Intellectual Property Laws Amendment Bill 2014

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Law and Bills Digest Section

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Date introduced: 19 March 2014
House: House of Representatives
Portfolio: Industry
Commencement: Varying dates of commencement are set out in the table contained in clause 2 of the Bill.

Links: The links to the Bill, its Explanatory Memorandum and second reading speech can be found on the Bill’s home page, or through http://www.aph.gov.au/Parliamentary_Business/Bills_Legislation
When Bills have been passed and have received Royal Assent, they become Acts, which can be found at the ComLaw website at http://www.comlaw.gov.au/.
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The Bills Digest at a glance

Australia's intellectual property system

The objective of Australia's intellectual property (IP) system is to support innovation by encouraging investment in research and technology in Australia and help local businesses benefit from their original ideas.\(^1\)

The patent system seeks to find the right balance between encouraging innovation and giving businesses incentive to invest in new technologies and products, and facilitating access to new technologies. In particular, patents have an important role to play in encouraging innovation in the pharmaceutical sector.

However, there is international concern that patents should not be used as vehicles for healthcare monopolies. For instance, pharmaceutical patents may risk putting essential medicines beyond the reach of many people in need of treatment. Developing countries often do not have the capacity to manufacture the medicines necessary to treat epidemics such as malaria, HIV/AIDS and tuberculosis. The interim waiver and the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Protocol agreed to by the General Council of the World Trade Organisation (WTO) provide a mechanism to supply such countries with the medicines they need to address health epidemics.

The Intellectual Property Laws Amendment Bill 2014

A version of the Intellectual Property Laws Amendment Bill 2014 (the Bill) was introduced by the former Labor Government as the Intellectual Property Laws Amendment Bill 2013 (the 2013 Bill).

The major difference between the two Bills is the deletion of Schedule 1 of the 2013 Bill, which modified the operation of Crown use provisions (discussed under ‘History of the Bill’ on page 4 of this Digest).

The 2014 Bill mirrors the 2013 Bill in the following areas:

1. Implementation of the TRIPS Protocol
2. Jurisdiction of plant breeder’s rights matters
3. Establishment of a single trans-Tasman patent attorney regime and
4. Minor administrative changes.

What the Bill does

The practical effect of the Bill is to:

- enable manufacturers of generic pharmaceuticals to apply to the Federal Court for a compulsory licence to make and export a patented pharmaceutical product to address health crises in developing countries. This would deliver on the Government’s commitment to the WTO’s TRIPS Protocol\(^2\)
- extend the jurisdiction of the Federal Circuit Court to include plant breeder’s rights, thereby reducing costs of litigation
- allow for a single trans-Tasman patent attorney regime and single patent application processes for Australia and New Zealand and
- repeal document retention provisions in the *Patents, Trade Marks and Designs Acts*.  

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Purpose of the Bill
The purpose of the Intellectual Property Laws Amendment Bill 2014 (the Bill) is to amend the Patents Act 1990\(^3\) the Trade Marks Act 1995\(^4\), the Designs Act 2003\(^5\) and the Plant Breeder’s Rights Act 1994\(^6\). It also addresses minor oversights in the Intellectual Property Laws Amendment (Raising the Bar) Act 2012 (the Raising the Bar Act).\(^7\)

Structure of the Bill
This Bill is divided into five Schedules. The first two are about adjusting the balance in the patent system. The third and fourth Schedules are about lowering costs for Australian innovators. The fifth Schedule captures other amendments:

• **Schedules 1 and 2**: TRIPS Protocol interim waiver and TRIPS Protocol—amendments to the Patents Act to enable Australian pharmaceutical manufacturers to apply to the Federal Court for a compulsory licence to manufacture generic versions of patented medicines to supply to developing countries

• **Schedule 3**: Plant Breeder’s Rights Act 1994: Federal Circuit Court—amendments to the Plant Breeder’s Rights Act to give the owners of plant breeder’s rights the option of taking action in the Federal Circuit Court against alleged infringers

• **Schedule 4**: Australia New Zealand Single Economic Market—amendments to the Designs Act, Patents Act, Plant Breeder’s Rights Act and Trade Marks Act to enable a single trans-Tasman examination model for patent applications

• **Schedule 5**: Other amendments:
  – Part 1: Administrative changes to the Patents, Trade Marks and Designs Acts to repeal document retention provisions and
  – Part 2: Technical amendments to the Patents Act to address oversights in the drafting of the Raising the Bar Act.

Background

**History of the Bill**

The Gillard Government introduced the Intellectual Property Laws Amendment Bill 2013 during the 43rd Parliament.\(^8\)

The 2013 Bill was referred to the House of Representatives Standing Committee on Social Policy and Legal Affairs, the Senate Economics Legislation Committee. It was also examined by the Senate Standing Committee for the Scrutiny of Bills, and the Parliamentary Joint Committee on Human Rights.

