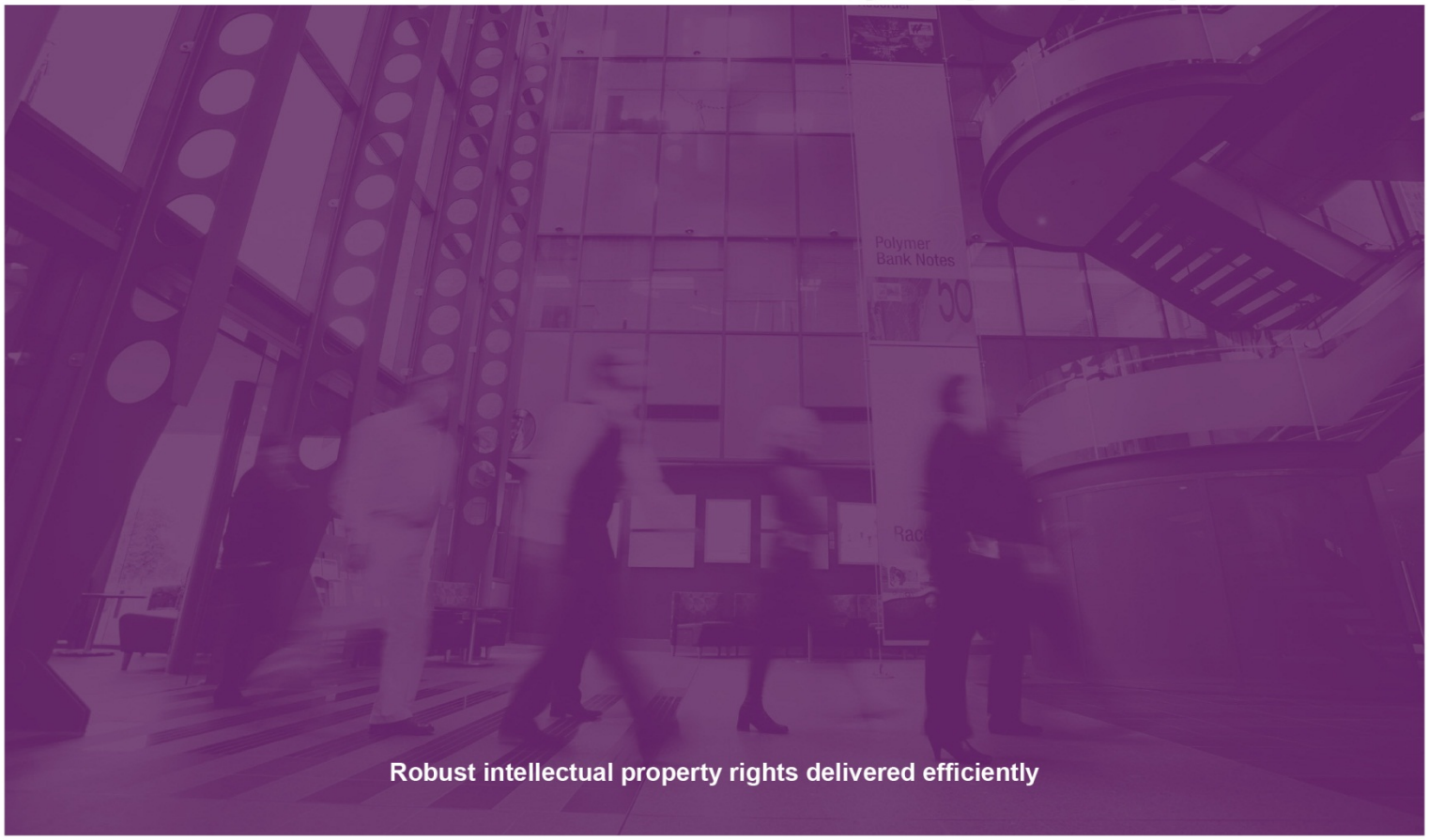
Australian Government
IP Australia

Exposure Draft Intellectual Property Legislation Amendment Regulation: Explanatory Statement

December 2014



Robust intellectual property rights delivered efficiently

Contents

Introduction

This Explanatory Statement accompanies an Exposure Draft of the Intellectual Property Legislation Amendment Regulation, which is proposed to implement a number of measures in the Intellectual Property Laws Amendment Bill 2014.

IP Australia invites interested parties to make written submissions on the Exposure Draft Regulation and this Explanatory Statement by **15 February 2015**.

Written submissions should be sent to consultation@ipaustralia.gov.au.

For accessibility reasons, please submit responses by email in Word, RTF or PDF format.

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 on our website and may be disclosed to other Commonwealth agencies, including, but not limited to, the Department of Industry.

When you make a submission, unless stated otherwise, you provide your consent to your personal information being published online. Information published online may be accessed world-wide, including by overseas entities. IP Australia will not be able to control any subsequent use under the *Privacy Act 1988*, nor are you able to seek redress under that Act, for the actions of any overseas entities.

IP Australia's Privacy Policy can be viewed at www.ipaustralia.gov.au/about-us/corporate/privacy-policy/. The privacy policy also includes the following information:

- how you may seek access to and correction of the personal information we hold;
- how you may make a complaint about a breach of the Privacy Act and how we will deal with your complaint; and
- IP Australia's Privacy Contact Officer details.

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.

Submissions should be received no later than 15 February 2015.

