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:

- 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

[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.

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 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:

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[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 >.

(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,

[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>.,

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 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.

[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.

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 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

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[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

the countries studied, 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.

Science (PLOS) Medicine, 31 August 2010, viewed on 12 September 2013 at <http://www.plosmedicine.org/article/info%3Adoi%2F10.1371%2Fjournal.pmed.1000333>.

[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.

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 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

[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.

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.

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

[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>.
[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.

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 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

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[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 (http://medicinesaustralia.com.au/about-us/our-members/)
[31] There are 11 members of the Generic Medicines Industry Association (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;

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.

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 **Attachment A** 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.

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

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

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

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.

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.

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

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

[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>

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 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

[38] http://www.aidslaw.ca/publications/interfaces/downloadFile.php?ref=2081 – viewed 4 December 2013

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 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.

[39] Annex to the TRIPS Agreement, paragraph 7.
[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>.

- 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.

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.

Attachment A

Regulatory cost calculation and off-set

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.[1] 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.[2] 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.[3]

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

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*.[4] 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.[5]

The ABS *Employee Earnings and Hours Survey* reports average earnings for a range of legal professionals.[6] As summarised in table 3, intellectual property lawyers,[7] 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,[8] and barristers,[9] 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)[10]

	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**

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.[11] 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.[12]

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.[13] 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.[14]

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.[15] The low cost estimate is $17,825 and the high is $23,375.

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%.[16]

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.

Table 8: Court Fees[17]

	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.[18] 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.[19]

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%.

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.[20]

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.[21]

Table 8: 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

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

[1] There are 52 firm members of Medicines Australia, which represents originator pharmaceutical companies operating in Australia (http://medicinesaustralia.com.au/about-us/our-members/) and the Generic Medicines Industry Association which has 11 members (http://www.gmia.com.au/about-gmia/gmia-members/)

[2] 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)

[3] http://ipta.org.au/find-an-attorney/ has a search capability where one can get a total 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.

[4] 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=

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

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

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

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

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

[10] Charge out rates for legal professionals can range from $120 per hour to $800 per hour or more (source). 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.

[11] http://www.ip-watch.org/2010/03/01/efficacy-of-trips-public-health-amendment-in-question-at-wto/

[12] 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]

[13] http://www.fedcourt.gov.au/forms-and-fees/legal-costs/national-guide-counsel-fees

[14] 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

[15] [Fixed fees of $12,590 + 1 days court fees of $3,135 + 1 days senior counsel at $5,925]

[16] 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.

[17] Source: Federal Courts fee schedule. See fee items 101 and 116 for Federal Court fees, and fee items 201 and 215 of Federal Circuit Court fees

[18] 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]

[19] See the ACIP review of PBR enforcement, page 86, footnote 104 for the details here: http://www.acip.gov.au/pdfs/ACIP_Final_Report_Review_of_Enforcement_of_PBR_Archived.pdf

[20] [$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]

[21] [$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]