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Intellectual Property Laws Amendment Bill 2013

Genevieve Butler
Law and Bills Digest Section

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The Bills Digest at a glance

The purpose of a patent system

A 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. The patent system has a particularly important role to play in encouraging innovation in the pharmaceutical sector. There is, however, international concern that the patent system should not be used as a vehicle for healthcare monopolies.

There has also been international concern that pharmaceutical patents put essential medicines beyond the reach of many people in need of treatment. Developing and least-developed 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 provide a mechanism to supply such countries with the medicines they need to address health epidemics.

What the Bill does

The Bill proposes several key amendments to Australia’s patent system. In particular the Bill addresses two of the mechanisms available to exploit patents without the patent holders’ authorisation—Crown use and compulsory licensing.

- The Bill clarifies the scope and operation of the Crown use provisions, which can be used for the services of the Government when it is in the public interest to do so. This issue has recently been at the forefront of public attention with international litigation over gene patents.
- The Bill recognises Australia’s obligations under international law, and introduces a new scheme to enable Australian laboratories to apply to the Federal Court for a compulsory licence to manufacture generic versions of patented medicines and export those medicines to developing countries.

The Bill also aims to lower costs for Australian innovators. It extends the jurisdiction of plant breeders rights matters to the Federal Circuit Court, to provide a more cost-effective and timely avenue for legal disputes than the Federal Court. Furthermore, it introduces two measures to support the single economic market arrangement between Australia and New Zealand: a single patent and examination process and a single Trans-Tasman patent attorney regime.

The outcome of the Social Policy and Legal Affairs Committee inquiry

The House of Representatives Standing Committee on Social Policy and Legal Affairs conducted an inquiry into the Bill. Although stakeholder concerns were raised about some of the proposed amendments, as well as the timing and a perception by some that there had been a lack of consultation, the Committee recommended that the Bill be passed.
Intellectual Property Laws Amendment Bill 2013

Date introduced: 30 May 2013

House: House of Representatives

Portfolio: Industry, Innovation, Climate Change, Science, Research and Tertiary Education

Commencement: Varying dates of commencement are set out in the table contained in item 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/.

Purpose of the Bill


The practical effect of the Bill is to:

• clarify the scope of Crown use6 and its operation, particularly in the context of healthcare
• 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 health
• 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 World Trade Organisation’s (WTO’s) TRIPS Protocol?7
• extend the jurisdiction of the Federal Circuit Court to include plant breeder’s rights, thereby reducing costs of litigation

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6. ‘Crown use’ is where ‘the Patents Act permits the Commonwealth or a state (or their authorised person) to exploit an invention described in a pending patent application or in a granted patent without the need for authorisation by the owner’. Explanatory Memorandum, Intellectual Property Laws Amendment Bill 2013, p. 6, accessed 4 July 2013.

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• 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*.

**Structure of the Bill**

This Bill is divided into six schedules. The first three are about adjusting the balance in the patent system. The fourth and the fifth Schedules are about lowering costs for Australian innovators. The sixth Schedule captures other amendments:

• **Schedule 1: Crown use**—amendments to the *Patents Act* to clarify the scope and operation of Crown Use provisions
• **Schedules 2 and 3: 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 4: 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 5: 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 6: 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*.

**Committee consideration**

**House of Representatives Standing Committee on Social Policy and Legal Affairs**

The Bill was referred to the House of Representatives Standing Committee on Social Policy and Legal Affairs (Social Policy and Legal Affairs Committee) for inquiry and report by 19 June 2013.

The ‘reason for referral’ was concern over the implications of the amendments, particularly Plant Breeder’s Rights and the Trans-Tasman patent application and examination processes. The

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8. An outline of each Schedule can be found at pages 6-8 of the Explanatory Memorandum to the Bill, op. cit.
Committee’s comments are discussed under the heading ‘Key issues and provisions’. Overall, the Committee recommended that the Bill be passed.

**Senate Economics Legislation Committee**

The Bill was also referred to the Senate Economics Legislation Committee. The Committee determined that it would not proceed with its own inquiry, given that the Social Policy and Legal Affairs Committee had conducted an inquiry into the Bill.  

**Senate Standing Committee for the Scrutiny of Bills**

In its *Alert Digest No. 6 of 2013*, released on 19 June 2013, the Senate Standing Committee for the Scrutiny of Bills (the Scrutiny of Bills Committee) examined the provisions of this Bill.  

The Scrutiny of Bills Committee commented on:

- **retrospectivity, trespass on personal rights and freedoms**—item 14 of Schedule 6 of the Bill—
  the retrospective application of the amendment to *proposed paragraph 119(3)(b)* of the *Patents Act* and whether it is possible that a person’s rights may be adversely affected and the extent of any possible effect

- **merits review**—item 5 of Schedule 1 of the Bill—whether consideration has been given to the appropriateness of merits review (in the Administrative Appeals Tribunal) of decisions made by the relevant Minister which enable Crown exploitation of an invention in *proposed sections 163 and 163A* of the *Patents Act*, as these decisions do not appear to be currently reviewable and

- **rights, liberties or obligations unduly dependent on non-reviewable decisions**—item 25 of Schedule 5 of the Bill—whether the possible reduction in administrative law accountability for decisions made under Commonwealth legislation where the relevant powers are exercised by a New Zealand patents official is appropriate (for example—no coverage of the freedom of information (FOI) laws).

The views of the Scrutiny of Bills Committee are further explained and discussed under the headings Crown Use, Australia New Zealand Single Economic Market and Administrative Matters in this Bills Digest.

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Parliamentary Joint Committee on Human Rights

In its *Eighth Report of 2013*, the Parliamentary Joint Committee on Human Rights (Human Rights Committee) examined all Bills introduced in the period 27 May—6 June 2013, which included this Bill.12

The Human Rights Committee identified this Bill as requiring further information to determine human rights compatibility. The Committee noted that the Bill engages the following human rights:

- right to benefit from scientific production under article 15 of the International Covenant on Economic, Social and Cultural Rights (ICESCR)13
- right to privacy, article 17 of the International Covenant on Civil and Political Rights (ICCPR).

In summary, the Human Rights Committee sought clarification as to whether:

- a person whose patent is affected by Crown use receives compensation and/or can seek review of this use, and whether the Crown use provisions are consistent with the right to benefit from one’s scientific production and
- the disclosure of personal information to New Zealand officials is consistent with the right to privacy.14

The Minister’s response is in the Human Rights Committee’s tenth report.15 In light of the Minister’s response, the Committee made no further comment on the Bill.

Position of major interest groups

Correspondence on the Bill was submitted to the Social Policy and Legal Affairs Committee by the Law Council of Australia and the International Association for the Protection of Intellectual Property (AIPPI). Dr Matthew Rimmer from the Australian National University College of Law and Dr Luigi Palombi from Palombi IP also appeared in a private capacity at the public hearing into the Bill on 6 June 2013. The respective positions of each of these parties are discussed where relevant under the key issues in this Bills Digest.

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13. Article 15 of the International Covenant on Economic, Social and Cultural Rights provides for a right of everyone to ‘benefit from the production of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author’.
Policy position of non-government parties/independents

**Australian Greens**

Senator Siewert, also on behalf of Senators Di Natale and Heffernan, moved:

‘That the Senate—

a. notes the recent ruling by the United States Supreme Court that human genes are not eligible for patent protection;

b. recognises that this ruling is a significant development in the debate over gene patenting and the future of medical research; and

c. urges the Australian Government to consider the implications of this for the Patents Act 1990.’

