REGULATION IMPACT STATEMENT

EXPORT OF PATENTED PHARMACEUTICALS TO COUNTRIES EXPERIENCING A HEALTH CRISIS

1. BACKGROUND

1.1 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 2009, an estimated 272 million people were infected with malaria, HIV/AIDS or tuberculosis, causing 3.9 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 2010', World Health Organization, 2010, Part II Global Health Indicators, Table 3.
[2] 'World Malaria Report 2010', World Health Organization, 2010; ''UNAIDS Report on the Global AIDS Epidemic 2010', UNAIDS, 2010; 'Global Tuberculosis Control 2010', World Health Organization, 2010.
[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 $135 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 $100 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.

1.2 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.

---

[4] 'Options for Increasing Access to Medicines in the Developing World', Biotechnology Industry Organization, policy statement May 2010.
[5] 'ViiV Healthcare announces further initiatives to improve access to HIV medications for people living in the least developed countries', ViiV Healthcare media release, 16 July 2010.
[6] 'The Medicines Patent Pool Initiative', UNITAID, viewed 16 November 2010 at <http://www.unitaid.eu/en/The-Medicines-Patent-Pool-Initiative.html>.
[7] 'Australia's Global HIV/AIDS Initiative', AusAID, viewed 5 August 2011 at <http://www.ausaid.gov.au/keyaid/hivaids/response.cfm>
[8] 'AusAID-Clinton Foundation Partnership', AusAID, viewed 5 August 2011 at <http://www.ausaid.gov.au/keyaid/hivaids/foundation.cfm>.

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:

> (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 authorized predominantly for the supply of the domestic market of the Member authorizing 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 authorization.

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.

1.3 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 48[9] least-developed countries and potentially 100[10] developing countries that could fall into this category. Around 25 of these are in the Asia-Pacific region.

10. In November 2001, the Fourth WTO Ministerial Conference in Dohar, 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

[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 5 August 2011 at < http://www.unohrlls.org/en/ldc/25/>.
[10] 'World Economic Outlook', International Monetary Fund, April 2010, Table 'Emerging and Developing Economies'.
[11] 'Declaration on the TRIPS Agreement and public health', WT/MIN(01)/DEC/2, 20 November 2001.

provisions under the TRIPS Agreement, and a solution to this problem was needed.

1.4 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 license.

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]

[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;

- 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 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.

- Other options are available, such as parallel importation from countries such as India where the pharmaceuticals are not protected by patents.

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

1.5 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.

2. 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.

'Canada's Access to Medicines Regime', Canadian HIV/AIDS Legal Network, viewed 5 August 2011 at < http://www.aidslaw.ca/EN/camr/index.htm>.,

[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.

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 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

[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 5 August 2011 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 5 August 2011 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 5 August 2011 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

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, 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$100 in 2010 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

---

Diplomatique, December 2003, viewed on 5 August 2011 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 5 August 2011 at <http://www.plosmedicine.org/article/info%3Adoi%2F10.1371%2Fjournal.pmed.1000333>.

[20] 'WHO, WIPO, WTO join forces to put access-to-medicines under the microscope', WTO, 16 July 2010, viewed 5 August 2011 at <http://www.wto.org/english/news_e/news10_e/trip_16jul10_e.htm>; 'Little-used 'Par.6' system will have its day, WHO tells intellectual property and health review', WTO, 27 October 2010, viewed 5 August 2011 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.

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.

2.1 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 *Trade Practices Act 1974* (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.

3. 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.

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

4. 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.

4.1 Power to grant licences

32. As shown in Options 1 and 2, 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

[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.

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.

4.2 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.

4.3 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.

4.4 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 pharmaceutical 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.

---

[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.

5. IMPACT ASSESSMENT

5.1 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
- Australian public.

5.2 Who would be affected by each option?

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

5.2.1 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.

5.2.1.1 Costs

39. WTO Members that have implemented the TRIPS Protocol comprise the European Union, Norway, The Netherlands, Switzerland, Canada, China, India and South 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 East Timor, 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.

5.2.1.2 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.

5.2.2 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 can not 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 the Government's foreign aid objective of assisting developing countries to reduce poverty and achieve sustainable development.[28] It would also be consistent with the Government'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. The broader Australian pharmaceutical industry comprises:[30]

- over 40 originator companies, most of these subsidiaries of multi-national companies);
- up to 10 generic companies;
- 470 small-scale biotechnology companies, and
- over 20 major medical research institutes.

45. The broader industry has a total annual turnover of over $20 billion and employs over 40,000 people, with one third in the manufacturing sector. It sells over $11 billion worth of medicines domestically each year and over $4 billion in exports, making medical and pharmaceutical products Australia's largest manufactured

[28] 'Annual Report 09/10', Australian Agency for International Development, 2010.
[29] 'Annual Thematic Performance Report: Health 2008-09', AusAID, June 2010.
[30] Pharmaceutical Industry Strategy Group, 'Final Report', December 2008.

export.[31] In 2007-08, 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 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]

5.2.2.1 Costs

47. The system implemented in Australia would be designed to be simpler and easier to use than some foreign systems. However, due to the low use of the TRIPS Protocol in other jurisdictions, it is expected that only a small number of applications for a licence would be made in Australia. Most of the costs listed below would only be incurred where an application is made.