The House of Representatives Standing Committee on Social Policy and Legal Affairs recommended that the 2013 Bill be passed.\(^9\) The ‘reason for referral’ to the House Committee was concern over the implications of the amendments, particularly Plant Breeder’s Rights and the Trans-Tasman patent application and examination processes. However, the Committee inquiry focused on Crown use and on access to essential medicines under the TRIPS Protocol. The Bills Digest for the 2013 Bill provides further details on submissions to the Committee and the Committee’s deliberations.\(^10\)

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The Coalition opposed the 2013 Bill in debate in the House of Representatives and at the second reading.  
Sophie Mirabella and Dr Dennis Jensen voiced particular concerns about the application of the Bill to non-WTO countries (discussed further on page 12).

The 2013 Bill was introduced to the Senate on 28 June 2013, however, it lapsed immediately before the commencement of the 44th Parliament on 11 November 2013.

The current Bill was introduced on 19 March 2014 by the 44th Parliament. This Bills Digest is a revised version of an earlier Bills Digest prepared for the 2013 Bill.

Crown use
As noted above, the major difference between the two Bills is the deletion of Schedule 1 of the 2013 Bill, which modified the operation of Crown use provisions.

Crown use allows the Government to use a patented invention without the owner’s authorisation, and can be invoked when an invention is used for the services of the Commonwealth or state. It is an exceptional use enabling the Government to take the unusual route of using a patent for the benefit of a community need without first negotiating a licence. Crown use provisions provide a safeguard to ensure that the patent system does not prevent the Government from acting in the public interest. The debate surrounding the Crown use provisions in the 2013 Bill centred on the issues of gene patents and healthcare.

The 2013 Bill sought to clarify the scope of Crown use and its operation, particularly in the context of healthcare, and to allow any Australian, state or territory government to authorise private service providers to use an invention in areas where governments have primary responsibility, such as healthcare. The amendments in the 2013 Bill implemented the recommendations of the Productivity Commission in its inquiry report Compulsory Licensing of Patents (March 2013). The House of Representatives Standing Committee on Social Policy and Legal Affairs welcomed the implementation of the Productivity Commission’s recommendations in Schedule 1 of the 2013 Bill.

Financial implications
The Explanatory Memorandum states that the Bill is expected to have no financial impact on the Commonwealth.

Parliamentary Joint Committee on Human Rights
In its Fifth Report of the 44th Parliament, the Parliamentary Joint Committee on Human Rights (Human Rights Committee) examined all Bills introduced in the period 17–20 March 2014, which included this Bill. The Human Rights Committee considered that the Bill was unlikely to raise human rights concerns.

In its Eighth Report of 2013, the Parliamentary Joint Committee on Human Rights raised several concerns about the previous Bill. The Committee sought clarification as to whether the disclosure of personal information to New Zealand officials under the proposed trans-Tasman arrangements is consistent with the right to privacy (discussed on pages 16–17).

19. Ibid.
Statement of Compatibility with Human Rights

As required under Part 3 of the Human Rights (Parliamentary Scrutiny) Act 2011, the Government has assessed the Bill’s compatibility with the human rights and freedoms recognised or declared in the international instruments listed in section 3 of that Act. The Government considered that the Bill is compatible.

The Government notes that the amendments in the Bill ‘will advance the human right to health for everyone, including children, in developing countries by assisting with the treatment of serious health problems such as HIV/AIDS, malaria and tuberculosis’.

Senate Standing Committee for the Scrutiny of Bills

In its Alert Digest No. 4 of 2014, released on 26 March 2014, the Senate Standing Committee for the Scrutiny of Bills (the Scrutiny of Bills Committee) examined the provisions of the 2014 Bill. The Committee raised concerns about the retrospective provisions regarding administrative matters (discussed on page 16), and the delegation of powers and functions from the Australian Patents Commissioner to a New Zealand patents official (discussed on page 16).

Key issues and provisions

The patent system is a fundamental pillar of Australia’s intellectual property system. A patent is a legally-enforceable right to exclude others from commercially exploiting a device, substance, method or process that is new, inventive and useful at the time the patent was granted. Patent rights are personal property and may be assigned, licensed, willed or sold.

There are seven mechanisms in the Patents Act that allow a patented invention to be exploited without the patentee’s authorisation, including compulsory licencing. The amendments in the Bill would add a further mechanism to exploit a patented invention without authorisation. It implements the TRIPS Protocol, allowing the manufacture and export of patented pharmaceutical inventions to developing countries experiencing health crises.

The other main issues in the Bill centre on Plant Breeders’ Rights and the Australia New Zealand Single Economic Market.

Schedules 1 and 2 — TRIPS Protocol

Compulsory licencing in Australia

Background

Australia has a system of compulsory licensing for patents under sections 133–140 of the Patents Act, so that patent owners can be compelled to licence their inventions to others in a limited range of circumstances. Compulsory licencing is viewed as a safeguard and is only invoked in exceptional cases. Patent owners can be ordered to grant a compulsory licence if they fail to satisfy the ‘reasonable requirements of the public’ for their invention, or their behaviour in connection with the patent is contrary to the competition law.

Compulsory licencing is an increasingly controversial issue, particularly in the context of access to affordable healthcare. Other sensitive areas include climate change mitigation, food security, alternative energy technologies and technical standards essential patents. However, there have been only three applications for a compulsory licence in Australia, of which none were successful.

