

EXPOSURE DRAFT



EXPOSURE DRAFT (26/11/2014)

Intellectual Property Legislation Amendment Regulation 2014 (No. 1)

Select Legislative Instrument No. , 2014

I, General the Honourable Sir Peter Cosgrove AK MC (Ret'd),
Governor-General of the Commonwealth of Australia, acting with the
advice of the Federal Executive Council, make the following regulation.

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Dated

2014

Peter Cosgrove
Governor-General

By His Excellency's Command

Ian Macfarlane [**DRAFT ONLY—NOT FOR SIGNATURE**]
Minister for Industry

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1 Name

This is the *Intellectual Property Legislation Amendment Regulation 2014 (No. 1)*.

2 Commencement

Each provision of this instrument specified in column 1 of the table commences, or is taken to have commenced, in accordance with column 2 of the table. Any other statement in column 2 has effect according to its terms.

| Commencement information | |
|--|--|
| Column 1 | Column 2 |
| Provisions | Commencement |
| 1. Sections 1 to 4 and anything in this instrument not elsewhere covered by this table | The day after this instrument is registered. |
| 2. Schedule 1 | At the same time as Schedule 1 to the <i>Intellectual Property Laws Amendment Act 2014</i> commences. |
| 3. Schedule 2 | At the same time as Schedule 2 to the <i>Intellectual Property Laws Amendment Act 2014</i> commences. |
| 4. Schedule 3 | The day after this instrument is registered. |
| 5. Schedule 4 | At the same time as items 9 to 17 of Schedule 5 to the <i>Intellectual Property Laws Amendment Act 2014</i> commences. |
| 6. Schedule 5 | The day after this instrument is registered. |

3 Authority

This instrument is made under the following Acts:

- (a) the *Designs Act 2003*;
- (b) the *Patents Act 1990*;
- (c) the *Trade Marks Act 1995*.

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4 Schedules

Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.

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Amendments relating to the TRIPS Protocol interim waiver **Schedule 1**

Schedule 1—Amendments relating to the TRIPS Protocol interim waiver

Patents Regulations 1991

1 Subregulation 1.3(1)

Insert:

Council for TRIPS means the Council for Trade-Related Aspects of Intellectual Property Rights established under Article IV of the WTO Agreement.

eligible importing country: see regulation 1.4A.

least developed country means a country included in the list of least developed countries maintained by the United Nations, as in force from time to time.

Note: The list of least developed countries could in 2014 be viewed on the United Nations' website (<http://www.un.org>).

WTO Agreement means the Marrakesh Agreement establishing the World Trade Organization, done at Marrakesh on 15 April 1994.

WTO member means a country that is a full member of the World Trade Organization.

Note: The list of members of the World Trade Organization could in 2014 be viewed on the World Trade Organization's website (<http://www.wto.org>).

2 After regulation 1.4

Insert:

1.4A Meaning of *eligible importing country*

For the definition of *eligible importing country* in Schedule 1 to the Act, the following kinds of countries are prescribed:

- (a) a WTO member that notifies the Council for TRIPS, in accordance with the WTO General Council decision of 30 August 2003, of the member's intention to use the system set out in that decision as an importer;

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Schedule 1 Amendments relating to the TRIPS Protocol interim waiver

(b) a least developed country.

3 Before regulation 12.1

Insert:

Part 1—Compulsory licences (general)

4 Regulation 12.1 (heading)

Repeal the heading, substitute:

12.1 Applications for orders for compulsory licences

5 After regulation 12.2

Insert:

Part 2—Patented pharmaceutical invention compulsory licences (for manufacture and export to eligible importing countries)

12.2A Applications for PPI orders

- (1) An applicant for a PPI order in relation to the export of a pharmaceutical product to an eligible importing country must lodge, with the Registrar of the Federal Court, an application that includes the following:
 - (a) the name and address of the applicant;
 - (b) the applicant's address for service in relation to the application;
 - (c) the name of the eligible importing country;
 - (d) if the pharmaceutical product is to be imported by a person on behalf of, and with the authorisation of, the eligible importing country—the name and address of that person;
 - (e) the name of the pharmaceutical product;
 - (f) the proposed use of the pharmaceutical product in the eligible importing country;

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Amendments relating to the TRIPS Protocol interim waiver **Schedule 1**