Overview

The Intellectual Property Laws Amendment Bill 2014 ('Bill') was passed in the House of Representatives in November 2014, and is currently awaiting debate in the Senate. If the Bill is enacted, the *Intellectual Property Laws Amendment Act 2014* ('Amendment Act') would amend the *Designs Act 2003*, the *Patents Act 1990*, the *Plant Breeder's Rights Act 1994* ('PBR Act') and the *Trade Marks Act 1995*—collectively, 'the Acts'—to introduce a range of improvements across Australia's intellectual property (IP) system. The amendments would make refinements to existing arrangements, and would implement new initiatives aimed at increasing efficiency and effectiveness.

The Exposure Draft of the Intellectual Property Legislation Amendment Regulation ('Exposure Draft Regulation') is proposed to amend the *Designs Regulations 2004*, the *Patents Regulations 1991* and the *Trade Marks Regulations 1995* to:

- prescribe matters required under the provisions of the Acts as amended by Schedules 1, 2 and 5 to the Amendment Act; and
- delete no-longer-required provisions and correct minor errors in those regulations.

The regulations that would be required under the provisions of the Acts as amended by Schedule 4 to the Amendment Act ('Australia New Zealand Single Economic Market') are not included in the Exposure Draft. They are the subject of the accompanying Consultation Paper.

The explanatory notes in this statement are summarised in the table below:

Part	Brief description
A	Explanatory notes to Schedule 1 to the Exposure Draft Regulation—amendments to the Patents Regulations to implement the TRIPS Protocol interim waiver
B	Explanatory notes to Schedule 2 to the Exposure Draft Regulation—further amendments to the Patents Regulations to implement the TRIPS Protocol (when this international arrangement comes into effect)
C	Explanatory notes to Schedule 3 to the Exposure Draft Regulation—amendments to repeal unnecessary document retention provisions in the Designs Regulations, the Patents Regulations and the Trade Marks Regulations
D	Explanatory notes to Schedule 4 to the Exposure Draft Regulation —amendments to the Patents Regulations as a consequence of corrections to drafting oversights in the *Intellectual Property Laws Amendment (Raising the Bar) Act 2012* ('Raising the Bar Act')
E	Explanatory notes to Schedule 5 to the Exposure Draft Regulation—amendments to make technical fixes to the Designs Regulations, the Patents Regulations and the Trade Marks Regulations that do not depend on the Bill

A—Explanatory notes to Schedule 1

Overview

Schedule 1 to the Amendment Act would amend the Patents Act by inserting new provisions to implement the decision of the World Trade Organization ('**WTO**') General Council of 30 August 2003 on the implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health ('**WTO Decision**').

Schedule 1 to the Amendment Regulation would amend the Patents Regulations to complete Australia's legislative implementation of the WTO Decision, by prescribing several matters for the new provisions in the Patents Act.

The WTO Decision operates as an interim waiver from several obligations in the *Agreement on Trade Related Aspects of Intellectual Property Rights* ('**TRIPS Agreement**'). It will continue to operate until the *Protocol amending the World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property* ('**the TRIPS Protocol**') comes into effect. (Part B below discusses the further amendments required to complete Australia's legislative implementation of the TRIPS Protocol.)

Commencement

Schedule 1 to the Amendment Act and Schedule 1 to the Amendment Regulation would both come into effect six months after the Amendment Act receives the Royal Assent.

Details of proposed amendments to Patents Regulations

Items 1 and 2—new definitions of 'Council for TRIPS', 'eligible importing country', 'least developed country', 'WTO Agreement' and 'WTO Member' to be inserted

These items would amend the Patents Regulations to define several expressions used in the proposed new Part 2 of Chapter 12 of the Patents Regulations. The defined expressions are:

- Council for TRIPS—the Council for Trade-Related Aspects of Intellectual Property Rights established under Article IV of the WTO Agreement
- eligible importing country—discussed below
- least developed country—discussed below
- WTO Agreement—the Marrakesh Agreement establishing the World Trade Organization, done at Marrakesh on 15 April 1994
- WTO member—discussed below.

Item 27 of Schedule 1 to the Amendment Act would amend the Patents Act to define '**eligible importing country**' as a foreign country of a kind prescribed by regulation. For the definition of 'eligible importing country', proposed new regulation 1.4A of the Patents Regulations would prescribe the following kinds of countries:

- a WTO member that notifies the Council for TRIPS, in accordance with the WTO Decision of 30 August 2003, of the member's intention to use the system set out in that decision as an importer; and
- a least developed country.

The first bullet-point is to ensure that a WTO member that **is not** a least developed country could only be an eligible importing country **if** it complies with the requirement in the WTO Decision to notify its **intention to use** the system as an importer. No such notification is required for a WTO member that **is** a least developed country.[1]

The expression '**WTO member**' is defined so that the Patents Regulations would not require amendment each time a country becomes a full member of the WTO (the list is available via www.wto.org).

The expression '**least developed country**' is defined so that the Patents Regulations do not require amendment each time the United Nations adds or removes a country from its list of least developed countries or removes a country from that list (the list is available via www.un.org/ohrlls/).

Some least developed countries are not WTO members. These countries would also be eligible importing countries for the purposes of the proposed legislation. This is to ensure that all least developed countries could access affordable medicines under the Australian legislation.

Item 3—new part heading in Chapter 12 to be inserted

This item would insert a new part heading before the existing provisions for applications for orders for general compulsory licences in Chapter 12 of the Patents Regulations. This is to distinguish them from the new provisions for compulsory licences for manufacturing pharmaceutical products in Australia for export to eligible importing countries ('**PPI compulsory licences'**).