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21. The Statement of Compatibility with Human Rights can be found at page 39 of the Explanatory Memorandum to the Bill.
24. The seven mechanisms are: compulsory licencing (sections 133–140); Crown use (sections 163–170); Crown acquisition (section 171); for the purpose of obtaining regulatory approval (sections 119A–119B); for experimental purposes related to the subject matter of the invention (section 119C); when exploitation, or ‘definite steps’ (contractually or otherwise) to exploit, occurred immediately before the ‘priority date’ (date the patent became effective) (section 119); use in or on foreign vessels, aircraft or vehicles temporarily in Australia (section 118). Productivity Commission, Compulsory licensing of patents, op. cit., p. 6, accessed 16 May 2014.
26. Patents Act, section 133.
28. Ibid., p. 3.
The Productivity Commission undertook a thorough examination of the main issues in this area in its inquiry report. Among the issues canvassed, the Commission found that while the lack of use of the compulsory licensing provisions was consistent with its status as a rarely needed safeguard, another factor may be the costly and time-consuming process involved in obtaining a compulsory licence order from the Federal Court. However, the Commission concluded that there were no clear alternatives to the Federal Court that would make compulsory licence applications significantly less costly and time consuming, without also raising concerns about the quality of outcomes and scope for appeals.

The compulsory licence provisions in the Patents Act are designed to meet the needs of the Australian public. There is no provision in the current legislation to allow patented pharmaceuticals to be exported under compulsory licence to address the needs of another country.

**Pharmaceutical Patents Review**

Intellectual Property Australia (IP Australia) released the *Pharmaceutical Patents Review Report* in May 2014. The review evaluated whether the system for pharmaceutical patents is effectively balancing the objectives of securing timely access to competitively priced pharmaceuticals, fostering innovation and supporting employment in research and industry.

In conducting the review, the panel examined Australia’s obligations under international agreements, including free trade agreements and the World Trade Organisation agreements. The panel found that:

- In their negotiation of international agreements, Australian Governments have lacked strategic intent, been too passive in their IP negotiations, and given insufficient attention to domestic IP interests ... The Government does not appear to have a positive agenda regarding the IP chapters of the TPP Agreement.

- The Government has rightly agreed to only include IP provisions in bilateral and regional trade agreements where economic analysis has demonstrated net benefits, however this policy does not appear to be being followed.

The report found that international agreements partly explain why patent terms in Australia have been increasing. Patents have a 20 year life span under TRIPS. However, the Australia–United States Free Trade Agreement (AUSFTA) added a further extension to patents for pharmaceuticals beyond the legislated 20 years. The Report found that the agreement was made ‘without careful regard to whether... this was in our own economic interest’. It recommended that:

- In negotiating such agreements in the future, Australia needs a more active strategic engagement with the issues.
- While the patent system must be strong to be effective, it should also be parsimonious, avoiding restrictions on trade and innovation that are not necessary for it to deliver incentives to innovate.

In the Government statement on the *Pharmaceutical Patents Review Report*, the Coalition Government noted that the *Pharmaceutical Patents Review Report* was commissioned by the previous Labor Government and conducted by an independent panel: ‘The government has no plans to respond to the report at this stage but may take information in the report into account when considering future policy. The views expressed and recommendations made in the report are those of the review panel and do not necessarily reflect government policy’.

**Compulsory licensing in other countries**

Compulsory licensing is also rarely used in other countries. Developing countries, particularly Brazil, India and Thailand, have recently sought to access patented medicines at lower prices. Among developed countries, the United States is one of the few countries not to have compulsory licensing provisions in its patents legislation.

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29. Ibid.
30. Ibid., p. 2.
31. Ibid.
33. Ibid., Finding 3.1, p. xx.
34. Ibid., p. vi.
35. Ibid.
Instead, US competition and sector-specific laws provide for similar measures to compulsory licences. The US Government also invokes other powers to gain access to patented inventions for defence and other national security purposes. Consequently, compulsory licensing occurs most frequently in the US, particularly to remedy anti-competitive conduct and patent infringement:

... the United States appears to be relatively unusual in the emphasis it places on using compulsory licensing to remedy antitrust violations and open markets to competition, compared to other public interest grounds ... 37

Use of compulsory licensing provisions to export patented pharmaceuticals to developing countries with health crises: the TRIPS Agreement

As noted above, the patent system is particularly important for encouraging innovation in the pharmaceutical sector because of the high costs and risks associated with developing new medicines. During the landmark US Supreme Court Myriad Genetics case, Justice Scalia asked: ‘Why would a company incur massive investment if it ... cannot patent?’ 38 Without patent protection many new products would never reach consumers. However, the need for companies to receive a return on their investment, and the cost of production of pharmaceutical products, means that essential medicine is often beyond the reach of developing countries. 39

Over 100 countries are currently experiencing one or more serious epidemics. 40 In 2011 an estimated 262 million people were infected with malaria, HIV/AIDS or tuberculosis, causing 3.8 million deaths. 41 The World Health Organisation estimates that more than three billion people are at risk of contracting malaria. 42 Many of the countries suffering from such epidemics are developing countries which do not have the capacity to manufacture or distribute the necessary medicines. The United Nations estimates that nearly two billion people lack access to essential medicines, and has stated that improving access to existing medicines could save ten million lives each year, including four million in Africa and South-East Asia. 43

