powers of the Australian Commissioner.

Items 27 and 28: Filing documents with specified New Zealand patents officials

[s 214]

These items amend the Patents Act to permit prescribed documents filed with one of the specified New Zealand patents officials to be taken to be filed at the Patent Office. This will save applicants having to file the same document in both Australia and New Zealand: for example, applications for grant of a patent for the same invention in each country.

The specified New Zealand patents officials are:

- the New Zealand Commissioner
- a New Zealand Assistant Commissioner of Patents

- a person who is a delegate of the New Zealand Commissioner under New Zealand law.

The regulations would prescribe the documents that might be filed with those New Zealand patents officials, and the allowed means of filing them. For example, an application for grant of a standard patent in Australia could be prescribed.

As the New Zealand Commissioner intends to require documents to be filed electronically by particular means, those electronic means would be prescribed for the document in the regulations. As a result, that would be the only means of filing the document with the New Zealand Commissioner that would result in a valid filing under the Australian patents legislation.

The regulations could also prescribe when a prescribed document filed by the prescribed means with a New Zealand patent official is taken to have been filed at the Patent Office. It is proposed that the regulations would provide that the time of filing in New Zealand is taken to be the time in Canberra, Australia when all of the information in the document enters the IT systems provided in New Zealand for electronic filing.

Some prescribed fees are due when filing some documents (e.g. an application for grant of a standard patent in Australia). Item 37 amends the Patents Act to permit those fees to be paid in New Zealand dollars to New Zealand patents officials.

Under the single application system, the Patent Office will also receive applications for the grant of patents in New Zealand. The New Zealand legislation will provide for the effect of such filings in New Zealand.

Items 29 to 32: Service of documents in Australia and New Zealand

[s 221]

These items broaden the allowable addresses for service of documents under the Patents Act, and provide flexibility in specifying the means of service.

Currently, an address for service under the Patents Act must be a physical or postal address in Australia, and the permitted means of service are by post or personal delivery to that address (see also section 28A of the *Acts Interpretation Act 1901*).

Item 30 amends the Patents Act to allow an address in Australia or New Zealand to be an address for service of documents. As a result any person applying for grant of a patent in Australia will be able to nominate an address in either Australia or New Zealand as their address for receiving notices and other documents from the Commissioner of Patents (e.g. evidence filed by a person opposing grant of the patent under section 59 of the Patents Act).

Item 31 amends the Patents Act to allow a document to be served on an address for service in Australia or New Zealand by means prescribed in the regulations. Initially, the prescribed means would be those currently available: by post. This means that for the purposes of an application for grant of a patent in Australia, the address for service must be a physical or postal address in either Australia or New Zealand.

In future, IP Australia proposes to develop electronic means for routinely and securely serving notices on electronic addresses in Australia or New Zealand. When appropriate means are available, these may be prescribed in the regulations.

There might be some uncertainty about whether an electronic address can be an address for service in Australia or in New Zealand. To put this beyond doubt, item 32 inserts new subsections 221(2) to (5) to allow an electronic address to be an address for service in Australia or in New Zealand. This will apply from a time specified in regulations, but not before those regulations are registered in the Register of Legislative Instruments under the *Legislative Instruments Act 2003.* The question of whether a particular electronic address is in Australia or in New Zealand is to be determined in accordance with the regulations.

For example, the regulations might provide that a document could be served by transmitting the information in it to a digital mail-box in Australia or New Zealand nominated by the person to be served. The regulations would provide that the digital mail-box is an address for the purposes of section 221. Permitted addresses could also include a digital mail-box set up by IP Australia or by the Intellectual Property Office of New Zealand: if the person to be served nominates that digital mail-box.

These amendments do not affect the rules of courts or tribunals governing service. The courts and tribunals decide what constitutes effective service in proceedings before them, including service on persons outside Australia.

Items 33 and 34: Extensions of time for errors or omissions of New Zealand delegates

[s 223]

These items amend the Patents Act to remedy any default in doing a relevant act in time owing to an error or omission by a New Zealand delegate of the Australian Commissioner (see item 25), just as such defaults owing to errors or omissions by Australian officials and employees in the Patent Office can be remedied.

The Australian Commissioner must extend the time for doing the relevant act—if it is not done (or cannot be done) because of the error or omission of an Australian official or employee or a New Zealand delegate.

Item 34 inserts new subsections 223(1A) and 223(1B) stating that, for the purposes of subsection 223(1) of the Patents Act, it is immaterial whether

- the relevant act took place or is to take place in New Zealand
- the error or omission preventing the act being done in time took place in New Zealand.

This puts it beyond doubt that the Australian Commissioner is able to extend the time for doing a relevant act if the relevant act or the error or omission took place in New Zealand. See the notes for items 14 and 15 above.

Item 35: Administrative Appeals Tribunal review

[s 224]

This item amends the Patents Act to ensure that the decisions of New Zealand delegates of the Australian Commissioner are subject to review by the Administrative Appeals Tribunal ('AAT review') just as decisions of Australian delegates are reviewable. Generally, Australian legislation is presumed to only apply in Australia. See the notes to items 14 and 15.

New subsection 224(3A) states that it is immaterial for the purposes of section 224 whether a decision was made in New Zealand. That is, decisions under any of the provisions listed in paragraphs 224(1)(a), (b) and (c) are reviewable whether they are made in Australia or New Zealand.

Paragraph 224(1)(a) of the Patents Act lists the powers and functions of the Australian Commissioner that are subject to AAT review. These powers and functions are not usually exercised by Australian examiners of patents. They are therefore not expected to be delegated to New Zealand delegates examining Australian patent applications. However, in the future the Australian and New Zealand Governments might agree to one or more of those powers or functions being exercised or performed by New Zealand patents officials.[78]

In contrast to the decisions under the provisions listed in paragraph 224(1)(a), those listed in paragraphs 224(1)(b) and (d) are always expected to be made in Australia:

- a decision of the Designated Manager under section 198 not to register a person as a patent attorney
- a decision of the Director of Safeguards under sections 147, 149 or 152 of the Patents Act on the handling of patent applications containing 'associated technology' for the purposes of the *Nuclear Non-Proliferation (Safeguards) Act 1987*.[79]

So new subsection 224(3A) is not expected to have any practical effect on the reviewability of those decisions.