Item 4—heading to regulation 12.1 to be substituted

This item would replace the existing heading to regulation 12.1 to make it clear that the regulation is about applications for orders for general compulsory licences, not merely the lodgement of such applications (as the current heading suggests).

Item 5—new Part in Chapter 12; new regulations 12.2A to 12.2F to be inserted

This item would insert a new part into Chapter 12 of the Patents Regulations to prescribe several matters for the provisions in the proposed new part 3 of Chapter 12 in the Patents Act (as detailed below). It would also insert a new part heading before the existing provisions for the surrender and revocation of patents, distinguishing them from the proposed new provisions that would apply only to PPI compulsory licences.

Regulation 12.2A—application for PPI orders

Proposed new section 136D of the Patents Act would allow a person ('**PPI order applicant**') to apply to the Federal Court for an order ('**PPI order**') requiring the patentee of a patented pharmaceutical invention to grant a PPI compulsory licence to the PPI order applicant. Under proposed new subsection 136D(5), the parties to those Federal Court proceedings would include:

- the patentee
- any person claiming an interest in the patent as exclusive licensee or otherwise
- at the option of the eligible importing country—that country.

Proposed new regulation 12.2A would set out the detailed information required in the application to the court. This would include an address for service complying with the relevant Federal Court Rules for service of the application. The PPI order applicant would be required to serve copies of the application on the parties in accordance with those rules.

[1] See paragraph 1(b) of the WTO General Council decision of 30 August 2003, available at http://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm

It is not expected that the PPI order applicant should serve a copy of the application on the eligible importing country. If that country does not maintain a diplomatic presence in Australia, such service could be difficult and would delay proceedings.

Regulation 12.2B—notification requirements

Proposed new section 136E of the Patents Act would permit the Federal Court to make the PPI order sought under new section 136D, if the court is satisfied of all of the matters listed in proposed new subsection 136E(1). One of these matters is that the notification requirements prescribed by the regulations in relation to the importation of the pharmaceutical product have been complied with.

Proposed regulation 12.2B would prescribe the notification requirements. These would depend on whether the eligible importing country is a WTO member or is a least developed country that is not a WTO Member.

A **WTO Member** would be required to have notified the Council for TRIPS in accordance with paragraph 2(a) of the WTO Decision.[2] That paragraph details the **notification of use** of the system that a WTO Member must make to import pharmaceutical products under that system. For the special case of a WTO member that is not a least developed country using the system as an importer, the notification of use would be additional to the required **notification of intention to use** by that member (see the discussion of the definition of 'eligible importing country' in the notes on items 1 and 2 above).

A **least developed country that is not a WTO Member** could not be expected to notify the Council for TRIPS under paragraph 2 (a) of the WTO Decision, since any such notification would have no legal effect. Accordingly, that eligible importing country would be required to notify the Commissioner of Patents of the same matters that a least developed country member must notify to the Council for TRIPS.

That eligible importing country would be required to confirm that it would meet the same conditions as a WTO Member using the system as an importer—as if Article 31 of the TRIPS Agreement and the WTO Decision applied to the country. In particular, if the pharmaceutical product is patented in the country, it would have to confirm that it has granted or intends to grant a compulsory licence for the pharmaceutical product.

Regulation 12.2C—labelling and marking requirements

Proposed new subsection 136F(1) of the Patents Act would require a PPI order to direct that a PPI compulsory licence be granted on specified terms. One of these terms is that the pharmaceutical product is labelled and marked in accordance with the regulations.

Proposed regulation 12.2C would prescribe the labelling and marking requirements in general terms. That is, the pharmaceutical product made under the PPI compulsory licence would be required to be labelled and marked so that it is:

- clearly identified as being exported from Australia under the PPI compulsory licence
- distinguished from the same pharmaceutical product
    - sold in Australia (e.g. sold commercially by the Australian patentee)
    - exported from Australia other than under the licence (e.g. exported commercially by the Australian patentee).

Two additional requirements are proposed to counter diverting of the pharmaceutical product from the eligible importing country. The labelling and marking must:

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[2] See http://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm for the WTO General Council decision of 30 August 2003

- be applied to both the immediate packaging of the pharmaceutical product and any other packaging containing that package. This is to ensure that the marking and labelling can be seen if, for whatever reason, an inner package becomes separated from outer packaging of the pharmaceutical product.
- remain clear and legible at all times while the product is being exported.

Proposed new subsection 136F(2) of the Patents Act would also permit the PPI order to specify other terms in the PPI compulsory licence, including other requirements relating to the labelling and marking of the pharmaceutical product. Proposed new subsection 136F(3) would require that a PPI order must be consistent with any regulations prescribed for proposed new subsection 136F(1). These would include proposed regulation 12.2C.

Accordingly, during the hearing of an application for a PPI order, the parties could make detailed proposals on distinguishing features to address the requirements in proposed regulation 12.2C. These distinguishing features could include combinations of labelling, aspects of packaging, marking, colour, size or shape of units of the pharmaceutical product. They could be features of the individual tablet, capsule or vial. They could be features of the containers of tablets etc.

It is for the Federal Court to determine whether the distinguishing features meet the requirements in proposed regulation 12.2C. It is expected that these features should not unduly add to the cost of manufacturing and packaging the pharmaceutical product for export. The court could be expected to specify the distinguishing features in the PPI order.