Development of the TRIPS Agreement

The WTO tried to address this dilemma in the TRIPS Agreement, 44 negotiated in 1994, which enables a country that is experiencing a serious epidemic to access patented drugs. The TRIPS Agreement introduced intellectual property rules into the multilateral trading system for the first time. Under Article 31, a patent may be used without authorisation if the user has already tried unsuccessfully to obtain authorisation on reasonable terms, the use is for the supply of the domestic market of the Member state, and the patent owner is paid adequate remuneration. However, there was uncertainty over the interpretation of Article 31, as it could potentially prevent countries that cannot afford to manufacture medicine from importing products that are manufactured without the consent of the patent owner. 45

In November 2001, the Fourth WTO Ministerial Conference in Doha, Qatar, adopted the Declaration on the TRIPS Agreement and Public Health (the Doha Declaration), which recognised that 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. 46

In August 2003, the General Council for TRIPS agreed to an interim waiver allowing Member countries with limited or no manufacturing capacity to access patented pharmaceuticals made under compulsory licence in

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38. *Association for Molecular Pathology v Myriad Genetics*, 133 S. Ct. 2107, 13 June 2013, p. 12, accessed 14 May 2014
another WTO country. In December 2005, the Protocol Amending the TRIPS Agreement (TRIPS Protocol) was drafted to give permanent effect to the waiver, enabling pharmaceutical products to be exported under compulsory licence. The TRIPS Protocol provides that:

- only pharmaceutical products that are needed to address public health problems in developing and least-developed countries are included
- products may be imported by any least-developed country Member, and any other Member that has notified its intention to use the system. 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 products
- prior efforts must have been made to obtain authorisation from the patent owner, and these efforts must have been unsuccessful within a reasonable period of time (this requirement may be waived during an extreme urgency)
- certain conditions must be placed on licences granted under the TRIPS Protocol to reduce the risk of pharmaceuticals being diverted from their intended recipients and
- where a licence is granted, adequate remuneration must be paid to the patent owner.

The protocol aims to encourage patent owners to either provide medicines to least developed countries at affordable prices, or to issue voluntary licences to generic manufacturers to provide medicines at affordable prices. If a patent owner is unwilling to do this, the protocol provides a mechanism to force the patent owner to issue a compulsory licence.

Countries that implement the TRIPS Protocol are able to export patented medicines under compulsory licence to countries in need. Australia became a signatory to the TRIPS Protocol in 2007, following a recommendation by the Joint Standing Committee on Treaties (JSCOT) to accept the Protocol. JSCOT supported amendments to the Patents Act to allow for compulsory licensing of patented medicines for export. Acceptance of the Protocol means that countries have the legal right to use this system, and that Australia is required to implement the TRIPS Protocol through its own laws.

Dr Matthew Rimmer from the Australian National University College of Law told the House Social Policy and Legal Affairs Committee inquiry into the 2013 Bill that the question about access to essential medicines was particularly important:

It has been a decade since the World Trade Organisation General Council decision laid down the framework to establish a regime for the export of essential medicines. Politicians, both from the conservatives and the ALP and the Greens have emphasised their support over the years for that measure ... If anything, Australia has probably taken too long to put in place a proper mechanism for access to essential medicines.

**Amendments in the Bill to implement the TRIPS Protocol**

The amendments will deliver on Australia’s commitment to implement the TRIPS Protocol. The approach aims to balance the interests of patent owners, importing countries and manufacturers of generic medicines.

The key objectives of government action 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 and
- maintain existing budget expenditure on foreign aid.

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According to the Explanatory Memorandum to the Bill, the proposed provisions under Schedule 1 will enable countries to source generic versions of patented pharmaceuticals from Australia, in accordance with Australia’s international obligations.53

**Item 19 of Schedule 1** of the Bill introduces a new scheme enabling Australian laboratories:

… to apply to the Federal Court for a compulsory licence to manufacture generic versions of patented medicines under specific conditions, and export these medicines to developing countries. Adequate compensation for the patent holder will be negotiated, to ensure that they are not disadvantaged by the arrangements.54

The process for obtaining and using a compulsory licence under the TRIPS Protocol is set out in the Explanatory Memorandum to the Bill and outlined below.55 The proposed provisions in Schedule 1 of the Bill that implement this process are also identified where relevant:

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

2. **Identify a suitable Australian manufacturer to make the product and identify the relevant patent(s)**
   - The importing country finds an Australian pharmaceutical manufacturer with the technical capacity to make the product—whether from basic chemicals or from active ingredients sourced outside Australia. The importing country and the Australian pharmaceutical manufacturer then identify any relevant patents in Australia.

3. **Attempt to obtain authorisation**
   - The Australian pharmaceutical manufacturer makes reasonable attempts to obtain authorisation from the innovator company (the patentee) to manufacture and export the product(s). This step may be omitted if the public health problem amounts to a national emergency or other circumstance of extreme urgency, in the importing country. (The Federal Court is required to be satisfied that an applicant has made a reasonable attempt to obtain authorisation from the patentee, in all situations except those involving emergency circumstances – see proposed paragraphs 136E(1)(c) and (e) of the Patents Act.)