**Liberal Party of Australia**

Sophie Mirabella expressed her concern that stakeholders had not been adequately consulted and that:

... the preparation of this bill has been both rushed and botched and the coalition cannot in all good conscience simply let this go through in its current form.

She also considered that inconsistencies existed between proposed Crown use section 160A and the Australia-US Free Trade Agreement (AUSFTA). She noted that the AUSFTA allows for Crown use of an invention without authorisation by the patentee only in the case of public non-commercial use or national emergency. However, the Bill proposes to allow application of Crown use in any situation in which such use is considered necessary for the proper provision of services, where those services are primarily funded by the Commonwealth or a state.

Ms Mirabella also said that the proposed amendments may place Australia in breach of a number of its obligations under the WTO’s TRIPS Protocol. The WTO defines an eligible importing country as a member of the WTO.

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 nonmembers to join the organisation.

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18. Ibid., p. 6721.
19. Ibid.
However, the Bill states that an importing country does not have to be a WTO member. This issue is further discussed in this Bills Digest under the heading ‘Non-WTO countries and compliance with international treaty obligations’.

Financial implications

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

Overview of the key issues

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, two of which are addressed in this Bill: Crown use and 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 are the Plant Breeders’ Rights and the Australia New Zealand Single Economic Market.

Changes to the Crown use and compulsory licensing provisions and the implementation of the TRIPS Protocol were the most widely debated issues in the public hearing before the Social Policy and Legal Affairs Committee.

Concerns were also raised by some public interest groups about the ‘haste’ in which the Bill was introduced and the lack of time for sufficient public consultation.

Structure of this Bills Digest

Each Schedule of the Bill is discussed under the heading ‘Key issues and provisions’. Also included is relevant background information and comments.

20. Ibid.
22. 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 (PC), Compulsory licensing of patents, Inquiry report, 61, PC, 28 March 2013, p. 6, accessed 4 July 2013.
Key issues and provisions

Schedule 1—Crown use

Background

What is Crown use?

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. Crown use is currently enshrined in sections 163-170 of the Patents Act.

How does it apply?

Governments can apply Crown use provisions in a similar way to compulsory licensing. However, the Crown use provisions are a less costly and more time effective option. With Crown use, patented inventions can be used without first seeking the owner’s permission. As soon as practicable after an invention has been used, the Government must inform the patent holder and provide any information that is reasonably required, unless it would be contrary to the public interest to do so. The patent holder is entitled to remuneration.

Crown use cases

There are only two cases where Crown use has been contested before the courts, both of which were allowed. They are: use of a central bearing structure for rail carriages by the NSW Government in 1964, and a water meter assembly by Brisbane City Council in 1994.

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23. Section 163 of the Patents Act. Also see footnote no. 6. ‘State’ includes the Australian Capital Territory, Northern Territory and Norfolk Island.
25. Section 165 of the Patents Act.
26. General Steel Industries Inc v Commissioner for Railways (NSW) (1964) 112 CLR 125. See also [1964] HCA 69. ‘The NSW State Commissioner for Railways’ use of an invention for central bearing structures for railway carriage construction was held to be allowed under section 125 of the Patents Act 1952 (Cth) (the predecessor to s. 163 of the current Patents Act). It was considered that the use was “for the services of the state”. Productivity Commission, Compulsory licensing of patents, op. cit., p. 166.
27. Stack v Brisbane City Council (1994) 131 ALR 333. ‘Brisbane City Council’s use of a patented invention for water meter assemblies was held to be within the scope of Crown use. It was considered that Brisbane City Council was an authority of a state for the purpose of s. 163. The focus of the case was on whether the functions of Brisbane City Council have the “stamp of government” and whether they have been given the power to direct or control the affairs of others on behalf of the state.’ Productivity Commission, Compulsory licensing of patents, op. cit., p. 166.
The Productivity Commission Inquiry Report

The Productivity Commission examined Crown use in its Inquiry Report *Compulsory Licensing of Patents*, released March 2013 (Productivity Commission Inquiry Report). In identifying reasons why the Crown use provisions are rarely used, the Productivity Commission observed:

- the provisions are intended to be a safeguard for rare instances in which the patents system is hindering government action to address an urgent issue. Patent holders may be usually willing to licence, or there may be few instances where urgent access is needed
- governments may be reluctant to use the provisions as they interfere with the rights of patent holders and could potentially damage confidence in the patents system if overused
- there may rarely be any problems for governments in accessing patents, because governments may usually offer just terms, or because the cost of litigation to challenge Crown use forces unwilling licensors to negotiate
- there may be a lack of knowledge about the provisions, and the appropriate arms of government are unclear on how and when to invoke them and
- there may be problems with the provisions that discourage governments from using them.

The recommendations of the Productivity Commission concerning Crown use are addressed under the section ‘Proposed changes to Crown use provisions’.

Reviews of Crown use

Previous reviews of Crown use include a review by the Advisory Council on Intellectual Property in 2005, *Consideration of Crown Use provisions for patents and designs*. This review found that some patent holders had been threatened with Crown use by organisations trying to gain an advantage in negotiations. Uncertainty was also raised about whether quasi-government organisations had the authority to invoke Crown use provisions. The Government did not issue a response, on the grounds that there was no substantial evidence the provisions were being misused.

Gene patents

In recent years there has been growing international debate over gene patents and their impact upon research, patient care and health care. Nearly 20 years ago, the US molecular diagnostic company Myriad Genetics obtained several patents after discovering the precise location and sequence of the BRCA1 and BRCA2 genes, mutations of which can dramatically increase the risk of breast and ovarian cancer. This knowledge enabled Myriad to develop medical tests for detecting mutations in these genes to assess a patient’s cancer risk.

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29. Ibid. p. 166.
The validity of the patents was challenged by a consortium of cancer patients, medical associations and scientists. On 13 June 2013, in the Association for Molecular Pathology v Myriad Genetics case, the US Supreme Court held that a naturally occurring DNA segment is a product of nature and not patent-eligible merely because it has been isolated – a ruling that appeared to overturn three decades of gene patent awards.\(^{33}\)

The court ruled that without an exception for laws of nature, natural phenomena, and abstract ideas, which are basic tools of scientific and technological work, there would be a danger that the grant of patents would tie up the use of such tools and inhibit future innovation premised upon them. ‘This would be at odds with the very point of patents, which exist to promote creation’, Thomas J concluded.\(^{34}\) He emphasised that ‘patent protection strikes a delicate balance between creating incentives that lead to creation, invention, and discovery, and impeding the flow of information that might permit, indeed spur, invention’.\(^{35}\)

As a result of this US Supreme Court decision, Myriad no longer has the exclusive right to isolate an individual’s BRCA1 and BRCA2 genes, but it can patent synthetic genetic material known as complementary DNA (cDNA), because it is not naturally occurring. While the ruling was seen as something of a compromise, it could have profound implications for the biotechnology and drug industry. Concerns have been raised that it could discourage investment in genetic research by taking away commercial incentive to continue researching into DNA. Some biotech research companies saw it as an about-turn in the international approach to intellectual property rights surrounding genetics.

This decision also contradicts a ruling on gene patenting in Australia’s Federal Court in February this year, which decided in favour of Myriad after a similar lawsuit was brought by Cancer Voices Australia.\(^{36}\) The Federal Court ruled that the two genes, extracted from natural cells obtained from the human body and ‘purged of other biological materials’, constituted a ‘manner of manufacture’ and could therefore be patented.\(^{37}\) The appeal against that decision was heard by the Full Court of the Federal Court in August 2013.\(^{38}\) A decision has not been delivered as of the time of publication of this Bills Digest.