Items 36 and 37: Payment of Australian fees in New Zealand

[s 227]

These items amend the Patents Act to permit a fee prescribed in the Australian legislation to be paid in New Zealand currency to a New Zealand patents official authorised to receive the fee on behalf of the Commonwealth, so as to meet the requirement to pay the fee in Australia. This will allow someone filing an Australian patent document with a New Zealand patent official to pay any fee due at filing, without having to make a separate payment in Australia (see also item 28).

[78] See the notes on items 24 to 26 for discussion of the proposed bilateral instrument.
[79] The Director of Safeguards is established by section 42 of the *Nuclear Non-Proliferation (Safeguards) Act 1987*; see subsection 4(1) of that Act for the definition of 'associated technology': it includes documents containing information about the design or production of nuclear weapons.

The relevant New Zealand patents officials are:

- the New Zealand Commissioner
- a New Zealand Assistant Commissioner of Patents
- a person who is a delegate of the New Zealand Commissioner under New Zealand law.

For example, someone could file with the New Zealand Commissioner applications for the grant of patents in Australia and New Zealand for the same invention. At the same time, the person could pay a single amount in New Zealand dollars, comprising the New Zealand filing fee and the New Zealand dollar amount of the Australian filing fee.

The regulations will provide for working out the New Zealand dollar amounts of the Australian fees. These will reflect the terms of an instrument to be established between senior officials in IP Australia and the New Zealand Ministry of Business Innovation & Employment for setting these amounts.

It is proposed that the instrument will also require that the money received by the New Zealand patents officials on behalf of the Australian government be held in trust and be reconciled periodically. Australian patents officials and employees will also receive Australian dollar payments of New Zealand fees on behalf of the New Zealand government (see new s227AA inserted by item 38 below).

Item 38: Payment of New Zealand fees in Australia; Application of administrative law regime to decisions made in New Zealand

[s 227AA]

This item inserts new section 227AA into the Patents Act to permit officials and employees in the Patent Office to receive specified New Zealand fees in Australian dollars. This will allow someone filing a New Zealand patent document at the Patent Office to pay any fee due at filing, without having to make a separate payment in New Zealand.

For example, someone could file at the Patent Office applications for the grant of patents in Australia and New Zealand for the same invention. At the same time, the person could pay a single amount in Australian dollars, comprising the Australian filing fee and the Australian dollar amount of the New Zealand filing fee.

The regulations will provide for working out the Australian dollar amounts of the New Zealand fees. These will reflect the terms of an instrument to be concluded between senior officials in IP Australia and the New Zealand Ministry of Business Innovation & Employment for setting these amounts.

It is proposed that the instrument will also require that the money received by IP Australia on behalf of the New Zealand government be held in trust and be reconciled periodically. New Zealand officials will also receive Australian dollar payments of New Zealand fees on behalf of the Australian government (see item 37).

The Australian dollar amounts that IP Australia collects on behalf of the New Zealand government would be paid into a Special Account established by a determination of the

Finance Minister under section 20 of the *Financial Management and Accountability Act 1997*.[80]

[s 227AB]

Item 38 also inserts new section 227AB into the Patents Act. This new section ensures that decisions made in New Zealand under the Australian Patents Act and its regulations are subject to judicial or administrative review, just as are decisions made in Australia.

New subsections 227AB(1) and (2) ensure that the following persons can seek judicial review in the Federal Court of Australia under the *Administrative Decisions (Judicial Review) Act 1977* ('AD(JR) Act review')

- an individual or company affected by a decision of the Trans-Tasman IP Attorneys Board or the Trans-Tasman IP Attorneys Disciplinary Tribunal—whether the Board or the Tribunal make the decision in Australia or New Zealand.[81]
- anyone affected by a decision of a New Zealand delegate exercising or performing one of the Australian Commissioner's powers or functions (see item 25).

By way of example, the Board might decide that an individual—whose only academic qualification is a Bachelor of Laws degree—does not have an appropriate qualification to be a patent attorney. This is because the particular degree course is not in a field of science or technology containing potentially-patentable subject matter. This decision would prevent the individual from being registered as a patent attorney, without undertaking a further course of appropriate study.[82]

It is immaterial whether the Board's decision is made when the members of the Board are sitting together in New Zealand, are sitting together in Australia or are meeting by video-conference from several locations in Australia and New Zealand. In any of these cases, the individual would have the same right to seek AD(JR) Act review.[83]

New subsections 227AB(3) and (4) will ensure that the decisions subject to Administrative Appeals Tribunal ('AAT review') under the Patents Act and its regulations will be reviewable whether they are made in Australia, in New Zealand or in Australia and New Zealand (see below). See the notes on item 35 above for discussion of the decisions under the Patents Act that are subject to AAT review. See regulation 22.26 of the *Patents Regulations 1991* for the decisions made under the Patents Regulations that are subject to AAT review.

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[80] For example, see the *Services for other Entities and Trust Moneys—IP Australia Special Account* established under the *Financial Management and Accountability (Establishment of Special Account for IP Australia) Determination 2011/11*

[81] The Board is the Professional Standards Board continued as the Trans-Tasman IP Attorneys Board (see item 40). The Trans-Tasman IP Attorneys Disciplinary Tribunal will be established by regulations made under paragraph 228(2)(r) of the Patents Act.

[82] See currently regulation 20.6 of the *Patents Regulations 1991*, which refers to decisions of the Professional Standards Board

[83] Alternatively, the individual might seek Administrative Appeals Tribunal review of the decision under regulation 20.5 ('evidence of academic qualifications'): see currently regulation 22.26(2)(b)(i).

By way of example, the Trans-Tasman IP Attorneys Disciplinary Tribunal ('Disciplinary Tribunal') will hear disciplinary proceedings brought by the Board against a registered patent attorney. Each disciplinary matter will be heard by a three-member panel drawn from a larger 'pool' of members residing in Australia or New Zealand, who must be legal practitioners, patent attorneys or former patent attorneys. When disciplinary proceedings are brought against a New Zealand-resident attorney, the panel will include at least one member who ordinarily resides in New Zealand.