4. **Notify intent to use the system**
   - If the Australian pharmaceutical manufacturer is unsuccessful in obtaining the innovator company’s authorisation within 30 days of seeking it, or circumstances of national emergency or extreme urgency apply in the importing country, the importing country notifies its intent to use the Protocol system and other details. Importing countries that are WTO members must notify the Council for Trade-Related Aspects of Intellectual Property Rights (TRIPS Council); those that are not WTO members must notify the Commissioner of Patents. (Required for an order under proposed section 136E of the Patents Act.)56

5. **Apply to the Federal Court for a compulsory licence**
   - The Australian pharmaceutical manufacturer applies to the Federal Court for a compulsory licence to use the patent(s). The Court hears the application, using an expedited process in urgent cases (proposed section 136D of the Patents Act).

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

52. Ibid., p. 14.
53. Ibid., p. 5
54. Ibid.
55. Ibid., pp. 44–45.
56. Ibid., p. 51.
• If the Federal Court grants the licence, the licensee must notify the Commissioner of Patents of the licence and of the address of the website where shipment information is to be posted (see number 9 below). (Proposed paragraph 136F(1)(h) of the Patents Act.) The Commissioner then provides this information to the TRIPS Council.

7. Determine remuneration
• If the Federal Court grants the compulsory licence, the Australian pharmaceutical manufacturer and the patentee can negotiate the remuneration due to the patentee for the use authorised by the licence. If they cannot agree, the Federal Court can determine the remuneration. This can occur when the court considers the application for the licence, or on a separate application later on (proposed section 136J of the Patents Act).

• If the pharmaceutical product is to address a public health crisis in the importing country, then the Australian manufacturer can make and export the pharmaceutical product before the remuneration is determined. For other public non-commercial use of the pharmaceutical product by the importing country, the remuneration must be determined before the Australian manufacturer can make and export the pharmaceutical product (proposed section 136J of the Patents Act).

8. Manufacture and export of the patented pharmaceutical
• The Australian pharmaceutical manufacturer makes and exports the patented pharmaceutical in accordance with the terms of the licence (proposed section 136F of the Patents Act sets out terms that must be included in a PPI compulsory licence).

9. Notify details of shipment
• Before sending the pharmaceutical to the importing country, the Australian pharmaceutical manufacturer posts the quantities, destinations, labelling and markings of the product(s) on the website referred to at number 6 (proposed section 136F of the Patents Act).

10. Take reasonable measures to prevent re-exportation
• The importing country and anyone importing the pharmaceutical product on its behalf must take reasonable measures to prevent re-exportation of the pharmaceutical product. This is to ensure that the pharmaceutical product is used in the importing country for the intended public health purposes. The measures taken by the importing country must be proportionate to the country’s administrative capacity and to the risk of the pharmaceutical product being diverted. (Proposed paragraph 136E(1)(g) and proposed subsection 136D(4) of the Patents Act.)

Under item 27 of Schedule 1, 'eligible importing country' means a foreign country of a kind prescribed by regulation.

Under proposed section 136L of the Patents Act, an order must not be made that is inconsistent with a treaty between the Commonwealth and a foreign country.

**Other countries’ implementation of the TRIPS Protocol**

Norway, Canada, India, the European Union, Hong Kong, China, Switzerland, the Philippines, Singapore, Albania, Croatia, Korea and Jordan have put in place regimes to implement the WTO General Council Decision of 2003. Japan has also said that its domestic rules comply. The only successful instance of importing essential medicines under the WTO Decision occurred in 2007, when Rwanda imported medicine manufactured in Canada under Canada’s Access to Medicines Regime.57

Dr Rimmer told the 2013 Social Policy and Legal Affairs Committee Inquiry:

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57. M Rimmer, Submission to the House of Representatives Standing Committee on Social Affairs [sic] and Legal Policy [sic], Intellectual Property Laws Amendment Bill 2013 [Cth], accessed 15 May 2014.
I guess the problem in terms of the scheme has been not enough countries that have implemented the regime thus far ... really there is a need for a more systematic international approach to implementing those kinds of international obligations.  

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Non-WTO countries and compliance with international treaty obligations

In 2013, there was debate over the Bill’s proposal to allow non-WTO countries to access essential medicines through compulsory licences.

The Intellectual Property Committee of the Business Law Section of the Law Council of Australia (LCA) informed the Social Policy and Legal Affairs Committee of concern regarding inconsistencies with the Australia–United States Free Trade Agreement (AUSFTA) and the TRIPS Agreement. The LCA said the compulsory licences provisions under the Bill were inconsistent with TRIPS because the proposed legislation provided for the export of pharmaceuticals to countries which are not members of the WTO, in breach of Article 31(f) of the TRIPS Agreement and thereby falling outside the exception.  

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IP Australia Director-General Philip Noonan told the Committee:

It is certainly possible to say that maybe the TRIPS Agreement should not extend to countries like East Timor, but the Bill very clearly, in the explanatory memorandum, adopts the policy position that it should extend to every country, because if a country were to come to us and say, 'We have a health emergency; you're the only one that can help us,' then it would just be an unreasonable position to say, 'No, you don't belong to a particular club; we can't help you'.  