Regulation 12.2D—shipment information requirements

Proposed new paragraph 136F(1)(d) of the Patents Act would require that before shipment of the pharmaceutical product begins, the shipment information prescribed by the regulations be made available on a website by, or on behalf of, the licensee for a minimum period prescribed by the regulations.

Proposed regulation 12.2D would prescribe the information that is required in relation to each shipment of a pharmaceutical product. This information must include the name and amount of the pharmaceutical product to be shipped, the name of the importing country, the name of the importer and the distinguishing features of the pharmaceutical product (as discussed in the notes on regulation 12.2C above).

The shipment information must be made available on the website that the licensee has previously advised the Commissioner of (discussed in the notes on proposed regulation 12.2E below). The shipment information must appear on the website before the shipment begins. This is to be understood as meaning that the information must appear on the website before the pharmaceutical product is loaded onto a ship or aircraft leaving Australia. The information must continue to appear on the website for the duration of the licence. This is to ensure that there is transparency in the actual use of the PPI compulsory licence.

Regulations 12.2E and 12.2F—giving information to the Commissioner and what the Commissioner must do with some of that information

Proposed new paragraph 136F(1)(h) of the Patents Act would require that the licensee must give the Commissioner information relating to the licence, as required by the regulations.

Proposed regulation 12.2E would prescribe the information the licensee must give the Commissioner in relation to the PPI compulsory licence, and when this information must be given. The licensee must advise the Commissioner:

- of the grant of the licence, including the details of the PPI order made by the Federal Court
- of any amendment of the licence ordered by the Federal Court (see proposed section 136G of the Patents Act)
- of any revocation of the licence ordered by the Federal Court (see proposed section 136H of the Patents Act)

- that an amount of remuneration for the licence has either been agreed between the licensee and the patentee, or has been determined by the Federal Court (see proposed section 136J of the Patents Act). It is not necessary for the licensee to disclose the actual amount, as this might be commercially sensitive information.

The information must be provided within one month following the Federal Court making the relevant order, or the agreement on remuneration being reached. The information must be provided to the Commissioner in the form approved by the Commissioner.

Proposed subregulation 12.2F(1) would require the Commissioner to:

- provide the information to the Council for TRIPS—if the eligible importing country is a WTO Member. The WTO Secretariat would then make the information available publicly by means of a dedicated page on the WTO website[3]; and
- publish the information on the internet—if the eligible importing country is not a WTO Member. This would ensure that information about the grant of a PPI compulsory licence is publicly available in all cases, not only when the eligible importing country is a WTO Member.

Proposed subregulation 12.2F(2) would require the Commissioner to notify the eligible importing country, when the licensee has advised the Commissioner that an amount of remuneration in respect of the licence has been agreed or determined. This would allow the eligible importing country to consider whether or not remuneration must be paid for any compulsory licence to import and use the pharmaceutical product in that country (see the second sentence in paragraph 3 of the WTO Decision).

It is expected that an eligible importing country that is not a WTO Member would also consider remuneration determined in that country for that pharmaceutical product, when issuing any compulsory licence for importing and using the product. That is because paying remuneration in both Australia and the eligible importing country would be inconsistent with the aim of promoting access to affordable medicines.

[3] See http://www.wto.org/english/tratop_e/trips_e/public_health_e.htm

B—Explanatory notes to Schedule 2

Overview

This schedule is proposed to amend the Patents Regulations to complete Australia's legislative implementation of the TRIPS Protocol.

Australia accepted the TRIPS Protocol in 2007, but it will not come into effect until two-thirds of WTO Members have accepted it: a third have done so.[4] When it comes into effect, it would amend the TRIPS Agreement to be a permanent replacement for the WTO Decision (see Part A above). It would do this by inserting new Article 31bis and adding an Annex to the TRIPS Agreement. There would be no difference between the operation of the WTO Decision and of the amended TRIPS Agreement.

Schedule 2 to the Amendment Act and Schedule 2 to the Amendment Regulation would then amend the Patents Act and Patents Regulations, changing existing references to the provisions of the WTO Decision so that they refer to the provisions of the amended TRIPS Agreement instead.

Commencement

Schedule 2 to the Amendment Act and Schedule 2 to the Amendment Regulation would both come into effect at the same time. This would be **at the later of**:

- immediately after the commencement of Schedule 1 of the Amendment Act (see Part A above); or
- immediately after the TRIPS Protocol comes into force for Australia.

IP Australia would notify the public of the commencement date once it is known.

Details of proposed amendments to Patents Regulations

Item 1—paragraph 1.4A(a) to be substituted

This item would substitute paragraph 1.4A(a) of the Patents Regulations, so that a WTO member that is not also a least developed country would be required to notify the Council for TRIPS of its intention to use the system in accordance with the provisions of the amended TRIPS Agreement, rather than the analogous provisions of the WTO Decision it replaces.

Item 2—subregulation 12.2B(3) to be amended

This item would amend subregulation 12.2B(3) of the Patents Regulations so that it correctly refers to a provision in the amended TRIPS Agreement, rather than to the analogous provision in the WTO Decision it replaces.

Item 3—paragraph 12.2B(5)(b) to be amended

This item would amend paragraph 12.2B(5)(b) of the Patents Regulations so that it correctly refers to provisions in the amended TRIPS Agreement, rather than to the analogous provisions in the WTO Decision it replaces.