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\(^{32}\) Association for Molecular Pathology v. Myriad Genetics, 569 US 12-398 (2013).


\(^{34}\) Association for Molecular Pathology v. Myriad Genetics, 569 US 12-398 (2013).

\(^{35}\) Ibid.

\(^{36}\) Cancer Voices Australia v Myriad Genetics Inc (2013) 99 IPR 567. See also [2013] Face, CA 65.

\(^{37}\) Ibid., paragraph 136.

\(^{38}\) ‘Maurice Blackburn, solicitors for Ms D’Arcy, one of the applicants in the case before Justice Nicholas, lodged an appeal against the decision on 4 March 2013. The other applicant, Cancer Voices, is not an applicant in the appeal’. M Mittiga, ‘Appeal lodged in gene patents decision,’ Dibbs Barker website, 7 March 2013, accessed 4 July 2013.
Crown use and gene patents

Several inquiries have been conducted into the impact of gene patents on access to healthcare, as well as genetic and biomedical research.\(^{39}\) It has been suggested that existing Crown Use provisions in the *Patents Act* could be used to address any potentially adverse effects of gene patents on genetic and biomedical research, as well as access to medical treatment.\(^{40}\)

The Australian Law Reform Commission (ALRC) examined Crown use in 2004 as part of a review of gene patents (2004 ALRC Review).\(^{41}\) The ALRC examined whether the Australian patent system was meeting the challenges of the rapidly developing science associated with the sequencing of the human genome.

The 2004 ALRC Review made 50 recommendations for reform but did not suggest a radical overhaul of the patents system. The ALRC recommended that the *Patents Act* should *not* be amended to exclude genetic materials or technologies from patentability, or to provide a new medical treatment exclusion, or to expand the existing circumstances in which social and ethical considerations may be taken into account in decisions about granting patents:

> The ALRC has concluded that there are significant impediments to amending the *Patents Act* to exclude genetic materials from patentability. These include a long history of patenting such inventions, international treaty obligations, and a biotechnology industry dependent on patents and inventions.\(^{42}\)

However, the ALRC did recommend amendments that specify healthcare services or products as a rationale for invoking the Crown use provisions.\(^{43}\) The Report noted that while Crown Use provisions are rarely used, they constitute an important mechanism in helping to ensure that patent protection does not adversely affect significant public interests.\(^{44}\) The ALRC recommended that policies should be developed about the circumstances in which it is appropriate for government to invoke Crown use for the purposes of promoting human health.\(^{45}\)

The recommendations were endorsed by the Senate Standing Committee on Community Affairs in its review of gene patents in 2010.\(^{46}\)

Proposed changes to Crown Use provisions

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41. Ibid.
42. Ibid., p. 17
43. Ibid., p. 608, recommendation 26-2.
44. Ibid., p. 23.
45. Ibid., p. 608, recommendation 26-1.
46. Senate Standing Committee on Community Affairs, *Gene patents*, op. cit., p. 146.

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There is widespread uncertainty as to the operation of the Crown use provisions under the *Patents Act*, exacerbated by the lack of jurisprudence on the issue. The Explanatory Memorandum to the Bill states that:

> The extent to which the phrase ‘for the services of the Commonwealth or a State’ can include non-government bodies that deliver goods or services in sectors where governments have primary responsibility is uncertain. There are also concerns that there is insufficient transparency and accountability in the process for using the Crown use provisions.\(^47\)

The Productivity Commission in its Inquiry Report made two key recommendations regarding amendments to the *Patents Act* in relation to Crown use:

1. Section 163 of the *Patents Act* should be amended to make it clear that Crown use can be invoked for the provision of a service that the Australian, state and/or territory governments have the primary responsibility for providing or funding\(^48\) and

2. The *Patents Act* should be amended to require:
   - the Crown to attempt to negotiate use of the patented invention prior to invoking Crown use
   - the Crown to provide the patentee with a statement of reasons no less than 14 days before such use occurs
   - Crown use to be approved by a Minister (the relevant Federal Minister or state Attorney-General) and
   - that the patentee is entitled to remuneration determined on the same basis as that for a compulsory licence.\(^49\)

The Productivity Commission specified that the first two requirements of the second recommendation should be able to be waived in emergencies. However, in all cases patentees should be provided with immediate notice that their patents have been used, and a statement of reasons as soon as practical thereafter.\(^50\)

The Commission concluded that the proposed requirements would not significantly alter the cost and time advantage of Crown use over compulsory licensing. Governments were already obliged under the *Patents Act* to inform patent holders about Crown use as soon as practicable after it occurs, and under administrative review legislation can be directed to provide the reasons for Crown use. Regarding compensation, patent holders already have a right to seek adjudication by the Federal Court. The proposed requirements would not remove the right of governments to invoke Crown use without having to obtain authorisation from the Federal Court. Concerns about timeliness

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\(^{49}\) Ibid., recommendation 7.2.

\(^{50}\) Ibid.
would be addressed by allowing the recommended requirements (except for Ministerial approval and compensation) to be waived in emergencies. 51

Stakeholder comments

IP Australia

IP Australia Director General Philip Noonan told the Social Policy and Legal Affairs Committee that the Bill would give greater certainty for the Crown in using the system:

... because at the moment the definition of the Crown is quite uncertain at the edges. Many government services are administered by private entities that are funded or sponsored by the government. 52

He further noted that the amendments ensure that any service that is predominantly provided or funded by the Commonwealth or states would be within the ambit of the Crown use provisions. 53

The second recommendation of the Productivity Commission introduces some new accountability measures to balance Crown use with ‘appropriate respect for the patent owner’. 54 Mr Noonan said that none of those provisions are contained in the current legislation.

Social Policy and Legal Affairs Committee views

The Social Policy and Legal Affairs Committee welcomed the implementation of the Productivity Commission’s recommendations in Schedule 1 of the Bill: 55

Crown use provisions have been rarely used. This low rate of use and past reviews have indicated that reforming Crown use may be necessary particularly around the scope of Crown use and improving transparency and accountability of governments seeking to use the provisions.

...

The Committee is aware there have been difficulties with the existing Crown use provisions and believes that maintaining the status-quo could result in continued uncertainty about when Crown use could be invoked.

The Committee does not believe that the provisions in Schedule 1 will result in an increase in Crown use. The Committee is aware of only two instances where Crown use has been invoked and welcomes the idea that its use is clarified so that in future, where necessary, the provision can be used with more certainty. 56

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51. Ibid.
53. Ibid.
54. Ibid.
56. Ibid., pp. 2 and 8.

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Crown use and healthcare

As noted above, the scope of Crown use has been debated in relation to gene patents, which are currently at the forefront of public attention due to litigation in the US and Australia involving Myriad Genetics’ gene patents.

The Productivity Commission found that it appears that Crown use can be applied to healthcare-related patents, given that governments have a major role in providing healthcare. However, the following uncertainties were flagged:

- the Patents Act states that Crown use can only be used ‘for the services of’ a government, which the courts could interpret narrowly to exclude healthcare. However, it could also be argued that this is unlikely, given that Crown use has previously been allowed for railways and domestic water supply.
- healthcare services are sometimes supplied by non-government organisations, which could be considered to be outside the scope of Crown use. However, it can also be argued that non-government providers can be included because the Patents Act allows a government to authorise other parties to undertake Crown use on its behalf and
- genetic samples taken in one state are sometimes tested by a laboratory in another state. It was questioned whether states can apply Crown use outside their borders in such cases and whether states have to invoke Crown use individually, rather than coordinate their actions. Alternatively, it could be argued that the Patents Act does not limit the geographic location of Crown use, or inter-jurisdictional coordination.57

The Productivity Commission advised that the proposed primary responsibility test should not remove the existing right of individual government bodies to exploit a patented invention under Crown use, regardless of their share of the relevant market.