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The Coalition voiced opposition to the 2013 Bill in the House of Representatives. Sophie Mirabella argued that the proposed amendments could place Australia in breach of a number of its obligations under the WTO’s TRIPS Protocol, as the WTO defines an ‘eligible importing country’ as a member of the WTO, and the 2013 Bill stated that an importing country does not have to be a WTO member.  

Ms Mirabella said: ‘I might also stress that one of the reasons for the General Counsel’s decision to limit waivers under Article 31(f) of TRIPS in such a way to member countries was that it provided a clear incentive for non-members to join the organisation’.  

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Similarly, Dr Dennis Jensen, MP stated:

Many of our neighbours in the region are in the process of getting WTO membership, but are not there yet—and that is the key... If under the TRIPS amended provision the Commonwealth were to provide generic drugs in the event of a pandemic in, say, East Timor—noting here that East Timor is not a WTO member—there is nothing to stop East Timor, or any other non-WTO member, from acting unscrupulously and selling on to generic and occasioning profit contrary to the humanitarian intent... I wish to remind all in this place that breaking an international treaty is no small matter. It is no trifling matter. The Commonwealth exposes itself to the full weight of sanction of the WTO. How reckless and irresponsible a measure to endanger the economic sustainability of the nation and the livelihoods of millions. To entrench the budgetary emergency borders on treason. Forgive my incredulity, but the Gillard Government is actually rushing to this treason.  

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Despite such concerns raised in 2013, the proposal to allow non-WTO members to access the system was not changed in the 2014 Bill. The Explanatory Memorandum states:

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. 64

Views of the Social Policy and Legal Affairs Committee 2013 Inquiry
The Committee commended the actions of the previous Government in introducing legislation to ensure that developing countries experiencing a health crisis can access vital medicines quickly and reasonably, while also respecting the rights of patent owners:

Introducing regulation to implement the TRIPS protocol in Australia to provide for another avenue for developing countries to obtain vital medicines is a worthy and entirely necessary step in the view of the Committee.

Although the Committee is aware that some have raised concerns about implementation, the outcome is long overdue and the Committee does not consider any of the concerns raised are sufficient to delay the implementation. 65

Schedule 3 — Plant Breeders Rights

Background
Plant breeder’s rights (PBR) are exclusive commercial rights for a registered variety of plant, administered under the Plant Breeder’s Rights Act. These rights are used to protect new varieties of plants that are distinguishable, uniform and stable. A PBR is legally enforceable and gives the owner exclusive rights to commercially use it, sell it, direct the production, sale and distribution of it, and receive royalties from the sale of plants. 66

Currently, civil proceedings under the Plant Breeder’s Rights Act may only be commenced in the Federal Court and are appealable to the High Court, making the litigation very costly. Most disputes over plant breeders rights are less complex matters, and many of the parties involved are small businesses with limited resources. 67

During the 1990s, some sectors of industry lobbied the Government for a quicker, more cost effective mechanism to deal with IP disputes. Concerns were also raised about difficulties in enforcing plant breeder’s rights and the cost and time involved in dealing with IP disputes. The Government asked the Advisory Council on Intellectual Property (ACIP), 68 an independent body that advises the Minister on IP matters, to conduct a review of the enforcement of plant breeder’s rights. The review included consideration of whether the jurisdiction of the Federal Magistrates Court (now the Federal Circuit Court) should be extended to include PBR matters. 69 The Government released ACIP’s final report on 18 January 2010 and the Government response was issued on 3 June 2011. The Government accepted ACIP’s recommendation that the jurisdiction of the Federal Magistrates Court be extended to include PBR matters. 70

Proposed amendments in this Bill
Schedule 3 of the Bill proposes that the Plant Breeders Rights Act will be amended to enable the owners of plant breeder’s rights to take action against alleged infringers in the Federal Circuit Court (proposed section 56A of the Plant Breeders Rights Act). The amendments are designed to provide a means to resolve disputes about the infringement of plant breeder’s rights in a way that is quicker and less formal than the Federal Court.

In 2013, the House of Representatives Standing Committee on Social Policy and Legal Affairs noted that this change was supported by the ACIP’s review: ‘The Committee supports streamlining processes for owners of

68. Ibid.
69. Ibid.
plant breeder’s rights to take action against alleged infringers and consider the Federal Circuit Court to be an appropriate avenue to hear such cases’.71

Schedule 4 — Australia and New Zealand Single Economic Market

The Bill proposes a single patent application and examination process and a single trans-Tasman patent attorney regime to support the single economic market arrangements between Australia and New Zealand. The aim of these proposed amendments is to streamline the processes for applying for patents in Australia and New Zealand, thereby reducing duplication and saving costs for inventors.