48. The potential costs of this option to developing countries and manufacturers of generic pharmaceuticals would be as follows:

- Acquiring familiarity with the new legislative provision.
- Fees charged by the Federal Court. This would probably total a few thousand dollars for a corporation in each case.[34]
- Legal advice and representation. Legal costs could total tens of thousands of dollars but would vary significantly according to whether there is an attempt to negotiate a voluntary licence with the patent owner and whether the applicant or the patent owner appealed the Court's decision.
- Anti-diversion arrangements such as unique marking and packaging of the pharmaceuticals. These are difficult to quantify.
- Remuneration paid to the patent owner, which would depend heavily on the type and quantity of pharmaceutical in each case. As a guide, jurisdictions that have implemented a specific formula for calculating remuneration have limited it to a maximum of 4% of the total price paid by the importing country, or on its behalf.[35]

[31] Australian Bureau of Statistics, 'ABS catalogue 5368.0 International Trade in Goods and Services, Australia', Table 12a. MECHANDISE EXPORTS, Standard International Trade Classification (1 and 2 digit), FOB Value, July 2010.
[32] Australian Bureau of Statistics, 'Research and Experimental Development, Businesses', Catalogue 8104.0.
[33] 'The Australia Pharmaceuticals Industry: Winds of Change. Report of the 2009 Medicines Australia Member Economic Survey', Medicines Australia, 2010, pages 5-6; Generic Medicines Industry Association (GMiA), viewed 5 August 2011 at < http://www.gmia.com.au/gmia_members_ co.html>.
[34] *Federal Court of Australia Regulations 2004*, Schedule 1 Fees.
[35] 'Canada's Access to Medicines Regime – Consultation Paper', Industry Canada & Health Canada, 2006; *Regulation (EC) No 816/2006 of the European Parliament and of the Council of 17 May 2006*, Article 10(9). In Europe the maximum of 4% applies in situations of national emergency only. In all other cases remuneration is to be determined by the competent authority.

49. The potential costs of this option to patent owners include the following:

- Acquiring familiarity with the new provisions.
- Any legal advice and representation. Again, this would vary according to whether there is an attempt to negotiate a voluntary licence and how contentious the case is.
- Loss of royalty income due to the Court ordering that a licence be granted at a price lower than that originally offered to the generic manufacturer.
- Loss of control over pharmaceuticals that are diverted from the intended recipients. However, the design of the implementation can significantly reduce this risk.
- Monitoring compliance with any licences granted. Depending on the degree of risk, this could be in the tens of thousands of dollars.

50. 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.

51. 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.

5.2.2.2 Benefits

52. 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. Countries in the Asia-Pacific region that have an established relationship with Australia, particularly in regards to receiving humanitarian aid, would be able to use that relationship to minimise the burden of obtaining pharmaceuticals under the TRIPS Protocol. This could save them valuable time and money, however the amount is heavily dependent on specific circumstances and difficult to quantify.

53. 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.

54. 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.

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

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

56. 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 can not reach agreement the issue would be determined by the Federal Court.

5.2.3.1 Costs

57. 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.[36] 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.

58. 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.

59. 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.

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

5.2.3.2 Benefits

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.

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

60. 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.[37]

61. In 2009-10, Australia spent over $490 million of the aid budget on the health sector. Priority areas include tackling regional threats such as HIV, malaria and emerging infectious diseases.[38] Option 4 would involve increasing the level of funding and would be consistent with current priorities.

5.2.4.1 Costs

62. 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.

5.2.4.2 Benefits

63. 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.

---

[37] For example, see 'Intensifying the response: Halting the spread of HIV – Australia's international development strategy for HIV', AusAID, 2009, pages 19-20.
[38] 'Annual Thematic Performance Report: Health 2009', AusAID, January 2011.

6. CONSULTATION

6.1 The consultation process

64. There has been extensive consultation on the implementation of the TRIPS Protocol. In 2009 and 2010, IP Australia consulted a number of Government agencies on a proposed model. This included the Department of Innovation, Industry, Science and Research, the Attorney-General's Department, the Federal Court of Australia, the Department of Health and Ageing and the Therapeutic Goods Administration.

65. In April 2010, IP Australia released a public consultation paper seeking views on the proposed model. The paper was circulated 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.

6.2 Views expressed during the consultation process

66. Submissions in response to the 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.

67. Across all sectors there is strong support for introducing regulation to implement the TRIPS Protocol in Australia in order to provide another avenue for developing countries to obtain vital medicines. There was general support for the initial model proposed by IP Australia, although significant concerns were raised about some aspects.

68. 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. They believed 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.

- '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. This requirement should only be waived in urgent circumstances.

- measures to prevent the diversion of pharmaceuticals from the intended recipients need to be robust.

69. 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 not be subject to extra requirements, such as additional anti-diversion measures, as this would be an unfair burden.

6.3 How stakeholders' views have been taken into account

70. In light of stakeholder views, IP Australia has revised the proposed model. The main changes are as follows:

- The Federal Court of Australia, rather than the Commissioner of Patents, would have the power to grant, amend and revoke licences.

- Where the applicant for the compulsory licence is the Government or a similar public non-commercial organisation, the applicant must first attempt to obtain a voluntary licence from the patent owner. This requirement may only be waived in urgent circumstances.

7. CONCLUSION AND PREFERRED OPTION

71. 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.

72. 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. Therefore it does not meet the government's objective. 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.

73. 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.

8. IMPLEMENTATION AND REVIEW

74. Amendments to the Patents Act 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. The expected timeline for implementation is as follows:

- March 2011 – policy approval obtained for the proposal.
- August-October 2011 – drafting of amendments.
- November 2011 – release of exposure draft of amendments for comment.
- February 2012 – proposal finalised.
- March-April 2012 – introduction of legislation into Parliament.
- June-July 2012 – passage of legislation.
- January 2013 – commencement of new provisions.

75. 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.

76. 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 five-yearly 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.

[39] Annex to the TRIPS Agreement, paragraph 7.
[40] See the Office of Best Practice Regulation's *Best Practice Regulation Handbook*, August 2007, Chapter 2. See <http://www.finance.gov.au/obpr/about/index.html>.