For instance, if disciplinary proceedings were brought against a New Zealand-resident attorney ('the charged attorney'), the three-member panel of the Disciplinary Tribunal will include a New Zealand-resident patent attorney. The Disciplinary Tribunal might, at its discretion, choose to:

- sit together in New Zealand to hear the charged attorney and witnesses in person
- sit together in Australia, with the charged attorney and the witnesses appearing remotely from New Zealand by video-conference[84]
- sit in Australia and New Zealand by video-conference, with the charged attorney and the witnesses also appearing remotely from New Zealand by video-conference.[85]

It is immaterial whether the decision of the Disciplinary Tribunal following the hearing is made in Australia, New Zealand or in both Australia and New Zealand. In all of these cases, an attorney found guilty by the Disciplinary Tribunal has exactly the same right to seek AAT review.[86]

Items 39 to 46: Trans-Tasman IP Attorneys Board

[s 227A]

These items amend the Patents Act to continue the Professional Standards Board for Patent and Trade Marks Attorneys under the new name 'the Trans-Tasman IP Attorneys Board' ('the Board') and with a new constitution reflecting the extended role of the Board as:

- the regulator of individuals and companies registered as patent attorneys in both Australia and New Zealand under the Patents Act
- the regulator of individuals and companies registered as trade mark attorneys in Australia under the Trade Marks Act.

'IP' refers to intellectual property: including patents, trade marks, designs, and plant breeder's rights.

For ease of reference, the Trans-Tasman IP Attorneys Board is referred to as 'the Board' throughout the rest of the Patents Act: see the definition of 'the Board' in item 49.

[84] It is proposed that regulations would be made under Division 2 of Part 6 of the *Trans-Tasman Proceedings Act 2010* prescribing the Disciplinary Tribunal and the Administrative Appeals Tribunal as Australian tribunals
[85] See above
[86] Currently, see regulation 22.26 (2) (d) of the *Patents Regulations 1991*

Substitute subsection 227A(1) continues the Professional Standards Board in existence under its new name and constitution. This ensures that any disciplinary proceedings the Professional Standards Board is conducting before commencement are not terminated by its renaming and re-constituting.

New subsections 227A(2A) and (2B) provide that the Board consists of up to ten members:

- a Chair
- the Director-General of IP Australia, who is one of the two *ex officio* members on the Board.
- the New Zealand Commissioner, who is the other of the two *ex officio* members.
- at least two ordinary members nominated by the New Zealand Patents Minister[87] to represent the New Zealand patent attorney profession
- at least two other ordinary members.

New subsection 227A(2D) requires that the Chair and the ordinary members must have substantial experience or knowledge, and significant standing, in one or more of these fields:

- Australian or New Zealand patent attorney practice
- Australian trade mark attorney practice
- the regulation of persons engaged in a prescribed occupation. This is to allow experienced regulators of professionals to become Board members
- public administration
- academia.

Under new subsections 227A(2C) and (2F), the Australian Minister of State who administers the Patents Act ('the Minister') appoints the Chair and the ordinary members by written instrument for the following periods:

- the Chair—for a period of up to three years
- the ordinary members including the members nominated by the New Zealand Patents Minister—for periods of up to five years.

It is expected that the position of Chair would usually be occupied alternately by someone ordinarily resident in Australia ('Australian resident') and then by someone ordinarily resident in New Zealand ('New Zealand resident') on a three-year cycle.

In a cycle, any vacancy would usually be filled for the rest of that cycle by someone else resident in the same country as the former chair. For example, say the Minister appoints a person ordinarily resident in Australia as Chair for a three-year term and the Chair resigns at the end of two years. The Minister would usually appoint another Australian resident as Chair for the remaining twelve months of the three-year period. If there was no suitable Australian resident willing to be Chair for the rest of the period, the Minister might appoint a suitable New Zealand resident for a three-year term.

[87] See the definition in item 56

The three-year maximum period for the Chair, and the expected alternation of the country of residence of its occupant, will ensure that there are no long intervals between either country's interests being represented at the highest level on the Board. The five-year maximum for the appointment of the ordinary members and the ongoing role of the two *ex officio* members allow them to support each newly appointed Chair with a depth of current experience. The Minister might re-appoint the ordinary members for further terms.[88] Although it is possible for the Minister to appoint someone who is or was an ordinary member to the office of Chair, it is not appropriate for that person to hold both of those offices at the same time.

The members of the Board would hold office on a part-time basis (new subsection 227A(2E)). Existing subsection 227A(4) provides for members of the Board to be paid remuneration determined by the Remuneration Tribunal. Substitute paragraph 227A(3)(a) inserted by item 43 will allow the regulations to specify the other terms and conditions on which the Chair and the ordinary members hold office. The *ex officio* members do not receive the remuneration or allowances paid to the Chair or the ordinary members of the Board: as public servants; they are already duly remunerated and paid allowances for performing their official duties.

New subsections 227A(2G) to (2M) permit the *ex officio* members to deputise public servants to attend Board meetings in their place. These deputies are also not entitled to any remuneration or allowances for attending a meeting, other than what they are usually paid for undertaking their duties as public servants.

Item 43 repeals paragraph 227A(3)(a) which permits regulations to be made for and in relation to the constitution and membership of the Professional Standards Board. This regulation-making power is no longer appropriate, as the constitution and membership of the Board is now set out in section 227A (see above). In place of that power, this item substitutes new provisions for making regulations governing the Chair and the ordinary members of the Board relating to:

- the terms and conditions on which they hold office (see discussion above)
- how they may resign their appointments
- how their appointments may be terminated.

Items 41, 44 and 45 replace several references in section 227A of the Patents Act to the Professional Standards Board with references to the Board, as a consequence of its renaming (see items 40 and 49).

Item 46 inserts new subsection 227A(7) stating that the Board may perform its functions in Australia or New Zealand. This puts it beyond doubt that the Board can operate as a trans-Tasman Board: whether in Australia, in New Zealand or in both Australia and New Zealand (i.e. meeting by audio-conference or video-conference from several locations in Australia and New Zealand).[89]

[88] See section 33AA of the *Acts Interpretation Act 1901*
[89] See the discussion of new section 227AB, inserted by item 38 above.

Item 47: Reference to the Professional Standards Board

[s228]

This item replaces a reference to the Professional Standards Board in subparagraph 228(2)(r)(ia) of the Patents Act with reference to the Board, as a consequence of its renaming (see items 40 and 49). That subparagraph is inserted by item 28 in Schedule 4 to the Raising the Bar Act, with effect from 15 April 2013.