[4] At 10 September 2014, 53 WTO members have accepted the Protocol. On the **current membership of 160 members**, the Protocol would commence only when a further 54 members accept it.

C—Explanatory notes to Schedule 3

Overview

This schedule is proposed to amend the Designs Regulations, the Patents Regulations and the Trade Marks Regulations to give effect to the amendments to be made by Part 1 of Schedule 5 to the Amendment Act. These Act and regulation amendments would simplify records management at IP Australia. They would allow the disposal of documents that are no longer required, in accordance with the *Archives Act 1983* and relevant disposal authorities issued by the National Archives of Australia.

Commencement and application

This Schedule is proposed to commence on the day following registration of the Amendment Regulation in the Federal Register of Legislative Instruments. The amendments in this Schedule are proposed to apply to material and documents provided or filed before, on or after commencement. This would ensure that from that date, all material and documents in IP Australia's possession is governed solely by the Archives Act and relevant disposal authorities.

Details of proposed amendments to Designs Regulations, Patents Regulations and Trade Marks Regulations

Items 1 and 2—Designs Regulations; subregulation 5.08(2) to be repealed

These items would repeal subregulation 5.08(2) of the Designs Regulations as a consequence of the proposed repeal of paragraph 69(3)(c) of the Designs Act by the Amendment Act.

Paragraph 69(3)(c) of the Designs Act requires the Registrar to retain material concerning the newness or distinctiveness of a registered design for the prescribed period. Currently, subregulation 5.08(2) of the Designs Regulations prescribes a period ending six years after the term of registration of the design ceases.

Item 3—Patents Regulations; regulation 22.18 to be repealed

This item would repeal regulation 22.18 of the Patents Regulations, as a consequence of the proposed repeal of paragraph 228(2)(u) of the Patents Act by the Amendment Act.

Currently, paragraph 228(2)(u) of the Patents Act and regulation 22.18 of the Patents Regulations only permit the destruction of documents relating to a patent application that was filed at least 25 years ago.

Items 4 and 5—Trade Marks Regulations; regulation 21.32 to be repealed, subregulation 17A.39(1) to be amended consequentially

Item 5 would repeal regulation 21.32 of the Trade Marks Regulations, as a consequence of the proposed repeal of paragraph 231(2)(h) of the Trade Marks Act by the Amendment Act.

Currently, paragraph 231(2)(h) of the Trade Marks Act and regulation 21.32 of the Trade Marks Regulations permit the destruction only of documents relating to a trade mark whose registration ceased at least 25 years ago.

D—Explanatory notes to Schedule 4

Overview

This schedule is proposed to amend the Patents Regulations as a consequence of amendments to the Patents Act to be made by Part 2 of Schedule 5 to the Amendment Act. These Act amendments will correct a number of drafting oversights in the *Intellectual Property Laws Amendment (Raising the Bar) Act 2012* ('Raising the Bar Act'). Among other things, this schedule would repeal several provisions inserted into the Patents Regulations as interim means to address drafting oversights made by the Raising the Bar Act.

Commencement

This schedule would commence at the same time as items 9 to 17 of Schedule 5 to the Amendment Act. This would be either a single day to be fixed by proclamation within the 6 months beginning when the Amendment Act receives the Royal Assent, or, if those items do not commence in that period, commencement would happen on the day after the end of the 6 month period.

Details of proposed amendments to Patents Regulations

Item 1—regulation 3.11 to be amended

This item would delete the superseded reference to subsection 29B(2) of the Patents Act, so that regulation 3.11 solely prescribes the period for making a Convention application for the purposes of subsection 38(1A) of the Patents Act. This is a consequence of the Amendment Act making subsection 38(1A) the sole provision in the Patents Act governing the period for making a Convention application.

Item 2—subregulation 3.12(4) to be substituted, new subregulation 3.12(5) to be inserted

This item would repeal and replace current subregulation 3.12(4) of the Patents Regulations, which explains the expression ***clearly discloses*** used in provisions for determining the priority dates of claims to inventions (in regulations 3.13A to 3.13E of the Patents Regulations).

Substitute subregulation 3.12(4) of the Patents Regulations would put it beyond doubt that a set of documents considered together can clearly disclose an invention. This would follow from the proposed amendment to paragraph 43(2A)(b) of the Patents Act to make it clear that the priority date of a claim to an invention is not limited to being based on a single document disclosing the invention, but also can be based on sets of documents considered together.

The item would also insert new subregulation 3.12(5), to put it beyond doubt that a document or set of documents can clearly disclose an invention relating to a micro-organism that is deposited with a prescribed depositary institution in accordance with the Budapest Treaty.[5] This follows from proposed new subsection 43(2B) of the Patents Act which makes it clear that (in relevant circumstances) a properly deposited sample of a micro-organism can be taken into account when determining whether a claimed invention has been disclosed for determining a priority date of the claim (see following).

[5] Australia is party to the *Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure*; see the definitions of ***Budapest Treaty*** and ***prescribed depositary institution*** in Schedule 1 to the Patents Act.

Items 3 to 13—regulations 3.13A to 3.13E to be amended

These items would amend regulations 3.13A to 3.13E of the Patents Regulations, which are about determining the priority dates of claims to inventions. The proposed amendments are not intended to change the existing policy of regulations 3.13A to 3.13E, but rather to ensure that those regulations clearly match the provisions of amended subsection 43(2A) and proposed new 43(2B) of the Patents Act.