The primary responsibility test would take account of all providers of similar services. For example, genetic testing by private providers for private patients would be included in an assessment of whether governments have primary responsibility for providing or funding the testing. As governments are responsible for providing or funding most genetic tests, they would be found to have primary responsibility. Genetic testing would therefore be eligible for Crown use, including when it is undertaken by private providers for private patients. The private providers could be authorised to exercise Crown use on behalf of a government, as is already allowed under subsection 163(1) of the Patents Act.58

Comments of major interest groups

Cancer Council Australia

58. Ibid.
Cancer Council Australia considered that the Bill would introduce new safeguards to protect consumers from commercial monopolies over vital services such as genetic testing for cancer risk.

Cancer Council Australia CEO Professor Ian Olver said in a media release on the proposed legislation that the Bill should help clarify the *Patents Act* in respect of Crown use provisions.  

Olver referred to a 2008 case where the commercial licensee for patents on the BRCA1 and BRCA2 breast and ovarian cancer genes sought to enforce its patent claims over the state and territory laboratories that were providing those tests as a public service. The licensee later withdrew its claim, but there was uncertainty at the time over whether Crown use provisions could be invoked to prevent a potential monopoly over the genes and the tests.

Professor Olver said he was encouraged by the Government’s recognition that more work was required to get the balance right between rewarding innovation and ensuring equitable access to medical technology:

> The establishment of a patent audit committee and consultations on further changes to the Act have the potential to deliver some long overdue protection for healthcare consumers.

**Dr Matthew Rimmer**

Referring to the 2004 ALRC Report recommendation that there was a need to clarify Crown use, in part to address problems with gene patents, and the concerns of the Cancer Council, Dr Rimmer saw an urgent need for the Crown use amendments to be implemented. Dr Rimmer also noted that the Commonwealth Department of Health and Ageing made similar arguments in its submissions to the Productivity Commission:

> I think there are very particular cases in which that has been not just a theoretical issue but also a very practical and significant issue.

Dr Rimmer also pointed to the application of the reforms to domestic emergencies:

> I think that the provisions make the Crown exploitation of inventions much clearer in terms of when they can be invoked ... It should also be noted that, in certain circumstances, such conditions can be waived in terms in emergencies. I think that a really critically important part of the reforms is that they also deal with Crown exploitation in relation to domestic emergencies, which could arise, for instance, in relation to issues about access to essential medicines.

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60. Ibid.
61. Ibid.
62. House of Representatives Standing Committee on Social Policy and Legal Affairs, transcript of evidence, op. cit., p. 3.
63. Ibid., p. 7.
Crown use in other countries

Dr Luigi Palombi

Dr Luigi Palombi from Palombi IP submitted that it would be appropriate for consideration to be given to the application of the US approach in Australia:

I think it is important to look at what the United States does. In the United States the government does not go through this process. It simply provides an immunity from patent infringement to any contractor that basically does work at the request of the US government. It is not a question of trampling the rights because even the current provisions effectively allow a patentee to seek compensation in the event that the Crown would exercise those rights. It is a question ultimately of negotiation in terms of working out what that compensation is. 64

*United States Code* (USC) 28 section 1498 empowers the US government to make use of any patented invention without the need for notice to the patent owner. The only recourse open to the patent owner is to sue for `reasonable and entire compensation` in relation to any act of patent infringement committed by a third party as a consequence of providing services to the US Government:

This clearly obviates any requirement for the US government to provide the patent owner with any advance warning or the reasoning for such use of a patented invention. 65

He noted a recent en banc decision of the US Court of Appeals for the Federal Circuit, *Zoltek Corp v The United States of America and Lockheed Martin Corp*, 66 which provides an overview of the history of *USC* 28 section 1498. The legislation provided the US government contractor with immunity from a patent infringement suit - the liable party was the US government. The US government may challenge the validity of any patent that is alleged to be infringed by a government contractor.

Overview of position of major interest groups in relation to Crown use

Law Council of Australia

The Intellectual Property Committee of the Business Law Section of the Law Council of Australia (LCA) identified the following issues in relation to consistencies with the Australia-United States Free Trade Agreement (AUSFTA) 67 and the TRIPS agreement in relation to Crown use:

1. AUSFTA Article 17.9.7 permits Crown use of an invention without authorisation by the patentee in the case of "public non-commercial use, or national emergency", whereas the legislation in clause 160A would extend authorisation to any use which is necessary for the "proper provision of services" where those services are "primarily funded by" the Commonwealth or a state, clearly a wider concept than "public non-

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64. Ibid., p. 7.
67. See Department of Foreign Affairs and Trade (DFAT), *Australia-United States Free Trade Agreement*, Fact sheets, DFAT, accessed 1 July 2013.
commercial use or national emergency" and broader than existing section 163 of the Patents Act. For example it appears the provision would extend to authorising the commercial marketing of products where those products are primarily funded by the relevant government.

2. Similarly, the legislation does not take account of the effect of AUSFTA Article 17.10.4(a). That article requires, in relation to regulated products such as pharmaceuticals, measures to prevent other persons from "marketing a product where that product is claimed in a patent" without the acquiescence of the patent owner. Yet clause 160A appears to permit the Commonwealth or States to authorise exactly such conduct.

3. If clause 160A extends as described above, the regime under section 165A of the Patents Act may be unduly burdensome on a patentee in circumstances where the authorisation has been given to a commercial competitor. In light of the foregoing, clause 160A may also be inconsistent with Articles 30 and/or 31 of TRIPS. 

Dr Matthew Rimmer

Dr Rimmer was fully supportive of the Bill, arguing that the reforms were necessary and urgently needed to provide safeguards in relation to patent law and the public interest. He suggested that the minimal use of the Crown use provisions could be partly due to the uncertainty around the provisions:

There seems to be a problem in terms, perhaps, of conservative interpretation of the current Crown use provisions. However, the language is such that a number of the submissions to the Productivity Commission raised concerns about the uncertainty in terms of interpreting those provisions. So I do think it is necessary to clarify the Crown use provisions and to modernise the provisions, and also to deal with circumstances that are not properly dealt with under the current legislation—like questions of emergencies, which is a very critically important issue, which is not properly delineated in terms of the regime.

Dr Luigi Palombi

Dr Luigi Palombi disagreed that there was a need for urgency in passing the legislation and questioned the need for clarification in the legislation:

I think the problem with Crown use is not so much the scope of the powers; it is just the reticence on the part of the relevant authorities within the state and federal bodies actually exercising that power.