Item 48: Regulations for matters in Australia or New Zealand

[s228]

This item inserts new subsections 228(4A) to (4E) into the Patents Act. These new subsections ensure that the Patents Regulations can provide appropriately for:

- functions to be performed, or powers to be exercised, in New Zealand
- Administrative Appeals Tribunal review of decisions made in New Zealand
- any matters (including acts or omissions) governed by the Patents Regulations, which happen to take place in New Zealand.

As a result, the Patents Regulations will be able to govern the conduct of registered patent attorneys in New Zealand, including providing for their discipline there by the Board and by the Trans-Tasman IP Attorneys Disciplinary Tribunal.[90]

The Patents Regulations confer powers and functions on the Australian Commissioner, who may delegate them to New Zealand patents officials (see item 25 above). Those regulations will also be able to make any necessary provision for the exercise or performance in New Zealand of those delegated powers or functions.

Items 49 to 59: Amendments to Schedule 1 (definitions)

The following items amend Schedule 1 of the Patents Act to insert, amend or repeal definitions of expressions used in that Act and its regulations.

Items 49 and 58 'Board' and 'Professional Standards Board'

Item 49 inserts the definition of the expression 'Board' as the Trans-Tasman IP Attorneys Board continued in existence by substituted subsection 227A(1) (see item 40). Item 58 repeals the definition of the expression 'Professional Standards Board' as a consequence of it being replaced throughout the Act by the expression 'Board' (see items 41 to 45 and 47).

Item 50 company

This item repeals the definition of the expression 'company'[91], and substitutes a new definition referring to a company registered under the Australian or the New Zealand

[90] The Board is the Professional Standards Board continued as the Trans-Tasman IP Attorneys Board (see item 40). The Trans-Tasman IP Attorneys Disciplinary Tribunal will be established by regulations made under paragraph 228(2)(r) of the Patents Act.

corporations legislations. This puts it beyond doubt that a provision in the Patents Act referring to a company also governs New Zealand companies. See for example, the provisions for registering companies as incorporated patent attorneys in new subsections 198(9) to (11) of the Patents Act.[92] See also Part 2 of Chapter 20 of the Patents Act for the offences committed by companies that are not registered as patent attorneys.[93]

Item 51 Director-General of IP Australia

This item inserts the definition of the expression 'Director-General of IP Australia'. For examples of its use, see new subsections 227A(2A) and (2G) to (2J) inserted by item 42.

Item 52 file

This item inserts a note to the definition of the expression 'file', pointing the reader to section 214 which is amended by item 28.

Item 53 New Zealand Assistant Commissioner of Patents

This item inserts the definition of the expression 'New Zealand Assistant Commissioner of Patents'. For examples of its use, see new subsections 214(2) and 227(6) inserted by items 28 and 37 respectively. Currently, section 4 of the Patents Act 1953 (NZ) provides for one or more persons to be Assistant Commissioners of Patents. The Patents Bill currently before the New Zealand Parliament would, if enacted, continue these offices.[94]

Item 54 New Zealand Commissioner of Patents

This item inserts the definition of the expression 'New Zealand Commissioner of Patents'. For examples of its use, see new subsections 214(2), 227(6) and 227A(2A) inserted by items 28, 37 and 42 respectively. Currently, section 3 of the Patents Act 1953 (NZ) provides for a Commissioner of Patents. The Patents Bill currently before the New Zealand Parliament would, if enacted, continue this office.[95]

Item 55 New Zealand delegate

This item inserts the definition of the expression 'New Zealand delegate' as a New Zealand patents official who is a delegate under subsection 209(1A) (see item 25). The expression 'New Zealand patents official' is defined in turn in item 57.

Item 56 New Zealand Patents Minister

This item inserts the definition of the expression 'New Zealand Patents Minister', used in new paragraph 227A(2A)(d) inserted by item 42.

Item 57 New Zealand patents official

This item inserts the definition of the expression 'New Zealand patents official' used in new subsections 209(1A) and 227A(2K) inserted by items 25 and 42 respectively.

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[91] Inserted by item 29 in Schedule 4 to the Raising the Bar Act (with effect from 15 April 2013)
[92] inserted by item 21 in Schedule 4 to the Raising the Bar Act (with effect from 15 April 2013)
[93] As amended by items 24 to 27 in Schedule 4 to the Raising the Bar Act (with effect from 15 April 2013)
[94] See clause 266 of the Patents Bill 235-2 available at http://www.legislation.govt.nz/bill/government/2008/0235/latest/versions.aspx
[95] See note 74 above.

Item 59 Registrar of Companies of New Zealand

This item inserts the definition of the expression 'Registrar of Companies of New Zealand' used in new subsection 183(3) inserted by item 16.

Plant Breeder's Rights Act 1994

Items 60 to 68: Service of documents in Australia or New Zealand

[s 3, s 19, s 21, s 26, s 31 and 73]

These items broaden the allowable addresses for service of documents under the Plant Breeder's Rights Act, and provide flexibility in specifying the means of service.

Currently, an address for service of documents (including notices) under the Plant Breeder's Rights Act ('PBR Act') must be a physical or postal address in Australia, and the permitted means of service are by postal or personal delivery to that address (see also section 28A of the *Acts Interpretation Act 1901*).

These items amend the PBR Act to allow an address in New Zealand to be an address for service of documents. As a result any person seeking plant breeder's rights (PBR) in Australia will be able to nominate an address in Australia or New Zealand as their address for receiving documents from the Secretary or the Registrar of Plant Breeder's Rights.

Item 68 repeals the existing provision in section 73 of the PBR Act for the service of documents, substituting a new provision allowing a document to be served on an address for service in Australia or New Zealand by means prescribed in the regulations. Initially, the prescribed means would be those currently available: by post.

In future, IP Australia proposes to develop electronic means for routinely and securely serving notices on electronic addresses in Australia or New Zealand. When appropriate means are available, these may be prescribed in the regulations.

There might be some uncertainty about whether an electronic address can be an address for service in Australia or in New Zealand. To put this beyond doubt, new subsections 3(2) to (6) substituted by item 61 allow an electronic address to be an address for the purposes of the PBR Act. This will apply from a time specified in regulations, but not before those regulations are registered in the Register of Legislative Instruments under the *Legislative Instruments Act 2003.* The question of whether a particular electronic address is in Australia or in New Zealand is to be determined in accordance with the regulations.

Several addresses required in an application for PBR must continue to be physical addresses: the address of the applicant, that of any Australian or New Zealand agent and that of the breeder (if the breeder is not the applicant). See new subsection 3(4) inserted by item 61, which ensures that several references to addresses in existing subsections 26(2) and (3) do not include electronic addresses..