- (g) the amount of the pharmaceutical product proposed to be manufactured for export;
 - (h) the proposed duration of the PPI compulsory licence;
 - (i) the identity of the patent;
 - (j) the name of the patentee;
 - (k) if the patent is an innovation patent—the date of certification of the innovation patent.
- (2) For paragraph (1)(b), the address for service must be an address that is mentioned in Rules made by the Federal Court for the service of the application, as in force from time to time.
- (3) The applicant must:
- (a) serve a copy of the application on the patentee and any other person who claims an interest in the patent as soon as practicable after lodgement; and
 - (b) lodge with the Registrar notice of the date when, and the place where, he or she complied with paragraph (a).
- (4) For subregulation (3), the applicant must serve the copy in accordance with Rules made by the Federal Court for the service of the application, as in force from time to time.

12.2B PPI compulsory licences—notification requirements

- (1) This regulation sets out the notification requirements for paragraph 136E(1)(f) of the Act in relation to the importation of a pharmaceutical product into an eligible importing country.
- (2) Subregulation (3) applies if the eligible importing country is a WTO member.
- (3) The eligible importing country must have notified the Council for TRIPS in accordance with paragraph 2(a) of the WTO General Council decision of 30 August 2003.
- (4) Subregulation (5) applies if the eligible importing country is:
 - (a) a least developed country; and
 - (b) not a WTO member.
- (5) The eligible importing country must have given the Commissioner a written notice:

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Schedule 1 Amendments relating to the TRIPS Protocol interim waiver

- (a) stating:
 - (i) the name of the eligible importing country; and
 - (ii) the name of the pharmaceutical product; and
 - (iii) the expected quantity of the pharmaceutical product to be imported into the eligible importing country; and
- (b) confirming that, if the pharmaceutical product is patented in the eligible importing country, it:
 - (i) has granted; or
 - (ii) intends to grant;a compulsory licence that would accord with Article 31 of the TRIPS Agreement and the provisions of the WTO General Council decision of 30 August 2003 if the TRIPS Agreement and the decision applied to the eligible importing country.

12.2C PPI compulsory licences—labelling and marking of product

- (1) For paragraph 136F(1)(c) of the Act, the pharmaceutical product must be labelled or marked in a way that:
 - (a) clearly identifies the product as being exported from Australia under the PPI compulsory licence; and
 - (b) distinguishes the product from:
 - (i) the same pharmaceutical product as sold in Australia; and
 - (ii) the same pharmaceutical product as exported other than under the licence.
- (2) For subregulation (1), the labelling or marking must:
 - (a) be applied to:
 - (i) the immediate package containing the pharmaceutical product; and
 - (ii) any other package containing that package (whether or not other packages are involved); and
 - (b) remain clear and legible at all times while the product is being exported.

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Amendments relating to the TRIPS Protocol interim waiver **Schedule 1**

12.2D PPI compulsory licences—shipment information

- (1) For paragraph 136F(1)(d) of the Act, the following shipment information is prescribed in relation to each shipment of a pharmaceutical product:
 - (a) the name of the pharmaceutical product;
 - (b) the amount of the product in the shipment;
 - (c) the name of the licensee;
 - (d) the licensee’s address for service;
 - (e) the name of the eligible importing country;
 - (f) if a person is importing the pharmaceutical product on behalf of, and with the authorisation of, the eligible importing country—the name and address of the person;
 - (g) a description of the packaging (including colour, size and shape) and the labelling or marking of the pharmaceutical product.
- (2) For paragraph 136F(1)(d) of the Act, the shipment information must be made available for at least the duration of the licence.

12.2E PPI compulsory licences—giving information to the Commissioner

- (1) This regulation sets out for paragraph 136F(1)(h) of the Act the information that a licensee must give to the Commissioner in relation to the licence.

Grant of licence

- (2) The licensee must give the Commissioner the following information in relation to the grant of the PPI compulsory licence:
 - (a) the date of the PPI order;
 - (b) the place at which the PPI order was made;
 - (c) the name and address of the licensee;
 - (d) the licensee’s address for service;
 - (e) the name of the pharmaceutical product;
 - (f) the quantity of the pharmaceutical product that the Federal Court has determined may be manufactured for export;
 - (g) the eligible importing country to which the pharmaceutical product is to be exported;

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Schedule 1 Amendments relating to the TRIPS Protocol interim waiver

- (h) the duration of the licence;
 - (i) the identity of the patent;
 - (j) the address of the website on which the shipment information is to be made available.
- (3) The information mentioned in subregulation (2) must be given to the Commissioner:
- (a) in the approved form; and
 - (b) within 1 month after the Federal Court makes the order requiring the grant of the licence.