Dr Palombi contended that the existing Crown use provision is ‘more than adequate’, noting that it has been part of the law since Federation and was derived from English legislation, so there is authority as to what the ‘services’ of the Crown means. Dr Palombi referred to the House of Lords decision Pfizer v Ministry of Health, which confirmed that the term ‘services of the Crown’ has a broad meaning. He said if the Australian courts followed the same reasoning, it would cover the Commonwealth regardless of whether it was funding or providing the relevant service. The 1965

70. Ibid., p. 6.
*Pfizer* case allowed the National Health Service to obtain a patented antibiotic for its hospitals for administration to inpatients and outpatients.\(^{72}\)

Dr Palombi advised that the new conditions attached to the Crown use amendments would actually make the provisions more difficult to use. He pointed to the requirement that the relevant minister (or, in the case of a state, the Attorney-General) consider the matter, produce a written set of reasons as to why he or she has decided to exercise that power, and produce an instrument of approval. He told the Committee:

> All of these so-called safeguards, or balancing measures, actually do the exact opposite ... The problem is that we are going to make it much, much harder and it is unlikely to achieve any real objective in terms of facilitating the use of the Crown powers. So, if anyone thinks this is a safeguard against an abusive patentee who wishes to withhold certain medicines or other inventions, I think we need to reconsider this greatly. I certainly do not think that this legislation deals with the issue or the real nub of the problem, and I certainly would not recommend that it be rushed through the parliament in its current proposed form.\(^{73}\)

**Key provisions**

**Item 4 of Schedule 1** of the Bill amends Chapter 17 of the *Patents Act* to introduce **proposed section 160A**. This section provides for the exploitation of an invention (for which a patent application has been made) by the Commonwealth or a state (*relevant authority*), or by a person authorised by the relevant authority, for the services of that relevant authority where the exploitation of the invention is necessary for the proper provisions of those services in Australia (**proposed subsection 160(4)**).

If the relevant authority authorises a person to exploit an invention on its behalf, it must do so in writing (**proposed subsection 160A(2)**) and a person must not act before an authorisation is made (**proposed subsection 160A(3)**) but may be authorised before or after a patent has been granted for the application (**proposed subsection 160A(3)**).

The Bill implements both of the changes to Crown use provisions recommended by the Productivity Commission.

In relation to **Recommendation 7.1 of the Productivity Commission Inquiry Report — Crown use for the provision of a government service**:

Currently, section 163 of the *Patents Act* provides that Crown use applies where the invention is exploited for the services of the Commonwealth or a state.

**Proposed subsection 160A(5)** of the Bill clarifies that those services include services that the Australian, state and/or territory governments have the primary responsibility for providing or funding. The intention is that this primary responsibility test would take account of all providers of similar services.\(^{74}\)

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73. Ibid., p. 6.
Proposed section 160A(5) provides that:

*services, of a relevant authority, in relation to the exploitation of an invention by or for the relevant authority, includes:

(a) if the relevant authority is the Commonwealth—a service that is:

(i) primarily provided or funded by the Commonwealth; or

(ii) primarily provided or funded by the Commonwealth and one or more of the States; and

(b) if the relevant authority is a State—a service that is:

(i) primarily provided or funded by the State; or

(ii) primarily provided or funded by the State and one or more of the other States or the Commonwealth.

Example: The Commonwealth and the States primarily fund the provision of health services, including genetic tests covered by patents. Under this Chapter, a relevant authority can authorise a third party (an authorised person) to exploit such a patent. Any exploitation of the patent by the third party conducting the test on an individual is not an infringement under this Chapter.

The Explanatory Memorandum to the Bill notes that a test based on primary responsibility for providing or funding the service is not intended to limit the scope of ‘for the services of the Commonwealth or a state’ (or ‘for the services of a relevant authority’ as represented in proposed subsection 160A(5)), or to remove the existing right of individual government bodies to exploit an invention under Crown use, regardless of their share of the relevant market: 75

The Explanatory Memorandum provides an example of a patented invention concerning diagnostic genetic testing. In this case, genetic testing undertaken by private providers for private patients would be included in an assessment of whether governments have primary responsibility for providing or funding such testing:

As governments are responsible for providing or funding the vast majority of genetic tests in the health care sector, they would have primary responsibility. As a result, genetic testing would be eligible for Crown use, including when it is undertaken by private providers for private patients. In this scenario, private providers could be authorised to exercise Crown use on behalf of a government, as is presently allowed under existing subsection 163(1) of the Patents Act. 76

The Productivity Commission also identified uncertainty about the extent to which the infringement exemption arising under Crown use would extend to third-party non-government entities providing public services. 77 The amendments proposed in item 4 of Schedule 1 of the Bill seek to address this uncertainty by making clear that the term ‘services’ in relation to the Commonwealth or a state includes services primarily provided or funded by government.

75. Ibid., p. 48.
76. Ibid., p. 48.
In relation to Recommendation 7.2 of the Productivity Commission Inquiry Report — negotiation, approval, emergency situations and remuneration

Item 5 of Schedule 1 of the Bill repeals section 163 of the Patents Act and introduces proposed sections 163 and 163A. These two proposed sections allow for the exploitation by the relevant authority to be exempt from infringement of a patent if certain conditions (under proposed subsection (2) of each of these proposed sections) are met.

Prior Negotiation

The current legislation does not require the Crown to obtain consent from, or inform, the patent owner of its intention to exploit a patented invention before exploitation has commenced. The Crown can voluntarily seek consent before, during or after exploitation of a patent.

Proposed paragraph 163(2)(a) of the Patents Act requires a relevant authority to first attempt for a reasonable period to negotiate with the patent owner for authorisation to exploit the invention on reasonable terms.

The Explanatory Memorandum suggests that this requirement could be to the benefit of the Crown:

The requirement to negotiate with the patentee prior to invoking Crown use could result in a superior outcome for government because the agreement could for example incorporate other know-how of the patent owner. Instituting a requirement to seek prior consent in Crown use should help achieve better outcomes for all parties. This would further ensure more efficient exploitation of the patented invention in addressing the situation at hand and provide greater transparency on the intentions of the Crown to exploit the invention.  

Proposed paragraph 136D(1)(e) provides that 30 days is a reasonable period for trying to obtain authorisation, but it should be noted that this applies only to patented pharmaceutical inventions. Regarding the timeframe in proposed section 163, the Explanatory Memorandum states that: ‘Unlike section 136D, new section 163 is a technology neutral provision that allows for Crown exploitation of any technology that can be patented. In most cases, 30 days will be a reasonable period to try to obtain authorisation under new paragraph 163(2)(a). However, there may be some cases where a shorter or longer period is required’.  

Should the negotiation attempt be unsuccessful, the relevant authority will need to seek approval from the relevant Minister to rely on the Crown use provisions. If that approval is given, a statement of reasons for the approval is to be provided to the patent owner (paragraph 163(2)(c)).

Subparagraph 160A(3)(a) amends the Patent Act to provide that a person must be authorised to exploit an invention under the Crown use provisions before any act covered by that authorisation is done. Currently, a person could be authorised before or after the act had been done.

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81. Ibid., p. 45.
Ministerial oversight

Item 5 also amends that the *Patents Act* to insert new paragraph 163(2)(b) which introduces the condition that Ministerial approval must be obtained before a relevant authority can rely on the infringement exemption provided by the Crown use provisions.

The Explanatory Memorandum referred to previous reviews which found that there was a lack of clarity about which Crown entities constituted the Crown. 82 A number of entities could potentially qualify as the Crown, including: employees; commissions; statutory authorities; statutory corporations; government business entities; government owned corporations; and private corporations under contract to the government. Similar concerns of ambiguity relate to whether some research institutes have sufficient government involvement to be considered the Crown. 83 The Explanatory Memorandum concludes that this lack of clarity about which entities constituted the Crown may also lead to a lack of certainty as to who may authorise exploitation by non-government entities under the Crown use provisions. 84

The Ministerial approval requirement in proposed paragraph 163(2)(b) is intended to provide greater certainty for government or semi-government entities and for patent owners that the Crown use provisions apply to the exploitation of an invention.

