

Kluwer Patent Blog

Compulsory Licensing Australia

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Legal Analysis

In Australia, the law with respect to compulsory licenses is framed to prevent useful inventions from remaining unworked in Australia. A person who wishes to exploit a patented invention may apply to the Federal Court for an order requiring the patentee to grant the applicant a license. Such an application can only be made if more than 3 years have elapsed since the patent was granted.



Till date, a request for compulsory license has only been made three times. There are several possible reasons for the limited number of compulsory license applications:

1. Compulsory licensing is a safeguard that is rarely needed;
2. Compulsory licensing provisions may act as a deterrent against refusals to license on voluntary terms; and/or
3. Issues with the compulsory licensing provisions may be limiting their utilization.

However, as of now, no compulsory licenses have been granted in Australia.

The Australian Patent Act includes provisions which enable government authorities to exploit patented medical devices, pharmaceuticals and related technology in the certain circumstances. These provisions enable authorities to obtain, make, and supply essential technologies without a negotiated license. In the ordinary course, exploitation of a patented technology without a license would put the government authority at risk of an injunction and damages.

The compulsory licensing regime is available to any entity including government authorities, to obtain access to patented technology where it is not being sufficiently exploited by the patent owner.

Procedure for Granting Compulsory Licensing

Under section 133 of the Patent Act, the Federal Court has discretionary power to order the grant a compulsory license. Although, the Federal Court has discretionary power to order the grant a

compulsory license, the following conditions must be met:

- (a) demand in Australia for the original invention is not being met on reasonable terms;
- (b) authorisation to exploit the original invention is essential to meet that demand;
- (c) the applicant has tried for a reasonable period, but without success, to obtain authorisation from the patentee to exploit the original invention on reasonable terms and conditions;
- (d) the patentee has given no satisfactory reason for failing to exploit the patent to the extent necessary to meet the demand for the original invention in Australia;
- (e) it is in the public interest to provide the applicant with authorisation to exploit the original invention, having regard to the following:
 - 1. the benefits to the public from meeting the demand for the original invention;
 - 2. the commercial costs and benefits to the patentee and the applicant from providing authorisation to exploit the original invention; and
 - 3. any other matters the court considers relevant, including matters relating to greater competition and any impact on innovation.

In addition to conditions (a)-(e) above, if the applicant for a compulsory licence is the patentee of another invention (a dependent invention) and is seeking authorisation for the purposes of exploiting the dependent invention, a compulsory licence can only be granted where (1) the dependent invention cannot be exploited by the applicant without exploiting the original invention and (2) the dependent invention involves an important technical advance of considerable economic significance on the original invention.

Alternatively, the Federal Court may grant a compulsory license where the patentee has engaged in restrictive trade practices in connection with the patent in contravention of the Competition and Consumer Act 2010 (Cth) or under an application law within the meaning of that Act.

Form of order

In relation to a dependent invention, a compulsory license permits the original invention to be exploited only to the extent necessary to exploit the dependent invention. Further, if the patentee of the original invention requires, the patentee of the dependent invention must cross-license the dependent invention on reasonable terms.

A compulsory license cannot confer exclusive rights to the licensee to exploit the invention and the licensee can only assign the license in connection with an enterprise or goodwill in connection with which the license is used. The Federal Court may also direct that a compulsory license be granted on any other terms it sees fit.

Remuneration

The patentee must receive remuneration for a compulsory license in an amount agreed upon between the parties. However, if the parties cannot agree on the amount of remuneration, the Federal Court will determine the amount taking consideration of the following factors:

- 1. the economic value of the licence;

2. if the order is made because the patentee is in contravention of the Competition and Consumer Act 2010 (Cth) or a relevant application law – the desirability of discouraging such contraventions;
3. the right of the patentee to obtain a return on investment commensurate with the regulatory and commercial risks involved in developing the invention; and
4. the public interest in ensuring that demand in Australia for the original invention is met on reasonable terms.