These amendments do not affect the rules of courts or tribunals governing service. The courts and tribunals decide what constitutes effective service in proceedings before them, including service on persons outside Australia.

Neither Australia nor New Zealand registers specialists to assist businesses to obtain and maintain PBR.

Trade Marks Act 1995

Items 69 to 72 and 79 to 81: Replacing references to the Professional Standards Board with references to the Board

[Readers guide, s 6, s 228A and s 231]

These items amend the Trade Marks Act by replacing several references to the Professional Standards Board with reference to the Board, as a consequence of its renaming (see items 40 and 49). Items 71 and 72 repeal the definition of the expression 'Professional Standards Board', and define the expression 'Board' as having the same meaning as in the *Patents Act 1990*.

Just as the Professional Standards Board has now, the Trans-Tasman IP Attorneys Board will have a central role in accrediting persons for registration as trade marks attorneys, and in the discipline of registered trade marks attorneys.

Items 73 to 78: Service of documents in Australia or New Zealand

[s 215]

These items broaden the allowable addresses for service of documents under the Trade Marks Act, and provide flexibility in specifying the means for service of those documents.

Currently, an address for service under the Trade Marks Act must be a physical or postal address in Australia, and the permitted means of service are by postal or personal delivery to that address (see also section 28A of the *Acts Interpretation Act 1901*).

Item 73 amends subsection 215(5) of the Trade Marks Act to allow an address in Australia or New Zealand to be an address for service of documents under that Act. As a result any person seeking trade mark protection in Australia will be able to nominate an address in Australia or New Zealand as their address for receiving notices from the Registrar of Trade Marks.

Item 74 repeals and substitutes paragraph 215(6)(a) of the Trade Marks Act so that a document may be served on an address for service in Australia or New Zealand by means prescribed in the regulations. Initially, the prescribed means are proposed to be those currently available: by post. In future, IP Australia proposes to develop electronic means for routinely and securely serving notices on addresses in Australia or New Zealand. When appropriate means are available, these may be prescribed in the regulations.

There might be some uncertainty about whether an electronic address can be an address in Australia or in New Zealand. To put this beyond doubt, item 78 inserts new subsections 215(8) to (11) to allow an electronic address to be an address in Australia or in New Zealand for the purposes of section 215. This will apply from a time specified in regulations, but not before those regulations are registered in the Register of Legislative

Instruments under the *Legislative Instruments Act 2003*. The question of whether a particular electronic address is in Australia or in New Zealand is to be determined in accordance with the regulations.

Paragraph 215(6)(b) of the Trade Marks Act currently addresses the case of a person who does not have an address for service in Australia. In that case, a document may be served on an agent of the person in Australia, or be sent by post to any address of the person in Australia that is known to the Registrar. By analogy with the amendments made by items 73 and 74, items 75 to 77 will ensure that the document may be:

- served on an agent of the person in Australia or New Zealand
- be sent by a prescribed means to any address of the person in Australia or New Zealand known to the Registrar.

These amendments do not affect the rules of courts or tribunals governing service. The courts and tribunals decide what constitutes effective service in proceedings before them, including service on persons outside Australia.

In Australia, patent attorneys, trade marks attorneys and legal practitioners advise businesses on how to protect their trade marks. New Zealand does not register specialist trade marks protection professionals.

Part 2—Transitional provisions

Item 82: Transitional registration of New Zealand patent attorneys as Australian patent attorneys

This item provides that all patent attorneys registered in New Zealand, but not in Australia, will be entered into the Australian Register of Patent Attorneys. This will allow the Australian register to become the single trans-Tasman register of patent attorneys.

Shortly after commencement, the Designated Manager will register the patent attorneys currently registered in New Zealand, who are not also currently registered in Australia. These attorneys will not be required to apply for this transitional registration, or meet the usual requirements for registration under section 198 of the *Patents Act 1990*. Nor will they be required to pay an application or registration fee. Depending on when the schedule commences, they may, however, have to pay the annual renewal fee for the next year shortly after their registration in Australia. That fee falls due on 1 July of each year.

Item 83: Transitional qualification of persons who had not yet completed the New Zealand registration exams

This item allows regulations to be made to ensure that persons who are not registered in New Zealand as patent attorneys at commencement, but who have commenced the qualifying examinations in New Zealand will not be disadvantaged by the new regime.[96]

[96] The New Zealand qualifying examinations are conducted under Part 30 of the Patents Regulations 1954 (NZ), available via http://www.legislation.co.nz/regulation/public/1954/0211/latest/versions.aspx. Part 30 will not be affected by the enactment of the Patents Bill currently before the New Zealand Parliament: see Paragraph 295A(2)(d) of the Patents Bill 235-2 available at http://www.legislation.govt.nz/bill/government/2008/0235/latest/versions.aspx

A person who passes at least one of those qualifying examinations before commencement, and passes all the rest of the examinations within four years of commencement, will be able to apply for registration in Australia without obtaining any further qualification. In particular, the candidate will not be required to meet the academic or knowledge requirements prescribed under paragraph 198(4)(b) of the *Patents Act 1990*.[97] The candidate will have to comply with the other requirements under subsection 198(4): prescribed employment, good character and non-criminality. To rely on this provision, the candidate must apply for registration within six months of receiving written notification that all examinations have been passed, but this six-month period for applying may end after the four-year period for completing the examinations.

This exemption from the usual requirements ceases to apply to a candidate who fails to pass all the examinations within the four-year period, or fails to apply for registration within six months of receiving written notification that all examinations have been passed. It will be open to such a candidate to undertake any necessary tertiary study to meet the usual academic and knowledge requirements for registration in Australia. The Board may, in its discretion, accept that the qualifying examinations such a candidate has passed in New Zealand address some or all the Australian knowledge requirements.

Item 84: Deregistration of patent attorneys for conduct in New Zealand before commencement

This item allows regulations to be made prescribing grounds for deregistration of patent attorneys relating to their conduct in New Zealand before the commencement of the new regime. Section 199 of the Patents Act allows patent attorneys to be deregistered on the prescribed grounds (see also item 23 above).