Amendment of licence

- (4) If the licence is amended by order under section 136G of the Act, the licensee must give the Commissioner the following information in relation to the amendment:
- (a) the date of the amending order;
 - (b) the place at which the amending order was made;
 - (c) details of the amendment.
- (5) The information mentioned in subregulation (4) must be given to the Commissioner:
- (a) in the approved form; and
 - (b) within 1 month after the Federal Court makes the order amending the licence.

Revocation of licence

- (6) If the licence is revoked by order under section 136H of the Act, the licensee must give the Commissioner the following information in relation to the revocation:
- (a) the date of the revocation order;
 - (b) the place at which the revocation order was made.
- (7) The information mentioned in subregulation (6) must be given to the Commissioner:
- (a) in the approved form; and
 - (b) within 1 month after the Federal Court makes the order revoking the licence.

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Amendments relating to the TRIPS Protocol interim waiver **Schedule 1**

Agreement or determination of remuneration

- (8) If an amount of remuneration for the licence is agreed under paragraph 136J(3)(a) of the Act or determined by the Federal Court under paragraph 136J(3)(b) of the Act, the licensee must give the Commissioner a statement that an amount of remuneration has been agreed or determined, as the case may be.
- (9) The information mentioned in subregulation (8) must be given to the Commissioner:
 - (a) in the approved form; and
 - (b) within 1 month after the agreement is reached or the determination is made.

12.2F Dealing with information provided under regulation 12.2E

- (1) If the Commissioner receives the information mentioned in subregulation 12.2E(2) in relation to the grant of a PPI compulsory licence, the Commissioner must:
 - (a) if the eligible importing country is a WTO member—give a copy of the information to the Council for TRIPS; or
 - (b) in any other case—publish the information on the internet.
- (2) If the Commissioner receives the information mentioned in subregulation 12.2E(8) in relation to a licence, the Commissioner must give the eligible importing country to which the licence relates a notice stating that the licensee has advised that an amount of remuneration in respect of the licence has been agreed or determined, as the case may be.

Part 3—Surrender and revocation of patents

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Schedule 2 Further amendments relating to the TRIPS Protocol

Schedule 2—Further amendments relating to the TRIPS Protocol

Patents Regulations 1991

1 Paragraph 1.4A(a)

Repeal the paragraph, substitute:

- (a) a WTO member that notifies the Council for TRIPS, in accordance with the Annex to the TRIPS Agreement, of the member's intention to use the system set out in Article 31bis of the TRIPS Agreement and the Annex to that Agreement as an importer;

2 Subregulation 12.2B(3)

Omit "paragraph 2(a) of the WTO General Council decision of 30 August 2003", substitute "paragraph 2(a) of the Annex to the TRIPS Agreement".

3 Paragraph 12.2B(5)(b)

Omit all the words after "would accord with", substitute "Articles 31 and 31bis of the TRIPS Agreement and the Annex to that Agreement if the Agreement and Annex applied to the eligible importing country".

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Amendments relating to document retention **Schedule 3**

Schedule 3—Amendments relating to document retention

Designs Regulations 2004

1 Subregulation 5.08(1)

Omit “(1)”.

2 Subregulation 5.08(2)

Repeal the subregulation.

Patents Regulations 1991

3 Regulation 22.18

Repeal the regulation.

Trade Marks Regulations 1995

4 Subregulation 17A.39(1)

Omit “, 13.3 and 21.32”, substitute “and 13.3”.

5 Regulation 21.32

Repeal the regulation.

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Schedule 4 Amendments relating to amendments made by Part 2 of Schedule 5 to the Intellectual Property Laws Amendment Act 2014

Schedule 4—Amendments relating to amendments made by Part 2 of Schedule 5 to the Intellectual Property Laws Amendment Act 2014

Patents Regulations 1991

1 Regulation 3.11

Omit “subsections 29B(2) and 38(1A)”, substitute “subsection 38(1A)”.