The proposed amendments would make it clear that circumstances and priority documents currently mentioned in regulations 3.13A to 3.13E of the Patents Regulations are prescribed for the purposes of paragraphs 43(2A)(a) and (b) of the Patents Act.

The proposed amendments would also insert new provisions into regulations 3.13A to 3.13E of the Patents Regulations, to prescribe the circumstances for proposed new subsection 43(2B) of the Patents Act to apply. For an applicant to be able to rely on a deposited micro-organism to establish a priority date of a claimed invention, the following requirements must all be met:

- the micro-organism must have been properly deposited with a prescribed depositary institution on or before the date the priority document is filed; and
- the priority document (or several documents considered together) must include the relevant information on the characteristics of the micro-organism known to the applicant when the priority document or documents are filed; and
- the requirements of paragraph 6(c) of the Patents Act are satisfied by the complete specification that contains the claim.

This continues the current requirements for relying on a deposited micro-organism, but also makes it clear that the required information about the characteristics of the micro-organism can be in several documents filed at the same time.

The requirement in the final bullet-point means that the complete specification containing the claim must include the name of the prescribed depositary institution and the identifying details the institution has given the deposit. This information must appear in the complete specification at all times after the end of the relevant period prescribed in regulation 1.5 of the Patents Regulations. This is to allow someone who might be affected by a patent being granted for invention relating to the micro-organism to seek access to a sample of the micro-organism.[6]

Items 14 and 16—subregulations 3.15(3) and 10.1(1AA) to be repealed

These items would repeal subregulations 3.15(3) and 10.1(1AA) of the Patents Regulations, as a consequence of the proposed insertion of subsection 29A(6) into the Patents Act by item 10 of Part 2 of Schedule 5 of the Amendment Act.

Proposed new subsection 29A(6) would provide that an applicant under the Patent Cooperation Treaty ('**PCT**') cannot require that anything be done under the Patents Act for their PCT application unless it enters national phase in Australia. For that to happen, the applicant must comply with the requirements in existing subsection 29A(5) of the Patents Act: by paying the prescribed fees and filing the prescribed documents. If the PCT application is not in English, the applicant must also file a translation of the application.

In doing so, proposed new subsection 29A(6) of the Patents Act would make subregulations 3.15(3) and 10.1(1AA) superfluous.

[6] See discussion on accessing samples in the notes on item 6 in Schedule 5 to the Amendment Regulation, in Part E below.

Item 15—new subregulation 3.32 to be inserted

This item would insert new regulation 3.32 to prescribe the circumstances for a provisional specification disclosing an invention that is a micro-organism, in order to comply with the disclosure requirement in existing subsection 40(1) of the Patents Act. That subsection requires that a provisional specification must disclose the invention so that it can be performed by a person skilled in the relevant art.

Proposed new subsection 41(1A) of the Patents Act would make it clear that a properly deposited micro-organism can be taken into account for meeting the disclosure requirement for provisional specifications in subsection 40(1), just as it can for complete specifications.

Under proposed new subsection 41(1A) of the Patents Act and proposed new regulation 3.32 of the Patents Regulations, a provisional specification requiring a description of a micro-organism could comply with subsection 40(1) of the Patents Act if the following conditions apply:

- the micro-organism is deposited with a prescribed depository institution, in accordance with the applicable rules of the Budapest Treaty, on or before the date the provisional specification is filed; and
- at the time the provisional application was made:
    - the provisional specification clearly discloses the invention, other than in relation to the description of the micro-organism; and
    - a document filed for the provisional application (or several documents considered together) includes the relevant information on the characteristics of the micro-organism known to the applicant at that time;
- if a complete application is associated under section 38 of the Act with the provisional application for which the provisional specification is filed, the requirements of paragraph 6(c) of the Patents Act are satisfied by the complete specification filed for that complete application.

The condition in the final bullet-point would not apply unless a complete application is subsequently associated with the provisional application. Not every provisional application has a complete application associated with it. A provisional application is filed for the purpose of establishing an earlier priority date for claims that might appear in an associated complete application. So it is not necessary for a provisional specification to meet the requirements of paragraph 6(c) of the Patents Act: it would suffice that the specification for any associated complete application meets them.

E—Explanatory notes to Schedule 5

Overview

This schedule is proposed to amend the Designs Regulations, the Patents Regulations and the Trade Marks Regulations to make technical amendments unrelated to the Amendment Act. These technical amendments would correct errors, ensure consistency in terminology and remove obsolete references.

Commencement

This Schedule is proposed to commence on the day following registration of the Amendment Regulation in the Federal Register of Legislative Instruments.

Details of proposed amendments to Designs Regulations, Patents Regulations and Trade Marks Regulations

Item 1—Designs Regulations; new regulation 1.06 to be inserted

This item would insert a new regulation 1.06 into the Designs Regulations, modelled directly on existing regulation 2.3 of the Trade Marks Regulations.

Proposed new subregulation 1.06(1) would provide that the Registrar of Designs might give a document to a person by making it available to the person electronically and then notifying the person that the document is available.

Proposed new subregulation 1.06(2) would provide that the date a document is taken to have been given to the person is the date it is dated by the Registrar of Designs. This would apply whether access is provided to the document electronically or by another means. This is intended to avoid any uncertainty as to when a document is given to the person.

Item 2—Designs Regulations; new subregulations 11.13(1A) and (1B) to be inserted

This item would insert proposed new subregulations 13.13(1A) and (1B) into the Designs Regulations, modelled directly on subregulations 22.11(1A) and (1B) of the Patents Regulations. The proposed new provisions are to ensure that a person applying for an extension of time, to do a relevant act under the designs legislation, is not unduly affected by the time taken for opposition or review proceedings concerning the application.