Proposed paragraph 163(2)(c) of the *Patents Act* provides that where a Minister has approved an instance of Crown use, the Minister is required to provide the applicant and the nominated person, or the patentee, at least 14 days before the commencement of exploitation:

- notice of their approval of the Crown exploitation of the invention under proposed paragraph 163(2)(b) and
- a statement of reasons as to why the approval was given.

Providing the statement of reasons to the applicant and the nominated person, or the patentee, prior to the commencement of Crown exploitation will provide greater transparency to the patent owner about the decision to invoke Crown use. 85

Under proposed subsection 160A(5), the ‘relevant Minister’ is the Minister responsible for the administration of the *Patents Act*. In the case of exploitation by or on behalf of a state or territory, the relevant Minister is the appropriate state or territory Attorney-General.

The Explanatory Memorandum suggests that the new requirements will deliver increased oversight to ensure that Crown use is invoked appropriately:

85. Ibid., p. 45.
This may increase administrative burden to government bodies and departments. However, the increased clarity and transparency regarding Crown use is likely to enhance the Crown’s ability to meet the needs of the public in the rare circumstances Crown use is invoked, while providing greater certainty to patent owners that the Crown use provisions will not be used inappropriately. This will ultimately lead to a more effective application of Crown use. Ministerial consideration will ensure that Crown use is only invoked where the benefits outweigh the costs.\(^86\)

**Emergency situation**

**Proposed section 163A** provides for a modified approval process where the exploitation of the invention by the relevant authority is required due to an emergency.

**Proposed subsection 163A(2)** provides the preconditions for relying on the Crown use safeguard. These are that the Minister considers that the exploitation is necessary because of an emergency, and that the Minister approves the proposed exploitation before the exploitation starts. During a period of emergency the requirement for prior negotiation and the requirement to provide the statement of reasons prior to Crown exploitation do not apply.

The Explanatory Memorandum defines ‘emergency’ as including an unforeseen occurrence or a sudden and urgent occasion for action. It could include a public health crisis such as a plague or epidemic, or a medical emergency such as a pandemic. It could also include war, national security situations, perceived threats to law and order, natural disasters and other situations of urgency. It includes but is not limited to situations where a state of emergency has been declared by a government.\(^87\)

**Proposed subsection 163A(3)** of the *Patents Act* requires that in all cases the relevant Minister must as soon as practicable provide the patentee with a statement of reasons for approving the Crown exploitation.

**Remuneration**

There is no guidance for remuneration to a patent owner in the existing legislation.\(^88\) The Productivity Commission noted that previous reviews of the Crown use provisions found that the lack of guidance on pricing can leave patentees disadvantaged, and that the lack of an applied standard or criterion to refer to in negotiations could weaken their bargaining position in seeking to obtain fair and equitable agreement.\(^89\)

Existing subsection 165(2) of the *Patents Act* provides that, when parties fail to come to an agreement, either party can apply to a prescribed court for a determination on any terms of the exploitation, including remuneration.

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86. Ibid., p. 50.
87. Ibid., p. 51.
88. Ibid., p. 52.
89. Ibid.
Proposed subsection 165(2) provides that in determining the amount of remuneration, the court must determine an amount that is just and reasonable and must take into account the economic value of the exploitation of the invention. This does not prevent a court from also taking into account other relevant matters, such as any compensation already provided by the government.\(^90\)

Senate Scrutiny of Bills Committee

As noted above the Senate Scrutiny of Bills Committee raised the concern that a determination relating to Crown use exploitation under item 5 of Schedule 1 of the Bill did not appear to be reviewable even though the Patents Act provides for review of certain decisions.

The Scrutiny of Bills Committee sought the Minister's advice as to whether consideration had been given to the appropriateness of merits review (in the Administrative Appeals Tribunal) of decisions made by the relevant Minister which enable Crown exploitation of an invention in proposed sections 163 and 163A.\(^91\)

The Minister responded that such consideration had been given, and it was appropriate that decisions by the Minister to approve Crown exploitation of a patented invention were not subject to merits review, as the Minister’s decision to approve Crown exploitation would depend primarily on policy considerations.\(^92\)

The Committee then responded that it would leave the question of whether the proposed approach was appropriate to the consideration of the Senate as a whole.\(^93\)

Schedules 2 and 3—TRIPS Protocol interim waiver and later commencing amendments

Compulsory licencing in Australia

Background

Australia has a system of compulsory licencing 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.\(^94\) 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.\(^95\)

\(^90\). Ibid.
\(^91\). Senate Standing Committee for the Scrutiny of Bills, Alert Digest No. 6 of 2013, op. cit.
\(^93\). Ibid.
\(^94\). Productivity Commission, Compulsory licensing of patents, op. cit., p. 2.
\(^95\). Patents Act, section 133.
Compulsory licensing 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.

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 Draft Report in April 2013 (Draft Report). 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 Draft 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, AUSFTA added a further extension to patents for pharmaceuticals beyond the legislated 20 years. The Draft Report

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97. Ibid., p. 3.
98. Ibid.
99. Ibid., p. 2.
100. Ibid.
102. Ibid., p. xix.
found that the agreement was made ‘without careful regard to whether this was in our own economic interest’.\footnote{Ibid., p. v.} It recommended that:

In negotiating such agreements, 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 where it is not necessary for it to deliver incentives to innovate.\footnote{Ibid.}

The Pharmaceutical Patents Review Draft Report has yet to be responded to, an issue that was raised in the House Social Policy and Legal Affairs Committee inquiry into the Bill. Dr Palombi saw a need for further discussion of the Draft Report, and cautioned against introducing the proposed legislation ‘in haste’:

It seems to me that, in view of the issues concerning health and given what is happening with the pharmaceutical patents review, rather than pass legislation like this in a piecemeal way perhaps it would be more appropriate to wait for the government to respond to the pharmaceutical patents review final report and then put the legislation together.\footnote{House of Representatives Standing Committee on Social Policy and Legal Affairs, transcript of evidence, op. cit., p. 10.}

**Compulsory licencing 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. 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.\footnote{Productivity Commission, *Compulsory licensing of patents*, op. cit., p. 264.}

**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 *Myriad Genetics* case, Justice Scalia asked: ‘Why would a company incur massive investment if it cannot patent?’\footnote{Oral arguments of the *Association for Molecular Pathology v Myriad Genetics*, p. 12, accessed 4 July 2013.} 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.\textsuperscript{108}

In 2009 an estimated 272 million people were infected with malaria, HIV/AIDS or tuberculosis, causing 3.9 million deaths.\textsuperscript{109} 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.\textsuperscript{110}

Development of the TRIPS Agreement

The World Trade Organization (WTO) tried to address this dilemma in the TRIPS Agreement,\textsuperscript{111} 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.\textsuperscript{112}

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.\textsuperscript{113}

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 another WTO country.\textsuperscript{114} In December 2005, the Protocol Amending the TRIPS Agreement (TRIPS Protocol)\textsuperscript{115} was drafted to give permanent effect to the waiver, enabling pharmaceutical products to be exported under compulsory licence. The TRIPS Protocol provides that:

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109. Ibid.
110. Ibid.
• 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 in circumstances of 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
• 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 manufactures 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.116 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 Rimmer told the House Social Policy and Legal Affairs Committee inquiry into the 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. 117

Amendments in the Bill to implement the TRIPS Protocol

Item 19 of Schedule 2 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 ... and export those medicines to developing countries. Adequate compensation for the patent holder will be negotiated, to ensure that they are not disadvantaged by the arrangements.¹¹⁸

According to the Explanatory Memorandum to the Bill, the proposed provisions under Schedule 2 will enable countries to source generic versions of patented pharmaceuticals from Australia, in accordance with Australia’s international obligations. The approach aims to balance the interests of patent owners, importing countries and manufacturers of generic medicines.