This is to ensure that some effect can be given to a decision of a New Zealand court in disciplinary proceedings against a patent attorney registered in New Zealand. Under section 102 of the Patents Act 1953 (NZ), the New Zealand Commissioner or the New Zealand Institute of Patent Attorneys Incorporated (with leave in writing of the New Zealand Attorney-General) may apply to the New Zealand High Court for removal of a patent attorney's name from the New Zealand register of patent attorneys or suspension of the attorney from practice. The court may order the removal or suspension on several grounds, including conviction of a crime of dishonesty, professional misconduct or grave impropriety.[98]

New Zealand advises that such actions are rare. Nevertheless, this provision will continue to apply to all such conduct committed in New Zealand before the commencement of the new regime. That is, even after commencement, new actions for removal or suspension may be begun in the New Zealand High Court.

Regulations made for the purposes of section 199 will prescribe deregistration of an attorney on the grounds specified in the section 102 of the Patents Act 1953 (NZ). The Designated Manager must remove a patent attorney's name from the register, if the New Zealand Commissioner advises the Designated Manager in writing that:

[97] The academic and knowledge requirements are currently prescribed in regulations 20.6 and 20.8 of, and Schedule 5 to, the *Patents Regulations 1991*.
[98] See via http://www.legislation.govt.nz/act/public/1953/0064/latest/DLM281010.html

- the New Zealand High Court has determined that a person should not practise as a patent attorney in New Zealand, whether indefinitely or for some fixed period
- the decision is final—all rights of appeal in New Zealand have been exhausted and the decision still stands.

Item 85: Transitional registration of New Zealand patent attorneys as Australian trade marks attorneys

This item allows New Zealand-registered patent attorneys to be transitionally registered as trade marks attorneys in Australia in appropriate cases. The New Zealand patent attorney must apply to the Designated Manager—within 12 months of the legislation commencing—with evidence:

- demonstrating the attorney's competence in trade mark law and practice to the Designated Manager's satisfaction. This need not be a specific or substantial competency in Australian trade mark law and practice. It will suffice that the individual's level of competency in trade marks law and practice in Australia or New Zealand is sufficient to warrant the individual becoming a registered trade marks attorney in Australia.
- that in the previous five years the attorney has not been convicted in Australia or New Zealand of a prescribed offence. It is proposed to prescribe offences against either country's intellectual property legislation. These are what would be prescribed under paragraph 198(4)(e) of the Patents Act for individuals seeking registration as patent attorneys. See the notes on items 20 and 21 above.
- that the attorney is not under sentence of imprisonment in Australia or New Zealand for a prescribed offence. It is proposed to prescribe offences of dishonesty with a maximum penalty of at least two years imprisonment, just as would be prescribed under paragraph 198(4)(f) of the Patents Act.

New Zealand does not have a trade marks attorney profession. Instead some New Zealand-registered patent attorneys specialise in trade marks work. Those New Zealand attorneys will become Australian patent attorneys under the single trans-Tasman patent attorney regime (see item 82 above). Registration as a patent attorney does not, however, allow anyone to market oneself as a trade marks attorney in Australia.[99] This requires registration as an Australian trade mark attorney.

In contrast to the automatic transitional registration of New Zealand patent attorneys under item 82, transitional registration as an Australian trade marks attorney is discretionary. It will require consideration of an individual's competency in trade marks law and practice. Accordingly, the transitional applicant will have to pay a prescribed application fee. This would be set to the same amount as that paid for ordinary applications for registration as a trade marks attorney (currently $300).

[99] See the offence in subsection 156(1) of the *Trade Marks Act 1995*, as substituted by item 46 in Schedule 4 to the Raising the Bar Act (with effect from 15 April 2013)

Schedule 5—Other Amendments

Introduction

Part 1 of this schedule removes the document retention requirements in the Patents Act, Trade Marks Act and the Designs Act. This ensures that IP Australia's retention of documents is governed solely by the *Archives Act 1983* and its records disposal authorities. This will allow redundant physical documents to be disposed of sooner, reducing Government expense.

The legislation administered by IP Australia currently requires patents, trade marks and designs documents filed at IP Australia to be physically stored for an extended period of time. For example, the application documents for a trade mark cannot be destroyed until 25 years after the registration has ceased.

The retention and disposal of documents is already comprehensively governed by the Archives Act and the records disposal authorities issued by the National Archives of Australia. However, the patents, trade marks and designs legislation often require documents to be retained for longer periods of time than would otherwise be required by the National Archives. This leads to unnecessarily long retention periods and significant Government expense in maintaining warehouse facilities for documents that are no longer relevant.

Part 2 of this schedule primarily addresses a number of minor oversights in the drafting of the *Intellectual Property Laws Amendment (Raising the Bar) Act 2012* ('Raising the Bar Act'). The Raising the Bar Act made a series of reforms to Australia's intellectual property system, with effect from 15 April 2013. Part 2 also makes some minor technical corrections to drafting oversights in the Patents Act.

Part 1—Document Retention

Items 1 and 2: Designs Act 2003

[s 69]

These items remove the requirement for the Registrar of Designs to retain material provided under section 69(1) of the Designs Act. Retention of this material will continue to be governed by the Archives Act, as outlined in the introduction to this schedule.

Item 3: Patents Act 1990

[s 228]

This item removes the provision in the Patents Act that enables the Governor-General to make regulations that prevent documents relating to patent applications being scheduled for destruction before 25 years have elapsed from the filing date of the patent application. Retention of these documents will continue to be governed by the Archives Act, as outlined in the introduction to this schedule.

Item 4: Trade Marks Act 1995

[s 231]

This item removes the provision in the Trade Marks Act that enables the Governor-General to make regulations that prevent documents relating to a trade mark being scheduled for destruction before 25 years have elapsed from the date that registration of the trademark ceased. Retention of these documents will continue to be governed by the Archives Act, as outlined in the introduction to this schedule.

Item 5: Application of amendments

Amendments made by this schedule apply in relation to material and documents provided or filed before, on or after commencement.

Part 2—Technical amendments

Item 6: Heading replacement

[s 24]

This item is a consequential amendment to the heading of section 24 of the Patents Act, to reflect amendments made to section 24 in item 32 of Schedule 6 to the Raising the Bar Act.

Items 7 and 8: Requests from PCT applicants prior to national phase entry

[s 29A]

Items 7 and 8 repeal the note under section 29A and amend the Patents Act to reinstate the requirement that an international applicant under the Patent Cooperation Treaty (PCT) cannot require that anything be done under the Patents Act for their PCT application—unless it enters national phase in Australia. For that to happen, the international applicant must pay the prescribed fees and file prescribed documents, as mentioned in subsection 29A(5), as inserted by the Raising the Bar Act. If the PCT application is not in English, a translation must also be filed.