Under section 137 of the Designs Act, a person can apply for an extension of time to do a relevant act (e.g. to renew a registered design after the end of the six-month grace period). If the application is for an extension of more than three months, it must be advertised in the *Official Journal of Designs*. Another person can oppose the application for the extension of time. The proposed new regulations ensure that the initial applicant is not required to seek further extensions of time in order to allow for opposition proceedings to be heard.

If the Registrar grants the opposed extension of time, the Registrar must extend the time to include the period from filing of the notice of opposition to 21 days after the Registrar decides the opposed application. If either party seeks Administrative Appeals Tribunal ('**AAT**') review of the Registrar's decision, then the extension of time continues until the review is withdrawn, finally dealt with or otherwise determined.

Item 3—Patents Regulations; subregulation 2.1(2) to be substituted

This item would delete paragraph 2.1(2)(b) of the Patents Regulations to remove a requirement for a patentee to serve copies of an application on other patentee(s). This would be done by repealing and substituting a new subregulation 2.1(2) setting out the existing requirement in paragraph 2.1(2)(a).

If there is more than one patentee of a patent, any of them may apply to the Commissioner of Patents under section 17 of the Patents Act for a direction about the patent and rights under it. Currently, paragraph 2.1(2)(b) requires the applying patentee to serve copies of the application on the other patentee(s). This is inconsistent with the other multi-party proceedings in the patents legislation (e.g. oppositions). In those proceedings, a party files an application or other document with the Commissioner, who then provides it to the other parties. With the proposed deletion of paragraph 2.1(2)(b), it is the Commissioner who would provide a copy of an application under section 17 to the other patentee(s).

Item 4—Patents Regulations; regulation 3.2 to be substituted

This item would repeal and substitute a proposed new regulation 3.2 into the Patents Regulations to clarify the formality requirements for provisional specifications. This would align them with the existing requirements for complete specifications in existing regulation 3.2A. In particular, both provisional and complete specification would have to be in English.

Item 5—Patents Regulations; new paragraph 3.2C(2)(aa) to be inserted

This item would insert a proposed new paragraph 3.2C(2)(aa) into the Patents Regulations to require an applicant for a PCT application to provide the name(s) of the inventor(s) of the invention in the application. This information is required to ensure that the entitlement of the applicant to be granted a patent is clear.

Just as with the existing requirement for a PCT applicant to provide an address for service in Australia, the name(s) of the inventor(s) would not be required until after the PCT application has entered national phase in Australia.

Item 6—Patents Regulations; regulation 3.25 to be substituted, new regulations 3.25A to 3.25H to be inserted

This item would repeal existing regulation 3.25 of the Patents Regulations and replace it with new regulations 3.25A to 3.25H. These amendments are not intended to change the existing policy for accessing samples of deposited micro-organisms, but are to make the framework for access clearer and simpler.

As discussed in the notes on item 2 of Schedule 4, a properly deposited sample of a micro-organism can be taken into account when determining whether a claimed invention has been disclosed for determining a priority date of the claim. Under the Budapest Treaty, a sample of the deposited micro-organism supporting the grant of an Australian patent can be obtained from an International Depositary Authority (**IDA**).[7] To obtain a sample, a person can present the IDA with a certificate from the Commissioner authorising the release of the micro-organism to that person.

One of the existing requirements for obtaining the Commissioner's certificate is that the recipient gives an enforceable undertaking to use the sample of the deposited micro-organism only for experimental purposes or for legal proceedings concerning the application or patent.

The amendments would ensure that such limits apply only while the application is pending, or during the life of the granted patent. This protects the legitimate interests of the applicant or patentee in the invention, while also ensuring that samples of the deposited micro-organism would be available for commercial use once:

[7] An IDA is a prescribed depositary institution for the purposes of the patents legislation.

- the application lapses, is refused or is withdrawn (that is, no patent is granted); or
- the patent expires, ceases or is revoked.

Once any of those events occurs, no undertaking would be required to obtain a sample, and any undertaking previously given for the sample would cease to bind the person. This is consistent with the patents legislation, which gives no rights to inventions that are never patented. Similarly, the patents legislation does not prevent the free use of previously patented inventions, once the patent is no longer in force.

The amendments would ensure that it is also clear that a person authorised to use the invention relating to the micro-organism under the existing compulsory licensing or Crown use provisions (see sections 133 and 163 of the Patents Act) is not required to give an undertaking. Requiring an undertaking in these circumstances could reduce the public benefit of those provisions, since the use of the sample would be limited to experimenting or conducting legal proceedings. The amendment would clarify the existing policy intent, ensuring that inventions relating to micro-organisms are treated just like other inventions.

Item 7—Patents Regulations; note following subregulation 22.15(4) to be corrected

This item would repeal and substitute the note following subregulation 22.15(4) of the Patents Regulations so that the note correctly refers to subregulation 3.14D(1), which lists the documents prescribed for disclosure in a basic application.

