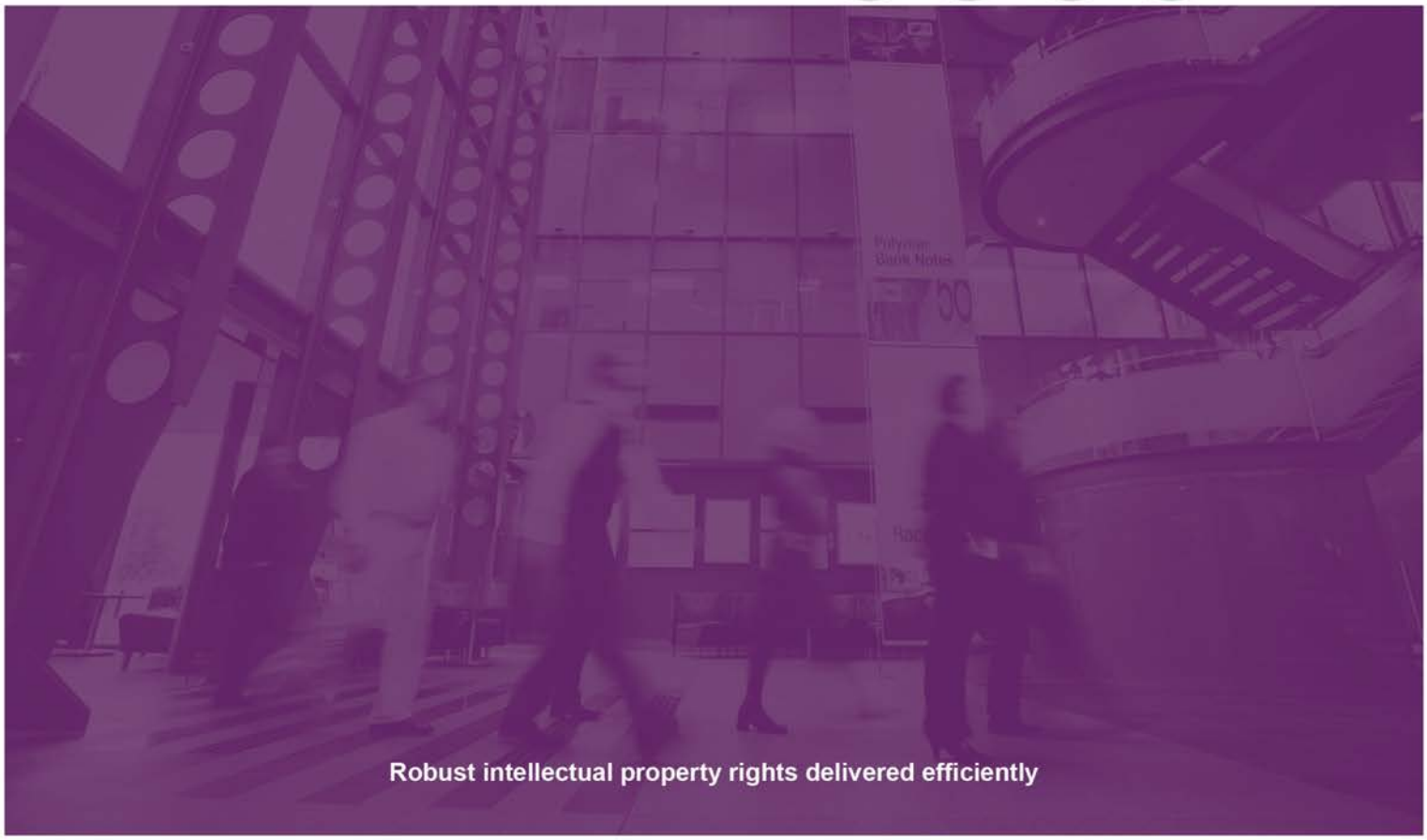
Australian Government
IP Australia

Public Consultation: Draft Intellectual Property Laws Amendment Bill 2014

January 2014



Introduction

This paper provides information and background on the draft Intellectual Property Laws Amendment Bill 2014 (the draft Bill). The draft Bill seeks to amend the *Patents Act 1990*, *Trade Marks Act 1995*, *Designs Act 2003*, and the *Plant Breeder's Rights Act 1994* to:

- implement the Protocol amending the World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property (TRIPS Protocol), enabling Australian medicine producers to manufacture and export patented pharmaceuticals to countries experiencing health crises, under a compulsory licence from the Federal Court
- extend the jurisdiction of the former Federal Magistrates Court, the Federal Circuit Court, to include plant breeder's rights matters
- allow for a single trans-Tasman patent attorney regime and single patent application and examination processes for Australia and New Zealand, as part of the broader Single Economic Market (SEM) agenda
- make minor administrative changes to the Patents, Trade Marks and Designs Acts to repeal unnecessary document retention provisions that are already adequately governed by the *Archives Act 1983*
- make minor technical amendments to the Patents Act to correct oversights in the drafting of the *Intellectual Property Laws Amendment (Raising the Bar) Act 2012* which was passed by Parliament in March 2012.

IP Australia invites interested parties to make written submissions on the draft Bill and explanatory memorandum **by 7 February 2014**. Comments are welcome from anyone interested in the operation or impact of the intellectual property system in Australia.

Submissions should be sent to consultation@ipaustralia.gov.au

For accessibility reasons, please submit responses via email in Word or RTF format. An additional PDF version may also be submitted.

The contact officer is Lisa Bailey, who may be contacted on (02) 6283 7961.

Please note that, unless requested otherwise, written comments submitted to IP Australia may be made publicly available or disclosed to another Commonwealth agency.

A request made under the *Freedom of Information Act 1982* for access to a submission marked confidential will be determined in accordance with that Act.

IP Australia complies with the *Privacy Act 1988* when collecting, using and disclosing personal information. IP Australia's Privacy Policy can be viewed at www.ipaustralia.gov.au.

Submissions should be received no later than 7 February 2014.

Background

The measures contained in the draft Bill previously formed part of the Intellectual Property Laws Amendment Bill 2013 ('2013 Bill') which was introduced into parliament in May 2013 by the previous government. The 2013 Bill was not passed before the 2013 Federal election was announced, and has since lapsed.

While much of the draft Bill remains unchanged from the 2013 Bill, revisions have been made to five key areas. The revisions address issues raised with the 2013 Bill and simplify the operations of the proposed legislation. The revisions are outlined below.

This paper seeks input on the revisions and on the remaining provisions in the Bill.

The draft Bill is planned for introduction to Parliament in March 2014 following the completion of this consultation process.

Revisions to the 2013 Bill

Crown use of patents

Schedule 1 of the 2013 Bill contained measures to modify Crown use provisions in the *Patents Act 1990* (the Patents Act).

These amendments were in response to recommendations of the Productivity Commission Inquiry Report into Compulsory Licensing of Patents, which found there was uncertainty around the scope of current Crown use provisions, particularly in the context of healthcare.

Following introduction of the 2013 Bill to Parliament, concerns were raised in relation to these measures. They have now been removed from the draft Bill and further consultation on amendments to the Crown Use provisions will take place as part of a separate legislative process.

TRIPS Protocol

Ancillary licences and cross-licences (dependent patent provisions)

In some cases, the applicant for a patented pharmaceutical invention (PPI) compulsory licence may be unable to work the invention without infringing another patent for a related invention. The 2013 Bill addressed this situation by giving the court the power to require that the owner of the patent for the pharmaceutical invention grant licenses to both the applicant (PPI compulsory licence) and the owner of the related patent to use the pharmaceutical invention (cross-licence). In addition, the applicant would be granted an ancillary licence to exploit the related patent.

However, it has been noted by stakeholders that this could disadvantage the owner of the patent for the pharmaceutical invention, who would be required to issue two separate licences for others to use their invention, and yet not receive a licence to use the related invention in return. This is an unintended adverse consequence and the provisions have now been removed from the draft Bill.