Under the PCT, an international applicant has 31 months from the earliest priority date of their PCT application to enter the national phase in Australia. Prior to the commencement of item 67 of Schedule 6 to the Raising the Bar Act, subsection 89(3) of the Patents Act provided that a PCT applicant was not entitled to ask that anything be done under that Act, unless their PCT application had entered national phase. This ensured that they could not request that the Commissioner examine and amend their application until they had provided the Commissioner with a copy of the application and paid the appropriate fees.

However, due to an oversight in drafting, section 29A inserted by item 34 of Schedule 6 to the Raising the Bar Act was only phrased as requiring a PCT applicant to meet the requirements of subsection 29A(5) (National Phase Entry) by a certain period. Section 29A does not permit the Commissioner to refuse early requests from the PCT applicant

before they have met the requirements of national phase entry. This could result in applicants requesting examination or amendment before they have paid their fees or provided a copy of the application to be examined.

Note that the new subsection 29A(6) under item 8 does not refer to the prescribed period in subsection 29A(5). This ensures that a PCT applicant who files the translation and prescribed documents, or pays the prescribed fee, outside of the prescribed period, is not prevented from asking for an extension of time under section 223 to extend the prescribed period.

Item 9: Prescribing period for Paris Convention applications

[s 29B]

This item amends subsection 29B(2) of the Patents Act inserted by item 34 of Schedule 6 to the Raising the Bar Act so that it does not refer to the prescribed period for Paris Convention applications. The Patents Act provides the prescribing period, with regard to Paris Convention applications, under two separate sections of the Act: 29B(2) and 38(1A). The amendment corrects a drafting oversight: the prescribed period was intended to be under subsection 38(1A), not under subsection 29B(2). This amendment is to remove duplication only; the prescribed period will remain the same.

Item 10: Reference correction

[s 29B(6)]

This item corrects a referencing error in existing subsection 29B(6), which incorrectly refers to subsection 29B(1). The item corrects this error so that subsection 29B(6) correctly refers to the definition of ‘convention country’ in subsection 29B(5).

Item 11: Subsection heading

[s 40]

This item inserts a subheading above subsection 40(2) to clarify that the subsection relates to requirements for complete specifications. This follows the amendment made by item 7 of Schedule 1 to the Raising the Bar Act, which inserted a subheading to subsection 40(1) of the Patents Act relating to provisional applications.

Item 12: Disclosure requirements for provisional applications for micro-organism inventions

[s 41]

This item inserts new subsection 41(1A) into the Patents Act to make it clear that a properly deposited micro-organism can be taken into account for meeting the disclosure requirements for provisional applications, just as it can for complete applications. This amendment ensures that applicants’ current practice of depositing micro-organisms meets the requirements of the Patents Act. It does not impose any new obligations on applicants.

Under the Patents Act, an applicant can either file a complete application or a provisional application. A provisional application establishes a priority date for a later complete application that discloses the same invention. Provisional applications are required to disclose the invention, but unlike complete applications they are not examined and cannot be refused for a failure to disclose the invention.

Often for inventions related to micro-organisms it is impracticable to describe the invention in writing. Section 41 of the Patents Act and the Budapest Treaty provide for the meeting of the disclosure requirement by depositing a sample of the micro-organism with a prescribed depositary institution.[100] However, section 41 applies only to the disclosure requirement for complete applications, not provisional applications. Item 7 of Schedule 1 to the Raising the Bar Act imposed a new disclosure requirement for provisional applications in subsection 40(1) of the Patents Act. However, as an oversight, no provision was made in section 41 for meeting the new disclosure requirement in subsection 40(1) in relation to micro-organisms by providing for a sample micro-organism to be deposited at a prescribed depositary institution. Although there is no direct consequence for failing to comply with subsection 40(1), it is desirable to clarify that a properly deposited sample can be relied on for the purpose of subsection 40(1) to avoid any doubt that the applicant has complied with the Patents Act.

The prescribed circumstances under new paragraph 41(1A)(b) will specify the date by which the deposit must be made, as well as other conditions necessary for the benefit of the deposit to be obtained.

Item 13: Combination of documents for disclosure of invention

[s 43]

This item amends paragraph 43(2A)(b) of the Patents Act to make it clear that subsection 43(2) refers not only to a prescribed document, but also to multiple prescribed documents considered together.

A basic principle of the patents legislation is that a patentee should get protection for no more and no less than what they disclose about the workings of the invention. In most cases, the disclosure is a single document. However, in certain circumstances two documents considered together, but not separately, can provide for this disclosure.

Item 10 of Schedule 1 to the Raising the Bar Act amended subsection 43(2) of the Patents Act to refer to a prescribed document (in singular form). Although paragraph 23(b) of the *Acts Interpretation Act 1901* ensures that the reference to the document (singular) includes a reference to document (plural), it is desirable to avoid any doubt that multiple prescribed documents can be considered together. This item makes that clear.

[100] Australia is party to the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure; see section 6 of the Patents Act for the ***deposit requirements***; see also the definitions of ***Budapest Treaty***, ***international depository authority*** and ***prescribed depositary institution*** in Schedule 1 to the Patents Act.

Item 14: Disclosure requirements to support the priority date for micro-organism inventions

[s 43]

This item inserts new subsection 43(2B) into the Patents Act to make it clear that, in relevant circumstances, a properly deposited sample micro-organism can be taken into account when determining whether a claimed invention has been disclosed for determining a priority date of the claim.

As discussed in item 12 above, section 41 of the Act permits the disclosure requirement in section 40 to be met for an invention related to a micro-organism by deposit of a sample with a prescribed depositary institution.

Under section 43 of the Patents Act, the priority date of the invention is the date the invention is first disclosed, either in the specification of the complete application in which the invention is claimed or in an earlier related patent application. However, due to an oversight, subsections 43(2) and (2A) inserted by item 10 of Schedule 1 to the Raising the Bar Act do not account for the situation where the requirement for a disclosure of an invention relating to a micro-organism can only be met by a deposit under the Budapest Treaty.[101] This item corrects that oversight.

The prescribed circumstances under new paragraph 43(2B)(b) will specify the date by which the deposit must be made as well as other conditions necessary for the benefit of the deposit to be obtained.