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.¹¹⁹ The proposed provisions in Schedule 2 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 136D(1)(c) and (e) of the Patents Act.)

4. Notify intent to use the system


¹¹⁹ Ibid., pp. 57–58.
• 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 136D of the Patents Act.)

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 136C of the Patents Act.)

6. Notify grant of the compulsory licence

• If the Federal Court grants the licence, the licensee must notify the Commissioner of Patents of the licence and of the address of the website where shipment information is to be posted (see number 9 below). (Proposed paragraph 136E(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 136P 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 136P 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 136E of the Patents Act sets out ‘Terms of PPI compulsory licence’.)

9. Notify details of shipment

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• 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 136E 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 136D(1)(g) and proposed subsection 136C(4) of the Patents Act.)*

Under **item 26 of Schedule 2**, ‘eligible importing country’ means:

(a) a foreign country (whether or not a member of the WTO) recognised by the United Nations as a least-developed country; or

(b) a foreign country that has made a notification to the Council for TRIPS of its intention to use, as an importer, the system set out in the WTO General Council decision of 30 August 2003; or

(c) a foreign country (whether or not a member of the WTO) included in a class of foreign countries prescribed for the purposes of this paragraph.

Under **proposed section 136R** 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.\(^{120}\)

Dr Rimmer said:

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. 121

Non-WTO countries and compliance with international treaty obligations

Stakeholder comments

Law Council of Australia

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 provides 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.122

IP Australia

Regarding compliance with international treaty obligations, Mr Noonan told the Committee that the Bill extends to non-WTO countries:

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.' 123

Mr Noonan also said that implementation of the TRIPS Protocol:

... frees-up Australia's hand to help out countries who are in often desperate need but [the legislation] introduces enough accountability and oversight, particularly through the Federal Court determining the terms of the licence and [the] criteria that must be respected ... to make sure that the system is not overused and patent owners are appropriately protected. 124

As outlined above, the Government in its Statement of Compatibility with Human Rights notes that the Bill enables the export of generic versions of patented medicines to developing countries that are experiencing serious public health issues and that have no capacity to manufacture the medicines or purchase them.125

121. House of Representatives Standing Committee on Social Policy and Legal Affairs, transcript of evidence, op. cit., p. 3.
124. Ibid., p. 1.
The amendments will advance the human right to health for everyone, including children, in developing countries by assisting with the treatment of serious health problems such as HIV/AIDS, malaria and tuberculosis.  

**Views of the Social Policy and Legal Affairs Committee**

The Committee commended the actions of the 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.

**Schedule 4—Plant breeder’s rights—Federal Circuit Court**

**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.

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.

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), 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. The Government released

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126. Ibid.
130. Ibid.
131. Ibid.
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.\textsuperscript{132}

**Proposed amendments in this Bill**

Schedule 4 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 that the Federal Court. ‘A couple of months ago that jurisdiction was conferred for trademarks and industrial designs, so this bill just extends that to a third intellectual property right,’ Mr Noonan told the Committee.\textsuperscript{133}

The Committee noted that this change was supported by the review of the Advisory Council on Intellectual Property:

> The Committee supports streamlining processes for owners of 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.\textsuperscript{134}

No issues were raised during the Social Policy and Legal Affairs Committee inquiry process in relation to this Schedule.

**Schedule 5—Australia New Zealand Single Economic Market**

**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.\textsuperscript{135} 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.\textsuperscript{136}

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.\textsuperscript{137} This group is working towards the introduction of the following Trans-Tasman processes:

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\textsuperscript{133} House of Representatives Standing Committee on Social Policy and Legal Affairs, transcript of evidence, op. cit., p. 1.

\textsuperscript{134} House of Representatives Standing Committee on Social Policy and Legal Affairs, Advisory report, op. cit., p. 9.


\textsuperscript{136} Ibid.

• 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.\(^{138}\)

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.\(^{139}\) The single patent examination process was also considered by the Productivity Commission in its *Strengthening Economic Relations Between Australia and New Zealand* review.\(^{140}\)

The majority of Australian and New Zealand patent attorneys are registered in both countries under the Trans-Tasman Mutual Recognition Arrangement (TTMRA),\(^{141}\) 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.\(^{142}\)

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.\(^{143}\)

**Proposed amendments in this Bill**

143. Ibid., p. 83.

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Single patent application and examination processes

Schedule 5 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:

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, in our view, so schedule 5 is implementing a measure that has been agreed with the New Zealand government to provide for single examination.144

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 18-22 of Schedule 5 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.145

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


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Committee viewed these 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. ¹⁴⁶

**Views of the Senate Standing Committee for the Scrutiny of Bills**

As noted above under the heading ‘Committee consideration’, the Scrutiny of Bills Committee raised concerns with item 25 of Schedule 5, which permits the Australian Patents Commissioner to delegate all or any of his or her powers and functions to a New Zealand patents official. 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 (this is confirmed by item 38, proposed section 227AB), 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.

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. ¹⁴⁷

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’. ¹⁴⁸ 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. ¹⁴⁹ ‘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.’ ¹⁵⁰

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

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¹⁴⁶ House of Representatives Standing Committee on Social Policy and Legal Affairs, Advisory report, op. cit., p. 9.
¹⁴⁹ Ibid.
¹⁵⁰ Ibid.
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.  

The Committee said the response addressed its concerns.  

Schedule 6—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. Items 2 to 4 of Schedule 6 of this Bill would remove those provisions and ensure that IP Australia’s retention of documents is governed by the Archives Act only.

The Bill also makes changes to address minor oversights in the drafting of the Intellectual Property Laws Amendment (Raising the Bar) Act.

No issues arose during the Social Policy and Legal Affairs Committee inquiry process in relation to this schedule.

Views of the Senate Standing Committee for the Scrutiny of Bills

As noted above under the heading ‘Committee consideration’, the Scrutiny of Bills Committee raised concerns with the retrospective amendment to paragraph 119(3)(b) of the Patents Act, which is intended to ‘correct an inadvertently created inconsistency’ between that provision and a related provision created when the Intellectual Property Laws Amendment (Raising the Bar) Act 2012 came into operation on 15 April 2013. The Explanatory Memorandum explains the need for the change as follows:

Ordinarily, if information about an invention is made publically available before a patent application is filed for the invention, the invention is not novel and so is unpatentable. However, section 24 of the Patents Act provides a ‘grace period’ so that, in certain circumstances, disclosure of an invention before filing the patent application for it does not make the invention unpatentable. To balance this against the interests of third parties who may have relied on the information being in the public domain, paragraph 119(3)(b) provides a countervailing exception to infringement. A third party does not infringe a patent if they derived the invention from information made publicly available by the applicant during the grace period.  

Item 32 of Schedule 6 to the Raising the Bar Act amended paragraph 24(1)(a) of the Patents Act to omit the words ‘through any publication or use of the invention’. This was so that the grace period applies more widely to information made publically available. However, as an oversight, the same words appearing in paragraph 119(3)(b) were not also omitted. This item corrects the oversight, ensuring that the grace period and the countervailing infringement exemption continue to be aligned.

151. Ibid., p. 338.
152. Ibid., p. 338.
As stated in the Explanatory Memorandum, the amendment will ensure that the longstanding provisions of section 24 and 119 of the *Patents Act* continue to be aligned. The Explanatory Memorandum states that it ‘is both unlikely to have a substantive impact on users, and is consistent with existing policy’.  