2 Subregulation 3.12(4)

Repeal the subregulation, substitute:

- (4) In this Division, a document, or a set of documents considered together, *clearly discloses* an invention if the document, or set of documents, discloses the invention in a manner that is clear enough, and complete enough, for the invention to be performed by a person skilled in the relevant art.
- (5) For the purposes of subregulation (4), a document, or a set of documents considered together, is taken to clearly disclose an invention as mentioned in that subregulation so far as such disclosure requires a description of a micro-organism, if:
 - (a) the micro-organism is deposited with a prescribed depository institution in accordance with such provisions of the Budapest Treaty as are applicable; and
 - (b) the prescribed circumstances for paragraph 43(2B)(b) of the Act apply.

3 Subregulation 3.13A(1)

Repeal the subregulation, substitute:

- (1) This regulation applies to a claim if:
 - (a) the circumstance mentioned in subregulation (2) (a prescribed circumstance for paragraph 43(2A)(a) of the Act) applies to the invention defined in the claim; and
 - (b) either:

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Amendments relating to amendments made by Part 2 of Schedule 5 to the Intellectual
Property Laws Amendment Act 2014 **Schedule 4**

- (i) a document mentioned in subregulation (4) (a prescribed document for paragraph 43(2A)(b) of the Act) clearly discloses the invention in the claim; or
- (ii) 2 or more of those documents (a prescribed set of prescribed documents for paragraph 43(2A)(b) of the Act), considered together, clearly disclose the invention in the claim.

4 Subregulation 3.13A(4)

Repeal the subregulation (not including the heading), substitute:

- (4) For paragraph (1)(b), the documents are the documents filed for the earlier application at the time the application was made.

5 At the end of regulation 3.13A

Add:

Prescribed circumstances for micro-organisms

- (6) For paragraph 43(2B)(b) of the Act, the prescribed circumstances for a disclosure that requires a description of a micro-organism are as follows:
 - (a) the deposit of the micro-organism with a prescribed depository institution, in accordance with such provisions of the Budapest Treaty as are applicable, occurs on or before the date when the documents mentioned in subregulation (4) are filed;
 - (b) either:
 - (i) a document mentioned in subregulation (4) includes the relevant information on the characteristics of the micro-organism that is known to the applicant at the time the documents are filed; or
 - (ii) 2 or more of those documents, considered together, include the relevant information on the characteristics of the micro-organism that is known to the applicant at the time the documents are filed;
 - (c) the requirements of paragraph 6(c) of the Act are satisfied by the complete specification that contains the claim.

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Schedule 4 Amendments relating to amendments made by Part 2 of Schedule 5 to the Intellectual Property Laws Amendment Act 2014

6 Subregulations 3.13B(1) and (2)

Repeal the subregulations, substitute:

- (1) This regulation applies to a claim if:
 - (a) the circumstance mentioned in subregulation (1A) (a prescribed circumstance for paragraph 43(2A)(a) of the Act) applies to the invention defined in the claim; and
 - (b) either:
 - (i) a document mentioned in subregulation (2) (a prescribed document for paragraph 43(2A)(b) of the Act) clearly discloses the invention in the claim; or
 - (ii) 2 or more of those documents (a prescribed set of prescribed documents for paragraph 43(2A)(b) of the Act), considered together, clearly disclose the invention in the claim.

Circumstance

- (1A) For paragraph (1)(a), the circumstance is that the specification containing the claim that defines the invention was filed for:
 - (a) a Convention application; or
 - (b) a complete application that has been amended to become a Convention application.

Documents

- (2) For paragraph (1)(b), the documents are the documents filed for a related basic application at the time when the application was made.

7 At the end of regulation 3.13B

Add:

Prescribed circumstances for micro-organisms

- (5) For paragraph 43(2B)(b) of the Act, the prescribed circumstances for a disclosure that requires a description of a micro-organism are as follows:
 - (a) the deposit of the micro-organism with a prescribed depository institution, in accordance with such provisions of

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Amendments relating to amendments made by Part 2 of Schedule 5 to the Intellectual Property Laws Amendment Act 2014 **Schedule 4**

the Budapest Treaty as are applicable, occurs on or before the date when the documents mentioned in subregulation (2) are filed;

(b) either:

(i) a document mentioned in subregulation (2) includes the relevant information on the characteristics of the micro-organism that is known to the applicant at the time the documents are filed; or

(ii) 2 or more of those documents, considered together, include the relevant information on the characteristics of the micro-organism that is known to the applicant at the time the documents are filed;

(c) the requirements of paragraph 6(c) of the Act are satisfied by the complete specification that contains the claim.