Item 15: Typographic error

[s 101E]

This item corrects a typographical error by inserting the conjunction ‘and’ at the end of subparagraph 101E(1)(a)(ix) of the Patents Act. The conjunction was inadvertently omitted when item 21 of Schedule 1 to the Raising the Bar Act substituted section 101E of the Patents Act to clarify the obligations of the Commissioner regarding certificates of examination for innovation patents.

Item 16: Infringement exemption

[s 119]

This item amends paragraph 119(3)(b) of the Patents Act to correct an inadvertently-created inconsistency between that provision and the related provisions of paragraph 24(1)(a) of the Patents Act.

Ordinarily, if information about an invention is made publically available before a patent application is filed for the invention, the invention is not novel and so is unpatentable. However, section 24 of the Patents Act provides a 'grace period' so that, in certain circumstances, disclosure of an invention before filing the patent application for it does not make the invention unpatentable. To balance this against the interests of third parties

[101] See note 101 above

who may have relied on the information being in the public domain, paragraph 119(3)(b) provides a countervailing exception to infringement. A third party does not infringe a patent if they derived the invention from information made publicly available by the applicant during the grace period.

Item 32 of Schedule 6 to the Raising the Bar Act amended paragraph 24(1)(a) of the Patents Act to omit the words 'through the publication or use of the invention'. This was so that the grace period applies more widely to ‘information made publicly available’. However, as an oversight, the same words appearing in paragraph 119(3)(b) were not also omitted. This item corrects the oversight, ensuring that the grace period and the countervailing infringement exemption continue to be aligned. The amendment would commence retrospectively, to ensure that without doubt, a third party does not infringe a patent if they derived the invention from information made publicly available by the applicant during the grace period.

This amendment will have little or no difference in practice, but puts the matter beyond legal doubt so that competitors of a patentee are not disadvantaged in relation to conduct before a patent application was filed. Infringement occurs where there is unauthorised use of a patented invention. As far as infringement is concerned, there is very little difference between the two meanings: the invention being made publicly available by publication or use; and information about the invention being made publicly available.

The commencement of item 16 is highly unlikely to have an effect on individual rights, liberties or obligations. It is the clear policy of the Patents Act as it stands that the infringement exemption be aligned with the grace period. This item, when enacted, will continue the existing policy that a patentee cannot sue a competitor for a use derived from information publicly disclosed by the patentee before they applied for a patent. Retrospective effect will ensure consistency of legislation, clarity for users, and put the matter beyond legal doubt.

Item 17: Commencement of actions for false representation

[s 178]

This item amends section 178(4) of the Patents Act to require that a proceeding for an offence under section 178 (1A) cannot be commenced without the consent of the Minister, or a person authorised by the Minister.

Section 178(1A) provides that a person must not falsely represent that he, she, or another person, is the patentee of an innovation patent that has been certified. Similar to the offence provisions related to standard patents in section 178(1) and (2), a prosecution for an offence should not be started without the relevant consent. However, due to a drafting oversight at the time section 178(1A) was inserted, section 178(4) was not amended to include a reference to section 178(1A).

This item will align section 178 so that ministerial consent is required for the commencement of actions for false representation for both standard and innovation patents.

Item 18: Rectification of the Patent Register in respect of entitlement disputes

[s 191A]

This item amends the Patents Act to make it clear that subsection 191A(4) only governs the right to a hearing in administrative proceedings concerning a person's entitlement to a patent or share in it.

Item 79 of Schedule 6 to the Raising the Bar Act introduced section 191A providing for the Commissioner to rectify the Register of Patents. One type of rectification is for the Commissioner to correct an error in entitlement to the patent. Before making such a rectification, the Commissioner is required under subsection 191A(4) to hear both the parties currently listed on the Register as being entitled to the patent and those people claiming that they should be listed as entitled.

However, the rectification power also provides for rectifications that do not relate to entitlement, for example, corrections of minor errors in the Register (e.g. an incorrectly recorded address for service). Due to an oversight, the right to a hearing in subsection 191A(4) applies even if the proposed rectification is not related to an entitlement matter.

This item makes it clear that subsection 191A(4) does not apply if the Commissioner proposes to correct some other type of error in the Register. The existing right to a hearing under section 216 of the Patents Act and regulation 22.22 of the *Patents Regulations 1991* apply instead.

Item 19: Remove reference to repealed provision

[s 224]

This item amends section 224(1)(a) to remove a reference to a repealed provision.

Section 224(1)(a) provides that a decision made by the Commissioner under section 142(2)(b) can be reviewed by the Administrative Appeals Tribunal.

The reference to s.142(2)(b) no longer applies, as it was repealed by Schedule 1, item 24 of the *Patents Amendment Act 2001*. However, due to an oversight the cross reference was not deleted at the time.

Item 20: Application of amendments

Sub-item (1): The amendments in items 6 and 16 apply to information that is publicly available at or after the time those items commence. These items are due to commence retrospectively, in line with the commencement of item 32 of Schedule 6 to the Raising the Bar Act. As noted above, these items correct drafting oversights made in preparing the Raising the Bar Act and seek to clarify existing laws only.

Sub-item (2): The amendments made by items 7, 8 and 9 apply in relation to applications made at or after the time those items commence.

Sub-item (3): The amendments in item 12 relating to provisional applications apply at or after commencement.

Sub-item (4): The amendments made by item 13 and item 14 apply in relation to the following:

- patents for which the complete application is made at or after the time of their commencement (paragraph a);
- standard patents for which applications had been made before their commencement, if no request had been made for examination of the application before their commencement (paragraph b);
- innovation patents granted at or after their commencement, provided the complete application to which the patent relates had been made before their commencement (paragraph c);
- complete patent applications made at or after the time of commencement (paragraph d);
- complete applications for standard patents made before commencement, if no request had been made for examination of the application before that time (paragraph e);
- complete applications for innovation patents made before their commencement, if a patent had not been granted in relation to the application on or before that time (paragraph f);
- innovation patents granted before their commencement, provided the Commissioner had not decided to examine the complete specification relating to the patent under section 101A of the Patents Act before that time, and if the patentee or any other person had not requested examination of the complete specification relating to the patent under section 101A of the Patents Act before that time (paragraph g).

Sub-item (5): The amendments made by item 18 apply on and after the date of commencement in relation to patents granted before, on or after commencement.