Under the revised provisions, where an applicant for a PPI compulsory licence also needs a licence to exploit a related invention/s, they will need to apply for separate licenses to use the pharmaceutical invention and the related invention (under proposed section 136D of the draft Bill). As these applications may be considered together by the Federal Court, this approach should not result in significant additional effort for the applicant.

The proposed approach is consistent with Australia's international obligations under the TRIPS Agreement, and with the approach taken by many other countries that have implemented the TRIPS Protocol.

Licence to work the invention

Section 13 of the Patents Act gives the owner of a patent the exclusive rights to exploit the invention. The expression 'exploit' is defined in Schedule 1 to the Act to include, in relation to an invention:

(a) where the invention is a product—make, hire, sell or otherwise dispose of the product, offer to make, sell, hire or otherwise dispose of it, use or import it, or keep it for the purpose of doing any of those things; or

(b) where the invention is a method or process—use the method or process or do any act mentioned in paragraph (a) in respect of a product resulting from such use.

In contrast, the expression 'work' has a narrower meaning, being defined in Schedule 1 to the Patents Act as follows:

'work', in relation to a patented invention, means:

(a) where the invention is a product—make or import the product; or

(b) where the invention is a method or process—use the method or process or do any act mentioned in paragraph (a) in respect of a product resulting from such use.

The 2013 Bill proposed that a TRIPS Protocol compulsory licence would be granted to the applicant to work the patented pharmaceutical invention (PPI) 'to the extent necessary for the purposes of manufacturing a pharmaceutical product in Australia for export to an eligible importing country'.

Following introduction of the 2013 Bill, concerns were raised about use of the expression 'work' and therefore the limited range of acts authorised by a PPI compulsory licence. After further consideration of this issue, it is now proposed that the expression 'work' in the provisions implementing the TRIPS Protocol system be replaced with 'exploit'. This will ensure that the licensee of a PPI compulsory licence clearly has the authority to do all acts in Australia necessary for the manufacture and export of a patented pharmaceutical to an eligible importing country.

The changes appear in:

proposed subsection 136D(1)

proposed paragraph 136E(1)(d)

proposed subparagraph 136E(1)(e)(i)

proposed paragraph 136F(1)(f).

Eligible importing countries

In accordance with the humanitarian principles of the TRIPS Protocol, the proposal extends the scheme to World Trade Organization (WTO) Member countries and non-Member countries, least developed countries (LDCs) and non-LDCs.

Before granting a PPI order, the Federal Court must be satisfied that the notification requirements prescribed by regulations under proposed paragraph 136E(1)(f) have been complied with. These notification requirements will depend on whether or not the importing country is a WTO member and whether or not it is an LDC.

The membership of the WTO and the countries designated as LDCs (by the United Nations) change, if only infrequently. Because of this, proposed new subsections 136E(3) and 228(5) have been inserted, the definition of 'eligible importing country' has been revised to refer to a foreign country of a kind referred to in the regulations, and a note inserted under that definition referring to new subsection 228(5).

These revisions mean that the regulations will not need to be amended every time the composition of WTO members or LDC countries changes. Instead, the regulations will be able to refer to the list of LDCs maintained by the United Nations via www.un.org, and the list of full WTO members maintained by the WTO via www.wto.org.

Heading changes

The 2013 Bill proposed to introduce two new headings into Chapter 12 of the Patent Act:

- '**Part 1—Compulsory licenses (general)**' to be inserted above the existing general compulsory licensing provisions, and
- '**Part 2—Compulsory licences (patented pharmaceutical inventions)**' to be inserted above the proposed TRIPS Protocol licensing provisions.

To clearly differentiate the proposed TRIPS Protocol provisions and the existing provisions in Chapter 12 of the Patents Act, the following headings are proposed to be inserted:

- '**Part 1—Introduction**'
- '**Part 2—Compulsory licenses (general)**'
- '**Part 3—Patented pharmaceutical invention compulsory licences (for manufacturing and export to eligible importing countries)**'
- '**Part 4—Surrender and revocation of patents**'
- '**Part 5—Other matters**'