Items 8 to 10—Patents Regulations; subregulation 22.26(2) to be corrected

These items would amend subregulation 22.26(2) of the Patents Regulations to correct several paragraphs specifying decisions that are reviewable by the AAT:

- Item 8 would repeal and substitute subparagraphs 22.26(2)(a)(iii) and (iv) to ensure that they correctly refer to the provisions governing dismissal and determination of oppositions by the Commissioner. The erroneous references were a result of substantial amendments made by the *Intellectual Property Legislation Amendment (Raising the Bar) Regulation 2013 (No.1)* ('Raising the Bar Regulation').
- Item 9 would repeal subparagraph 22.26(2)(a)(vaa) which provided for the now-superseded AAT review of certain decisions under regulation 10.7 of the Patents Regulations. Those decisions are now made under section 191A of the Patents Act, which provides for them to be appealed to the Federal Court.
- Item 10 would correct several erroneous references to the 'Disciplinary AAT' in paragraph 22.26(2)(d) of the Patents Regulations, so that they correctly refer to the 'Disciplinary Tribunal'.

Item 11—Patents Regulations; subclause 5(2) of Schedule 3 to be corrected

This item would remove an incorrect reference to subclause 6(2) from subclause 5(2) in Schedule 3 to the Patents Regulations. Clause 6 had been repealed by the *IP Legislation Amendment Regulations 2011 (No.1)*. The proposed amendment would also make it clear that the sheets of a specification must be numbered in accordance with subclause 5(2), except where the requirement in subclause 5(3) for numbering sheets of drawings applies instead.

Item 12—Patents Regulations; fee item 239 in Part 2 of Schedule 7 to be repealed

This item would repeal fee item 239 in Part 2 of Schedule 7 to the Patents Regulations, which imposed the fee for filing an application under subregulation 3.17A(5) for an extension of time to file search results. The fee item has been superfluous since the Raising the Bar Regulation repealed that subregulation.

Item 13—Trade Marks Regulations; new definition of 'Code of Conduct' to be inserted

For clarity, this item would insert a definition of the expression 'Code of Conduct' into regulation 2.1 of the Trade Marks Regulations. The Code of Conduct would be the standard of practice titled "Code of Conduct for Patent and Trade Marks Attorneys" that is established from time to time by the Board (that is, the Professional Standards Board for Patent and Trade Marks Attorneys).

Items 14, 15, 18 and 19—Trade Marks Regulations; regulations 17A.33, 17A.34B and 17A.34M to be corrected

This item would correct several references to 'applicant' in Part 17A of the Trade Marks Regulations, so that these correctly refer to 'holder of the IRDA' or 'The holder of an IRDA' as the case requires.

The expression 'applicant' means an applicant for registration of a trade mark in Australia. In contrast, the owner of an international registration designating Australia ('**IRDA**') is referred to as its **holder** (see the definitions in regulation 17A.2).

Items 16 and 17—Trade Marks Regulations; subregulation 17A.34H(5) to be corrected

These items would correct references to "opponent" and "opponent's" in subregulation 17A.34H(5) of the Trade Marks Regulations, so that these correctly refer to "holder" or "holder's" instead. This would address a drafting oversight in the Raising the Bar Regulation.

Item 20—Trade Marks Regulations; subregulation 17A.36(5) to be corrected

This item would correct an erroneous reference in paragraph 17A.36(5)(a) of the Trade Marks Regulations, so that it correctly refers to the subregulation requiring the Registrar to notify the International Bureau of the filing of a notice of opposition. The erroneous reference was a result of substantial amendments made by the Raising the Bar Regulation.

Items 21 and 22—Trade Marks Regulations; paragraph 20.14(b) to be corrected, paragraph 20.14 (e) to be repealed

Item 21 would correct a drafting oversight in paragraph 20.14(b) of the Trade Marks Regulations by replacing an occurrence of the expression 'Register' with 'Register of Patent Attorneys' instead. The Raising the Bar Regulation replaced each occurrence of the expression 'Register' in Parts 5, 6 and 7 of Chapter 20 of the Patents Regulations with the expression 'Register of Patent Attorneys'. The consequential amendments required to regulation 20.14 of the Trade Marks Regulations were overlooked.

Item 22 would repeal paragraph 20.14(e), as it would no longer be necessary with the amendment made by item 21.

Item 23—Trade Marks Regulations; new paragraphs 20.15 (d) and (e) to be inserted

This item would insert new paragraphs 20.15(d) and (e) into the Trade Marks Regulations to put beyond doubt the correct application of subparagraphs 20.33(2)(b)(i) and (ii) of the Patents Regulations to individual registered trade marks attorneys. In particular, this is so that the references to regulation 20.6 and 20.8 in those applied subparagraphs are clearly understood to be references to regulations 20.6 and 20.8 of the Trade Marks Regulations.

Item 24—Trade Marks Regulations; note following regulation 21.14 to be corrected

This item would repeal and substitute the note following regulation 21.14 of the Trade Marks Regulations, so that it correctly refers to the regulation dealing with directions as to procedure in opposition proceedings.

Item 25—Trade Marks Regulations; subregulation 21.21A(2) to be corrected

This item would correct the syntax of subregulation 21.21A(2).

Item 26—Trade Marks Regulations; paragraph 21.28(2)(b) to be corrected

This item would correct a drafting error in paragraph 21.28(2)(b) of the Trade Marks Regulations, so that an incorrect reference to regulation 17.48F refers to regulation 17**A**.48F instead.

Item 27—Trade Marks Regulations; clause 1 of Schedule 7 to be corrected

This item would correct a reference in clause 1 of Schedule 7 of the Trade Marks Regulations so that it correctly refers to regulation 5.18, which deals with the filing of a copy of a foreign application from which an opposed trade mark application claims priority.