8 Subregulations 3.13C(1) and (2)

Repeal the subregulations, substitute:

(1) This regulation applies to a claim if:

(a) the circumstance mentioned in subregulation (1A) (a prescribed circumstance for paragraph 43(2A)(a) of the Act) applies to the invention defined in the claim; and

(b) either:

(i) a document mentioned in subregulation (2) (a prescribed document for paragraph 43(2A)(b) of the Act) clearly discloses the invention in the claim; or

(ii) 2 or more of those documents (a prescribed set of prescribed documents for paragraph 43(2A)(b) of the Act), considered together, clearly disclose the invention in the claim.

Circumstance

(1A) For paragraph (1)(a), the circumstance is that the specification containing the claim that defines the invention was filed for a complete application that is associated with a provisional application under section 38 of the Act.

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Schedule 4 Amendments relating to amendments made by Part 2 of Schedule 5 to the Intellectual Property Laws Amendment Act 2014

Documents

- (2) For paragraph (1)(b), the documents are the documents filed for the provisional application at the time when the application was made.

9 At the end of regulation 3.13C

Add:

Prescribed circumstances for micro-organisms

- (4) For paragraph 43(2B)(b) of the Act, the prescribed circumstances for a disclosure that requires a description of a micro-organism are as follows:
- (a) the deposit of the micro-organism with a prescribed depository institution, in accordance with such provisions of the Budapest Treaty as are applicable, occurs on or before the date when the documents mentioned in subregulation (2) are filed;
 - (b) either:
 - (i) a document mentioned in subregulation (2) includes the relevant information on the characteristics of the micro-organism that is known to the applicant at the time the documents are filed; or
 - (ii) 2 or more of those documents, considered together, include the relevant information on the characteristics of the micro-organism that is known to the applicant at the time the documents are filed;
 - (c) the requirements of paragraph 6(c) of the Act are satisfied by the complete specification that contains the claim.

10 Paragraph 3.13D(1)(b)

Repeal the paragraph, substitute:

- (b) the specification mentioned in subsection 79B(1) of the Act (the *earlier specification*) clearly discloses the invention in the claim.

11 Subregulation 3.13D(2)

Repeal the subregulation, substitute:

- (2) However, this regulation does not apply to a claim if:
-

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Amendments relating to amendments made by Part 2 of Schedule 5 to the Intellectual
Property Laws Amendment Act 2014 **Schedule 4**

- (a) the deposit requirements must be satisfied in relation to the invention to comply with paragraph 40(2)(a) of the Act; and
- (b) when the divisional application under section 79B of the Act is made, the period prescribed in subregulation 1.5(1) has ended in relation to the earlier specification; and
- (c) the requirements of paragraph 6(c) of the Act are not satisfied in relation to the earlier specification.

12 At the end of regulation 3.13D

Add:

- (4) For subsection 43(2A) of the Act:
 - (a) the circumstance mentioned in paragraph (1)(a) is a prescribed circumstance; and
 - (b) the document mentioned in paragraph (1)(b) is a prescribed document.
- (5) For paragraph 43(2B)(b) of the Act, the prescribed circumstances for a disclosure that requires a description of a micro-organism are as follows:
 - (a) the deposit of the micro-organism with a prescribed depository institution, in accordance with such provisions of the Budapest Treaty as are applicable, occurs on or before the date when the document mentioned in paragraph (1)(b) is filed;
 - (b) the document mentioned in paragraph (1)(b) includes the relevant information on the characteristics of the micro-organism that is known to the applicant at the time the documents are filed;
 - (c) the requirements of paragraph 6(c) of the Act are satisfied by the complete specification that contains the claim.

13 At the end of regulation 3.13E

Add:

- (3) For subsection 43(2A) of the Act:
 - (a) the circumstance mentioned in paragraph (1)(a) is a prescribed circumstance; and
 - (b) the document mentioned in paragraph (1)(b) is a prescribed document.

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Schedule 4 Amendments relating to amendments made by Part 2 of Schedule 5 to the Intellectual Property Laws Amendment Act 2014

- (4) For paragraph 43(2B)(b) of the Act, the prescribed circumstances for a disclosure that requires a description of a micro-organism are as follows:
- (a) the deposit of the micro-organism with a prescribed depository institution, in accordance with such provisions of the Budapest Treaty as are applicable, occurs on or before the date when the document mentioned in paragraph (1)(b) is filed;
 - (b) the document mentioned in paragraph (1)(b) includes the relevant information on the characteristics of the micro-organism that is known to the applicant at the time the document is filed;
 - (c) the requirements of paragraph 6(c) of the Act are satisfied by the complete specification that contains the claim.

