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Guide to Patented Pharmaceutical Invention (PPI) Compulsory Licences

Australia's implementation of the TRIPS Protocol

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This guide should not be regarded as an authoritative statement on the relevant law and procedure. We recommend that you seek professional assistance before you consider applying to the Federal Court for a compulsory licence.

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Revision history

Date	Amendments
25/08/2015	Initial release
23/01/2017	Revised on the coming into force of the Protocol amending the TRIPS Agreement, and its replacing the interim waiver in the WTO General Council decision of 30 August 2003 for Australia; updating of format

Guide to PPI compulsory licences

1. Introduction

The World Trade Organization ('WTO') Agreement on Trade-Related Aspects of Intellectual Property ('the TRIPS Agreement') sets out an international mechanism to allow Member States to authorise the manufacture of patented pharmaceuticals for export to developing countries in need.[1] That mechanism is given effect in Australia by Part 3 of Chapter 12 of the Patents Act 1990 and Part 2 of Chapter 12 of the Patents Regulations 1991.

You can apply to the Federal Court of Australia for a compulsory licence to manufacture generic versions of patented pharmaceutical inventions ('PPI') under specific conditions, and export these medicines to developing countries in need. This type of licence is known as a PPI compulsory licence.[2]

This Guide provides general information on PPI compulsory licences. For further information, please contact IP Australia: www.ipaustralia.gov.au/about-us/contact-us/.

Before making an application to the Federal Court for a PPI compulsory licence, you may wish to seek professional advice from a registered patent attorney or a legal practitioner specialising in the licensing of pharmaceutical patents. You may also wish to seek the advice of a regulatory affairs consultant on meeting the requirements of the Therapeutic Goods Administration for the manufacture and export of pharmaceuticals.[3]

2. PPI compulsory licences

A PPI compulsory licence means that the licensee does not infringe the relevant patent(s) of the PPI by doing what is necessary to manufacture and export the pharmaceutical product. The pharmaceutical product must be for use in addressing a public health problem in the eligible importing country:

- in circumstances of national emergency or other circumstances of extreme urgency[4]

  OR

- in other circumstances — by the public non-commercial use of the pharmaceutical product.[5] This could include use by a government or a non-profit non-government organisation to address ongoing public health problems in the eligible importing country (e.g. diabetes).

The licence is called a compulsory licence because any person can ask the Federal Court to order the patentee to grant the licence to that person ('the PPI order applicant'). The patentee is entitled to be paid adequate remuneration for the compulsory licence (discussed in section 5 below).[6]

3. Which countries are eligible importing countries?

The following are eligible importing countries:

- A country identified by the United Nations as a least developed country.[7]

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[1] Article 31bis and the Annex to the TRIPS Agreement; Amendment of the TRIPS Agreement.
[2] *Patents Act 1990* (Cth) s 136D(1) ('*Patents Act*').
[3] See https://www.tga.gov.au/regulatory-affairs-consultants.
[4] *Patents Act* s 136E(1)(c)(i).
[5] Ibid s 136E(1)(c)(ii).
[6] Ibid s 136J.
[7] Ibid sch 1 (definition of 'eligible importing country'); *Patents Regulations 1991* regs 1.3(1) (definition of "least developed country"),1.4A(b) ('*Patents Regulations*').

- A member of the WTO that has notified the TRIPS Council of its intention to use as an importer the system set out in Article 31bis of the TRIPS Agreement and the Annex to that Agreement.[8] This information is available on the WTO website.

4. What must the Federal Court be satisfied of to grant a PPI compulsory licence?

The Federal Court may only grant a PPI order if it is satisfied of all of the matters listed in section 136E of the Patents Act, as discussed below.

The proposed use of the pharmaceutical product

The Federal Court must be satisfied that the proposed use of the pharmaceutical product is to address a public health problem in the eligible importing country.

The PPI compulsory licence must be necessary

The Federal Court must be satisfied that the PPI compulsory licence is necessary in order to exploit the PPI for the purposes of manufacturing the pharmaceutical product in Australia for export to an eligible importing country.

Application must be in good faith

The Federal Court must be satisfied that the application is in good faith. For example, the PPI order applicant must not seek a PPI compulsory licence to pursue commercial objectives in Australia.

The eligible importing country has made the applicable notification

The Federal Court must be satisfied that the eligible importing country has made the applicable notification. The required notification depends on whether or not the eligible importing country is a WTO member:

Notification by an eligible importing country that is a WTO member

- The importing country must have notified the Council for TRIPS in accordance with paragraph 2(a) of the Annex to the TRIPS Agreement.[9]
- The WTO has provided a model notification for members to use. Notifications are published by the WTO on a dedicated webpage.

Notification by an eligible importing country that is not a WTO member

- The importing country must have notified the Commissioner of Patents ('Commissioner') in accordance with subregulation 12.2B(5) of the Patents Regulations.
- A model notification will soon be made available on IP Australia's website. On receiving a notification, the Commissioner will publish it on IP Australia's website.

The importation must be by or on behalf of the eligible importing country

The Federal Court must be satisfied that the pharmaceutical product is to be imported by the eligible importing country or by a third party importer authorised by the eligible importing country.

[8] *Patents Regulations* reg 1.4A(a); paragraph 1(b) in the Annex to the TRIPS Agreement.
[9] *Patents Regulations* regs 12.2B(2)–(3).

Reasonable anti-diversion measures

The Federal Court must be satisfied that the PPI order applicant, the eligible importing country and any third party importer will take reasonable measures to prevent a pharmaceutical product that is exported from Australia from being used for a purpose other than addressing a public health problem in the eligible importing country.

Reasonable attempt to get the patentee's voluntary authorisation to use the invention

The Federal Court must be satisfied that the PPI order applicant has given the patentee an opportunity to voluntarily authorise use of the patented pharmaceutical invention, unless there are circumstances of extreme urgency in the eligible importing country. A copy of a draft notice in the approved form that may be used to do this will soon be made available on IP Australia's website.

5. Remuneration for the PPI compulsory licence

The licensee must remunerate the patentee for the use of the patented pharmaceutical invention authorised by a PPI compulsory licence.[10]

If the licensee and the patentee cannot agree on the terms for the licence, either party can ask the Federal Court to determine the remuneration. In determining adequate remuneration, the court will take into account the economic value to the eligible importing country of the use of the patented pharmaceutical invention authorised by the PPI compulsory licence.[11]

When must the remuneration be agreed or determined?

It is not necessary for the remuneration to have been agreed by the parties or determined by the Federal Court when the court considers the application for the PPI order. The Federal Court might determine the remuneration when making the PPI order, or might defer determining it. This can affect when the licensee is able to exploit the patented pharmaceutical invention:

Circumstances of extreme urgency in the eligible importing country:

- The licensee does not have to wait for the remuneration to be agreed with the patentee, or determined by the Federal Court.[12]
- The licensee and the patentee can conduct their negotiations in parallel with the manufacturing and exporting of the pharmaceutical product. If necessary, the remuneration can be agreed or determined after the licence ceases.[13]

No circumstances of extreme urgency in the eligible importing country:

- The licensee needs to wait for the remuneration to be agreed with the patentee, or to be determined by the Federal Court.[14]

[10] Ibid s 136J.
[11] Ibid.
[12] Ibid s 136J(6).
[13] Ibid s 136J; in particular, ss 136J(2)(b), (3)(a).
[14] Ibid s 136J(7).