The Scrutiny of Bills Committee concluded:

> 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 commencement of item 14 of Schedule 6 is highly unlikely to have an effect on individual rights, liberties or obligations. The likelihood of a person’s rights being adversely affected is so low that it is difficult to conceive of a situation where this might occur. 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 Committee noted that Minister’s advice that the Bill was unlikely to affect personal rights.

### Consultation on the amendments

At issue during the public inquiry was the ‘haste’ in which the Bill was introduced, with the Law Council of Australia and the International Association for the Protection of Intellectual Property (AIPPI) raising concerns over the time afforded to stakeholders for proper review of the Bill and its impact on Australia’s international obligations. The Intellectual Property Committee of the Business Law Section of the Law Council of Australia (LCA) submitted that the Bill ‘should be properly reviewed and that it should not be passed in haste’.

The AIPPI Australia endorsed the concerns raised by the LCA. The AIPPI was particularly concerned by ‘the inadequate time afforded to stakeholders for proper review of the precise form of the Bill and its impact on Australia’s obligations under TRIPS and the USFTA’.

Dr Palombi argued that the Bill should not be ‘rushed through in its current form’. He questioned the necessity of the amendments and the increased levels of bureaucracy they would bring.

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157. Ibid.
158. Correspondence from the LCA provided to the House of Representatives Standing Committee on Social Policy and Legal Affairs, 5 June 2013.
159. Ibid.
160. Ibid.
However, Dr Rimmer disagreed:

I think it is an outrageous fiction of the Law Council’s to suggest that the legislative measures in relation to access to essential medicines have been passed in haste. It has been a decade since the WTO General Council decision … There has been a long time in terms of consulting over the draft bill that has been put forward by IP Australia … So I think it is very disappointing that the Law Council, at this late stage, would want to filibuster on such an important and critical bill, especially given that there has been a long history of support from all the various political parties on the question of access to essential medicines. I am most surprised and shocked that at this late stage they have been trying to palm off this important legislative measure.161

Dr Rimmer saw an urgent need for the Bill to be passed:

The measures particularly in relation to crown use and access to essential medicines are timely and significant. Indeed, the questions about crown use and access to essential medicines are really long overdue. They are significant and important business that really needs to be fast-tracked in terms of the parliamentary business.162

The Standing Committee on Social Policy and Legal Affairs addressed this issue in its Report, making the following comments regarding consultation:

• the consultative processes for each of the schedules in the bill were extensive and have provided opportunities for many issues to be considered in some depth
• in conducting its review of compulsory licensing of patents, the Productivity Commission produced an issues paper, a draft report and held a public hearing as well as meetings with stakeholders. The Committee is confident that this consultative process has addressed any significant issues
• the amendment which enables the Federal Court to grant and amend licences under the TRIPS protocol is a proposal that has been through extensive consultation, both government and public and
• the Committee is aware that the Australia and New Zealand single economic market initiative proposed in Schedule 5 has undergone significant public consultation as well as involvement of key stakeholders in regular briefings.163

The Committee reported that it was satisfied that the amendments proposed have been appropriately developed with extensive consultation and adjustment from stakeholders.164

Economics Legislation Committee

161. Ibid., p. 10.
162. Ibid., p. 3.
164. Ibid.
On 21 June 2013, Senator Colbeck, in commenting on the Economics Legislation Committee Report on consideration of time critical bills, said ‘none of the concerns which were quite legitimately raised around this piece of legislation were actually reflected in the report of the Standing Committee on Social Policy and Legal Affairs on the Bill.’\(^{165}\)

Senator Colbeck said the Institute of Patent and Trademark Attorneys of Australia (IPTA) was not consulted in the development of the legislation:

> They have serious concerns about the drafting of this piece of legislation. Their complaints are quite legitimate, but they have not been reflected in any of the processes of the parliament. The Senate’s legislation committee has basically given this piece of legislation a tick and flick, and in the House members were given one hour for an inquiry and that process did not provide an opportunity for even dissenting comments on the report. The institute is quite legitimately concerned that none of their concerns have been reflected in this process.\(^{166}\)

Senator Colbeck quoted email correspondence from IPTA:

> We … are extremely disappointed by the mischaracterisation at the public hearing of our concerns in relation to the TRIPS Protocol amendments, and by the Report itself which recommends passage of the Bill by the House in a form which contains significant drafting errors. We have previously drawn IP Australia’s attention to these significant drafting errors, and it is of particular concern to us that [the department] did not relay our concerns to the Committee when given the opportunity. While some of our concerns did relate to the question of compliance with our international obligations it is not true to say, as [the department] said to the Committee, that all of the issues raised the question of compliance with international treaty obligations.

> There is nothing in the transcript of the Public Hearing or the Report which gives us any reason to believe that our concerns in relation to the erroneous drafting of the Bill were considered by the Committee before they recommended the Bill for passage. We first drew attention to the drafting problems when we commented on a draft of the Bill in September 2012. When we reviewed the Bill as introduced to Parliament we were dismayed that our concerns had not been addressed. We therefore sent an email to IP Australia on 5 June 2013 expressing again our concerns in relation to the drafting of the Bill...

> In summary, we remain of the view that, at the very least, the Bill should be amended to correct the erroneous drafting before it is passed. There should be no reference whatsoever to cross licences and ancillary licences in the TRIPS Protocol implementing provisions. We also remain of the view that an important Bill of this type deserves closer scrutiny before passage through Parliament. The errors in the Bill are of such a nature that they are likely to interfere with the ability of the legislation to achieve its worthy objectives.\(^{167}\)

**Concluding comments**

This Bill proposes a number of significant changes to the intellectual property system in Australia. IP Australia has sought to find an appropriate balance between protecting the intellectual property

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166. Ibid.
167. Ibid.
rights of patent owners and safeguarding the public interest in accessing essential services. The first three schedules are about adjusting that balance in the patent system.\textsuperscript{168}

The amendments aim to clarify the scope of Crown use, which may result in greater use of the provisions. However, ‘that is being balanced against accountability, to make sure that patent owners do not find that their rights are being trampled on by a Commonwealth, state or even local government without them even being aware of that’.\textsuperscript{169} In carrying out that balancing act, there is a crucial role for ministerial approval: ‘the bill reflects the policy very clearly articulated in the Productivity Commission that, in exchange for a broadening and a greater certainty, ministers must take responsibility for their actions and accountability for the decisions they make to appropriate what is a property right’.\textsuperscript{170}

The Bill 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.

Schedules 4 and 5 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.\textsuperscript{171}

The Bill was only introduced on 30 May 2013, but the issues covered in the amendments have been discussed and debated in the course of a range of inquiries during the preceding years. While some interest groups were concerned that there was insufficient time for consultation on the amendments and that the Bill was being passed in haste, the Standing Committee on Social Policy and Legal Affairs found that there had been adequate consultation on the issues addressed in the Bill.

In recommending that the Bill be passed the Committee considered that it ‘provides a set of progressive and appropriate initiatives’.\textsuperscript{172}

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\textsuperscript{168} House of Representatives Standing Committee on Social Policy and Legal Affairs, transcript of evidence, op. cit., p. 1.
\textsuperscript{169} Ibid., p. 6.
\textsuperscript{170} Ibid., p. 9.
\textsuperscript{172} House of Representatives Standing Committee on Social Policy and Legal Affairs, Advisory report, op. cit., p. 9.
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