14 Subregulation 3.15(3)

Repeal the subregulation.

15 At the end of Part 2 of Chapter 3

Add:

3.32 Provisional specifications—prescribed circumstances

- (1) For paragraph 41(1A)(b) of the Act, the prescribed circumstances are as follows:
- (a) the micro-organism was deposited with a prescribed depository institution, in accordance with such provisions of the Budapest Treaty as are applicable, on or before the date the provisional specification was filed;
 - (b) at the time the provisional application to which the provisional specification relates was made, the provisional specification clearly disclosed the invention, other than in relation to the description of the micro-organism;
 - (c) at the time the provisional application to which the provisional specification relates was made, either:
 - (i) a document filed for the provisional application included the relevant information on the characteristics of the micro-organism that was known to the applicant at that time; or

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Amendments relating to amendments made by Part 2 of Schedule 5 to the Intellectual
Property Laws Amendment Act 2014 **Schedule 4**

(ii) 2 or more documents filed for the provisional application, considered together, included the relevant information on the characteristics of the micro-organism that was known to the applicant at that time;

(d) if the circumstances mentioned in subregulation (2) apply—the requirements of paragraph 6(c) of the Act are satisfied by the complete specification mentioned in paragraph (2)(a) of this regulation.

(2) For paragraph (1)(d), the circumstances are that:

(a) a complete specification has been filed for a complete application; and

(b) the complete application is associated with the provisional application whose specification is referred to in paragraph (1)(b).

Note: A complete application may be associated with a provisional application when the complete application is filed, or as a result of a subsequent amendment to the complete application.

16 Subregulation 10.1(1AA)

Repeal the subregulation.

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Schedule 5 Other amendments

Schedule 5—Other amendments

Designs Regulations 2004

1 At the end of Chapter 1

Add:

1.06 Giving of documents by Registrar

- (1) For these Regulations, the Registrar may give a document to a person by:
 - (a) making the document available to the person in an electronic form; and
 - (b) notifying the person that the document is available.
- (2) If the Registrar gives a document to a person, the document is taken to have been given to the person on the day the document is dated by the Registrar.

2 After subregulation 11.13(1)

Insert:

- (1A) Subregulation (1B) applies if:
 - (a) an application for an extension of time for doing a relevant act is made under subsection 137(2) of the Act; and
 - (b) the relevant act has not been done; and
 - (c) a notice of opposition to the grant of the application is filed.
- (1B) If the Registrar grants the application, the Registrar must extend the time to include the period from the day on which the notice of opposition is filed to the end of:
 - (a) if an application is made to the AAT for a review of a decision of the Registrar—the day when the application is withdrawn or finally dealt with or determined; or
 - (b) in any other case—21 days after the end of the day on which the Registrar decides the application.

Patents Regulations 1991

3 Subregulation 2.1(2)

Repeal the subregulation, substitute:

- (2) A person making an application under that section must file with the application a notice stating the facts on which the application is based.

4 Regulation 3.2

Repeal the regulation, substitute:

3.2 Provisional specifications

- (1) A provisional specification must:
 - (a) be in the approved form; and
 - (b) be in English.
- (2) If the Commissioner treats a provisional specification as having been filed, the Commissioner may, within 1 month from the date of filing of the provisional specification, direct the applicant to do anything necessary to ensure that the provisional specification complies with the requirements mentioned in subregulation (1).
- (3) If an applicant to whom a direction has been given under subregulation (2) does not comply with the direction within 2 months from the date of the direction, the provisional specification is taken not to have been filed.