Revocation of a compulsory license

A compulsory license may be revoked by the patentee or the Federal Court where both the patentee and the licensee are agreed (or the Court on application made by either party finds) that the circumstances that justified the grant of the license have ceased to exist and are unlikely to recur and the legitimate interests of the licensee are not likely to be adversely affected.

Where a cross-license has also been granted for a dependent invention, the Federal Court must consider whether to revoke the cross?license.

Revocation of the patent

An interested party can also apply to the Court for revocation of a patent that is the subject of a compulsory license after 2 years have elapsed since the compulsory license was granted. The Court may revoke the license if it is satisfied that:

1. demand in Australia for the original invention is continuing to not be met on reasonable terms;
2. the patentee has given no satisfactory reason for failing to exploit the patent to the extent necessary to meet the demand for the original invention in Australia; and
3. it is in the public interest to revoke the patent.

Alternatively, the Federal Court may revoke a compulsory license where the patentee has engaged in restrictive trade practices in connection with the patent in contravention of the Competition and Consumer Act 2010 (Cth) or a relevant application law within the meaning of that Act.

Compulsory licenses to address foreign public health issues

A third party may also apply to the Federal Court to make an order requiring the grant of a compulsory license to exploit a patented pharmaceutical invention (PPI) for manufacture and export to address a public health issue in an eligible importing country. There is no time limit on when a third party may apply for such a license.

Grant of PPI compulsory license

The Federal Court has discretionary power to order the grant a PPI compulsory license for a PPI where all of the following conditions are met:

1. the application is made in good faith;
2. the pharmaceutical product is to be imported by (i) the eligible importing country or (ii) by a third-party importer or by a third-party importer authorised by that country;
3. the proposed use of the pharmaceutical product is (i) to address a public health problem in the eligible importing country in circumstances of national emergency or other circumstances of

- extreme urgency or (ii) by the public non-commercial use of the pharmaceutical product;
4. exploiting the patented pharmaceutical invention is necessary to enable the import and proposed use of the pharmaceutical product;
 5. if the proposed use is public non-commercial use, the applicant had tried for at least 30 days, without success, to obtain authorisation from the patentee to exploit the PPI on reasonable terms and conditions;
 6. the relevant notification requirements of the eligible importing country have been met; and
 7. the applicant for the PPI order, the eligible importing country and any third-party importer will take reasonable measures to prevent the exported pharmaceutical product from being used for any other purpose.

A PPI order must direct that the PPI compulsory licence is granted such that, inter alia, no more than the quantity of the pharmaceutical product that is necessary to meet the needs of the eligible importing country is manufactured.

A third party can also apply to the Federal Court to amend the terms of a PPI compulsory licence, such as the quantity of the pharmaceutical product concerned and the duration of the licence. The Court may allow the amendment if it is just to do so in all the circumstances and the legitimate interests of the patentee, licensee, importing country or other interested party are not likely to be adversely affected by the amendment.

Remuneration

The patentee must receive remuneration for a compulsory license in an amount agreed upon between the parties. However, if the parties cannot agree on the amount of remuneration, the Federal Court will determine the amount taking into account the economic value to the eligible importing country of the use of the patented pharmaceutical invention authorized by the PPI compulsory license.

If the proposed use of the PPI is to address a public health problem in the eligible importing country in circumstances of national emergency or other circumstances of extreme urgency, the licensee may exploit a patented pharmaceutical invention under a PPI compulsory license, whether or not an amount of remuneration has been agreed or determined. However, in the case of public non-commercial use, the PPI cannot be exploited unless the amount of remuneration has previously been agreed or determined.

Revocation of a PPI compulsory license

Any person can apply to the Federal Court for revocation of a PPI compulsory license. A PPI compulsory license may be revoked by the patentee or the Federal Court where the legitimate interests of the licensee or the eligible importing country are not likely to be adversely affected by the revocation and at least one of the following is satisfied:

1. the substantive circumstances that justified the grant of the licence have ceased to exist and are unlikely to recur;
2. the licensee has not complied with the terms of the licence; and
3. the amount of remuneration agreed or determined has not been paid within the time agreed or determined.

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