Background

The strong economic link between Australia and New Zealand is evidenced by the two-way trade between the countries, which was worth $21.6 billion in 2011.72 Australia and New Zealand agreed on a Single Economic Market Outcomes Framework agenda in 2009, setting out principles to remove regulatory barriers to firms operating in both markets to create a more seamless trans-Tasman business environment.73

The major work areas for the Single Economic Market were updated in February 2011 and are listed on the Trans-Tasman Outcomes Implementation Group website.74 This group is working towards the introduction of the following trans-Tasman processes:

• a single regulatory framework for patent attorneys
• a single trade mark regime
• a single patent application and examination process for patents
• a single regime for patent attorneys and
• a single plant variety right regime.75

Most patent applications filed in New Zealand are also filed in Australia. Currently, the applications are subject to similar but separate examination processes. Following the announcement of the single patent examination process by the Australian and New Zealand Prime Ministers in 2011, there was an extensive consultation process. This included a discussion paper, release of drafting instructions for proposed legislation to key Australian stakeholders, and regular updates for industry.76 The single patent examination process was also considered by the Productivity Commission in its Strengthening Economic Relations Between Australia and New Zealand review.77

The majority of Australian and New Zealand patent attorneys are registered in both countries under the Trans-Tasman Mutual Recognition Arrangement (TTMRA),78 paying fees in both countries annually for the renewal of their registrations. The TTMRA was signed in 1996 by the Commonwealth, states and territories and New Zealand to implement mutual recognition principles relating to the sale of goods and the registration of occupations. The TTMRA entered into force on 1 May 1998. It provides that a person registered to practise an occupation in Australia is entitled to practise an equivalent occupation in New Zealand, and vice versa, without the need for further testing or examination.79

73. Ibid.
77. Productivity Commission, Compulsory licensing of patents, op. cit.
In March 2013 Australia and New Zealand signed an agreement to establish a single trans-Tasman regulatory regime for patent attorneys, under a bilateral arrangement. The aim of the regime is to achieve efficiencies in the regulation of patent attorneys through:

- a single Trans-Tasman register of patent attorneys
- common requirements for registration
- a trans-Tasman code of conduct for patent attorneys
- a common disciplinary process and
- common regulatory bodies.  

**Proposed amendments in this Bill**

**Single patent application and examination processes**

Schedule 4 of the Bill proposes a single patent application and examination process and a single trans-Tasman patent attorney regime to support the single economic market arrangements between Australia and New Zealand. The aim of these proposed amendments is to streamline the processes for applying for patents in Australia and New Zealand, thereby reducing duplication and saving costs for inventors. IP Australia explained in 2013:

> This will save quite a bit of money that companies typically expend now going through two examination processes—looking at the question of whether something is novel and inventive twice with two different examiners and two different authorities. That is a waste of resources ...  

Under the proposed legislation, either country would accept the filing of applications and payment of fees, resulting in the filing of documents under each country’s law. An examiner in either country would consider patent applications under both countries’ laws.

Patents would be granted in both Australia and New Zealand, taking into account the separate national laws. However, the process would not create a single patent covering both Australia and New Zealand.

**Single trans-Tasman patent attorney regime**

**Items 17 to 22 of Schedule 4** of the Bill would also implement a bilateral arrangement for the trans-Tasman regulation of patent attorneys in both Australia and New Zealand. This would enable a single trans-Tasman register of patent attorneys, with registration giving a person the right to practice as a patent attorney in both countries.

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

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

The House of Representatives Standing Committee on Social Policy and Legal Affairs reported that it was unaware of any issues regarding the single patent application and examination processes for Australia and New Zealand, and considered that there were ‘clear advantages’ to the scheme. The Committee viewed these

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measures as part of a broader regulatory harmonisation between Australia and New Zealand, extending the
trans-Tasman cooperative trade opportunities and providing greater certainty for business.83

Views of the Senate Standing Committee for the Scrutiny of Bills

In 2013, the Senate Standing Committee for the Scrutiny of Bills raised concerns that the new provisions would permit the Australian Patents Commissioner to delegate all or any of his or her powers and functions to a New Zealand patents official (item 24 of Schedule 4 of the 2014 Bill).84 The Committee reported:

Although decisions made by a New Zealand delegate would continue to be decisions made under Commonwealth legislation and, thus, judicial review under the ADJR Act and any merits review rights would continue to be available ... the delegation of powers to New Zealand officials may mean that other accountability mechanisms are not available.

New Zealand delegates would not be ‘officers of the Commonwealth’ and, thus, their decisions would not be judicially reviewable under section 39B of the Judiciary Act. Further, as the jurisdiction of the Ombudsman and the coverage of the FOI Act is, in general, defined by reference to Commonwealth Government agencies, it appears that these administrative law accountability arrangements will not apply in relation to action taken in connection [with] decisions to be made under Commonwealth legislation where the relevant powers are exercised by a New Zealand patents official. The committee therefore seeks the Minister’s advice as to whether this possible reduction in accountability for decision-making under the Patents Act is appropriate.85

The Committee raised concerns that the provisions may be considered to make rights, liberties or obligations unduly dependent upon non-reviewable decisions, in breach of principle 1(a)(iii) of the committee’s terms of reference.86

The Minister responded that ‘the designation to a New Zealand examiner as a delegate of the Australian Commissioner provides that a decision made by that examiner would be deemed to be one that has been made by the Australian Commissioner’.87 The Minister also clarified that the jurisdiction of the Ombudsman Act 1976 has extraterritorial effect, and its application would apply to decisions made by a New Zealand examiner with the delegated powers of the Australian Commissioner.88 ‘Any decision made by a New Zealand delegate would be considered a decision of the Australian Commissioner and therefore would be reviewable through the normal procedure in the Patents Act.’89