5 After paragraph 3.2C(2)(a)

Insert:

- (aa) provide the name of the inventor of the invention to which the application relates; and

6 Regulation 3.25

Repeal the regulation, substitute:

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3.25 Request for Commissioner's certification authorising release of sample of a micro-organism

- (1) If a micro-organism is deposited with a prescribed depositary institution, a person may request the Commissioner to grant the certification referred to in Rule 11.3(a) of the Budapest Treaty in respect of the deposit.
- (2) The request:
 - (a) must be in the approved form; and
 - (b) must relate to a micro-organism:
 - (i) that is the subject of a patent application or patent; or
 - (ii) the use, modification or cultivation of which is the subject of a patent application or patent; and
 - (c) may nominate another person as a skilled addressee.
- (3) Before making a decision under regulation 3.25B (including a decision about imposing conditions under regulation 3.25G), the Commissioner must:
 - (a) give each person mentioned in subregulation (4) a written notice inviting the person to make, within a reasonable time specified in the notice, a submission about the matter; and
 - (b) if a person mentioned in subregulation (4) makes a submission within the time specified in the notice—take the submission into account.
- (4) For subregulation (3), the persons are as follows:
 - (a) the person who made the request;
 - (b) the applicant or patentee;
 - (c) any other person who apparently has an interest in the request.

3.25A Request for certification—micro-organism subject of application for standard patent

- (1) This regulation applies if:
 - (a) the micro-organism, or the use, modification or cultivation of the micro-organism, is the subject of an application for a standard patent; and
 - (b) the complete specification relating to the application is not open to public inspection.

- (2) The applicant may notify the Commissioner that, unless regulation 3.25E applies to the request, a sample of the deposited micro-organism is to be provided during the period mentioned in subregulation (3) only to a person who is a skilled addressee without an interest in the invention.
- (3) For subregulation (2), the period:
 - (a) begins when the complete specification relating to the application is open to public inspection; and
 - (b) ends when:
 - (i) the patent is granted on the application; or
 - (ii) the application lapses or is withdrawn or refused.

3.25B Grant of certification—when Commissioner must grant certification

- (1) Subregulation (2) applies to a request under regulation 3.25 in relation to a patent application if:
 - (a) the applicant for the patent has notified the Commissioner as mentioned in subregulation 3.25A(2); and
 - (b) the period mentioned in subregulation 3.25A(3) has not ended; and
 - (c) regulation 3.25E does not apply to the request.
- (2) The Commissioner must grant the certification if:
 - (a) the specification relating to the application is open to public inspection; and
 - (b) the Commissioner is reasonably satisfied that the nominated person is entitled to rely on the deposit for the purposes of the Act; and
 - (c) a person has been nominated as a skilled addressee by the person who made the request; and
 - (d) the Commissioner is reasonably satisfied that the nominated person:
 - (i) is appropriately skilled; and
 - (ii) does not have an interest in the invention; and
 - (e) regulation 3.25C applies to the request.
- (3) Subregulation (4) applies to any other request under regulation 3.25.

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- (4) The Commissioner must grant the certification if:
 - (a) the specification relating to the application or patent is open to public inspection; and
 - (b) the Commissioner is reasonably satisfied that the nominated person is entitled to rely on the deposit for the purposes of the Act; and
 - (c) one or more of regulations 3.25C, 3.25D, 3.25E and 3.25F apply to the request.

3.25C Grant of certification—limited use undertaking

- (1) For paragraphs 3.25B(2)(e) and (4)(c), this regulation applies to a request if:
 - (a) the person making the request or the person nominated as a skilled addressee has undertaken to use the micro-organism, during the period mentioned in subregulation (2), only for experimental purposes or in relation to:
 - (i) opposition proceedings under Chapter 5 of the Act in relation to the grant of a standard patent on that application; or
 - (ii) opposition proceedings under section 101M of the Act in relation to an innovation patent; or
 - (iii) relevant proceedings in relation to the patent; and not to make the micro-organism, or a culture derived from the micro-organism, available to another person during that period; and
 - (b) the Commissioner is reasonably satisfied that the undertaking given by the person making the request or the person nominated as a skilled addressee is given in good faith.
- (2) For paragraph (1)(a), the period is:
 - (a) for a request in respect of a patent application—the period beginning when the request is granted and ending when:
 - (i) the application lapses, or is refused or withdrawn; or
 - (ii) a patent granted on the application expires, ceases or is revoked; or
 - (b) for a request in respect of a patent—the period beginning when the request is granted and ending when the patent expires, ceases or is revoked.

3.25D Grant of certification—order under section 133 of Act

For paragraph 3.25B(4)(c), this regulation applies to a request if:

- (a) an order has been made, under section 133 of the Act, requiring the patentee to grant to the person making the request a licence to work the patented invention; and
- (b) the Commissioner is reasonably satisfied that the licence provides that the person making the request has a right to obtain a sample of the micro-organism.

3.25E Grant of certification—exploitation for purposes of Commonwealth or a State

For paragraph 3.25B(4)(c), this regulation applies to a request if:

- (a) the person making the request is authorised by the Commonwealth or a State, under subsection 163(1) of the Act, to exploit the invention for the purposes of the Commonwealth or State; and
- (b) the Commissioner is reasonably satisfied that the terms for the exploitation of the invention provide that the person making the request has a right to obtain a sample of the micro-organism.

3.25F Grant of certification—expired patent etc.

For paragraph 3.25B(4)(c), this regulation applies to a request if the request is in respect of:

- (a) a patent application that has lapsed or has been refused or withdrawn; or
- (b) a patent that is expired, ceased or revoked.

3.25G Imposing conditions on certification

If the Commissioner grants the requested certification under regulation 3.25B, the Commissioner may impose any conditions the Commissioner considers reasonable, including a condition that the person making the request give security for damages for any breach of the undertaking mentioned in paragraph 3.25C(1)(a) given by:

- (a) the person; or

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- (b) another person who has been nominated by the person as a skilled addressee.

3.25H Notice of decision on certification request

- (1) If the Commissioner makes a decision under regulation 3.25B (including a decision about imposing conditions under regulation 3.25G), the Commissioner must inform each person mentioned in subregulation (2) of the decision, and the reasons for the decision, by notice in writing given as soon as practicable after the date of the decision.
- (2) For subregulation (1), the persons are as follows:
 - (a) the person who made the request;
 - (b) the applicant or patentee;
 - (c) any other person who apparently has an interest in the request.

7 Subregulation 22.15(4) (note)

Repeal the note, substitute:

Note: For a list of these documents, see subregulation 3.14D(1).

8 Subparagraphs 22.26(2)(a)(iii) and (iv)

Repeal the subparagraphs, substitute:

- (iii) regulation 5.17 or 5.18 ('dismissal of opposition');
- (iv) regulation 5.19 ('determination of opposition');

9 Subparagraph 22.26(2)(a)(vaa)

Repeal the subparagraph.

10 Paragraph 22.26(2)(d)

Omit "AAT" (wherever occurring), substitute "Tribunal".

11 Subclause 5(2) of Schedule 3

Omit "if a specification is numbered in accordance with subclause 6(2),".

12 Part 2 of Schedule 7 (table item 239)

Repeal the item.

Trade Marks Regulations 1995

13 Regulation 2.1

Insert:

Code of Conduct means the standard of practice titled “Code of Conduct for Patent and Trade Mark Attorneys” that is established by the Board from time to time.

14 Subregulation 17A.33(3)

Omit “applicant”, substitute “holder of the IRDA”.

15 Subregulations 17A.34B(2) and (5)

Omit “applicant”, substitute “holder of the IRDA”.

16 Subregulation 17A.34H(5)

Omit “opponent”, substitute “holder”.

17 Subregulation 17A.34H(5)

Omit “opponent’s”, substitute “holder’s”.

18 Subregulation 17A.34M(2)

Omit “An applicant”, substitute “The holder of an IRDA”.

19 Paragraph 17A.34M(6)(c)

Omit “applicant”, substitute “holder of the IRDA”.

20 Paragraph 17A.36(5)(a)

Omit “17A.29(3)”, substitute “17A.32(2)”.

21 Paragraph 20.14(b)

Omit “the ‘Register’”, substitute “the ‘Register of Patent Attorneys’”.

22 Paragraph 20.14(e)

Repeal the paragraph.

23 At the end of regulation 20.15

Add:

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- ; and (d) the reference in subparagraph 20.33(2)(b)(i) of the *Patents Regulations 1991* to ‘regulation 20.6’ were a reference to ‘regulation 20.6 of the *Trade Marks Regulations 1995*’; and
- (e) the reference in subparagraph 20.33(2)(b)(ii) of the *Patents Regulations 1991* to ‘regulation 20.8’ were a reference to ‘regulation 20.8 of the *Trade Marks Regulations 1995*’.

24 Regulation 21.14 (note)

Repeal the note, substitute:

Note: Regulation 5.19 deals with directions as to procedure in opposition proceedings.

25 Subregulation 21.21A(2)

Omit “despite of”, substitute “despite”.

26 Paragraph 21.28(2)(b)

Omit “regulation 17.48F”, substitute “regulation 17A.48F”.

27 Clause 1 of Schedule 7

Omit “5.5”, substitute “5.18”.