The Minister also noted that the decisions of New Zealand examiners would be monitored and quality controlled:

The New Zealand examiners’ performance will be subject to the same quality review systems as Australian examiners. If New Zealand examiners do not maintain sufficient standards, then their delegated ability to examine under the Australian Patents Act will be revoked.90

This issue was addressed by the Scrutiny of Bills Committee in 2014. The Committee thanked the Minister for including key parts of the above information in the explanatory memorandum to the 2014 Bill, and made no further comment.91

The Parliamentary Joint Committee on Human Rights also examined this schedule in 2013. The Bill allowed for the disclosure of information (including personal information) by the Designated Manager to the Register of Companies of New Zealand or a New Zealand delegate. The Committee sought clarification as to whether the disclosure of information to New Zealand officials was consistent with the right to privacy under article 17 of the

85. Ibid.
86. Ibid., p. 43.
88. Ibid.
89. Ibid.
90. Ibid., p. 338.
International Covenant on Civil and Political Rights. In his response, the Minister noted that the individuals that the Bill would allow information to be disclosed to are New Zealand public servants:

Such individuals are bound by privacy legislation in New Zealand in the form of the Privacy Act 1993 (NZ). New Zealand’s law also provides for criminal sanctions in the event of its public servants disclosing private or confidential information they have obtained in the course of their duties, similar to the provisions of the Australian Crimes Act 1914. Information provided by Australian officials to New Zealand officials would therefore be protected under New Zealand law, to an appropriate standard.

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

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

### Schedule 5 — Administrative matters

IP Australia is currently required to keep documents longer than the Archives Act 1983 requires because legislation administered by IP Australia requires patents, trademarks and design documents to be stored for an extended period of time. Part 1 of Schedule 5 (items 1 to 6) of this Bill removes the document retention provisions in the Patents Act, Trade Marks Act and Designs Act, and ensures that IP Australia’s retention of documents is governed by the Archives Act only.

Part 2 of Schedule 5 makes changes to address minor oversights in the drafting of the Intellectual Property Laws Amendment (Raising the Bar) Act 2012. The Raising the Bar Act made a series of reforms to Australia’s intellectual property system, effective 15 April 2013. Part 2 also makes technical corrections to drafting oversights in the Patents Act.

The Senate Scrutiny of Bills Committee 2014 examined item 18, proposed new paragraph 119(3)(b), which had also been assessed by the Committee in 2013. The amendment to paragraph 119(3)(b) of the Patents Act aims to ‘correct an inadvertently created inconsistency’ between that provision and a related provision created when the Raising the Bar Act came into operation.

In 2013, the Scrutiny of Bills Committee noted:

> On the face of it the amendment appears reasonable and it appears that the provision is unlikely to have an adverse impact on individuals. However, in determining the appropriateness of any change being made retrospectively the committee seeks to understand whether it is possible that a person’s rights may be adversely affected and the extent of any possible effect. As a result, the committee requests the Minister’s advice on these matters."

The Minister’s response stated that the provision was ‘highly unlikely to have an effect on individual rights, liberties or obligations’:

> The likelihood of a person’s rights being adversely affected is so low that it is difficult to conceive of a situation where this might occur. It is the clear policy of the Patents Act as it stands that the infringement exemption be aligned with the grace period. Item 14, when enacted, will continue the existing policy that a patentee cannot sue a competitor for a use derived from information publicly disclosed by the patentee before they applied for a patent. Retrospective effect will ensure consistency of legislation, clarity for users, and put the matter beyond legal doubt.

The 2014 Committee referred to this advice, and thanked the current Minister for including it in the explanatory memorandum.

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92. Ibid., p. 8.
94. Senate Standing Committee for the Scrutiny of Bills, Alert Digest No. 6 of 2013, op. cit., p. 41.
Concluding comments

This Bill proposes a number of significant changes to the intellectual property system in Australia. It seeks to implement Australia’s international obligations by allowing developing countries to access patented essential medicines. The amendments to the compulsory licensing provisions implement the WTO General Council’s interim waiver and TRIPS Protocol, enabling Australian laboratories to manufacture generic versions of patented medicines for export to developing countries facing health emergencies. The TRIPS Protocol was accepted in 2007 and, as noted by Bob Baldwin, MP in his second reading speech on the Bill, its implementation in Australia is well overdue.95

Schedules 3 and 4 are focused on driving cost-savings and efficiencies. The jurisdiction of the Federal Circuit Court will be extended to include plant breeder’s rights. The single examination model for patents in Australia and New Zealand aims to remove duplication, drive efficiencies and reduce costs, facilitating the protection of intellectual property for businesses in both countries.96

The 2013 Bill was considered at length, with referral to several committees and a public inquiry conducted by the House Standing Committee on Social Policy and Legal Affairs. Some of the concerns raised during the Committee inquiry, namely regarding the amendments to the Crown use provisions, have been alleviated by omitting that issue from the current Bill. In recommending that the Bill be passed in 2013, the Committee considered that it provided ‘a set of progressive and appropriate initiatives’.97

96. Ibid., p. 2390.