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Public Consultation: Compulsory Licensing of Patents

August 2017



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Introduction

This paper discusses proposed amendments to the Patents Act 1990 (the Patents Act) to

- change the test required to obtain a compulsory licence over a patent;
- change the considerations of the court in determining the terms of a compulsory licence; and
- change the provisions for compulsory licensing in instances of patent dependency.

The purpose of this paper is to encourage discussion and seek views on the proposed amendments.

IP Australia invites interested parties to make written submissions in response to the questions presented in this paper by **Friday**, **17 November 2017**.

IP Australia will consider the submissions, and undertake further consultation during the legislation drafting process.

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) 6222 3695, or via email on Lisa.Bailey@ipaustralia.gov.au.

This paper is also available at:

www.ipaustralia.gov.au/about-us/public-consultation

Submissions should be received no later than 17 November 2017.

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Part 1: Compulsory Licensing of Patents

Background

A compulsory licence is an order for a patentee to grant a licence to another party, allowing that party nonexclusive rights to exploit the patented invention. Compulsory licencing is one of several safeguards in the *Patents Act 1990* (Patents Act) that allow a patented invention to be used without the authorisation of its owner. These safeguards can be invoked in exceptional circumstances where exercising the exclusive rights associated with a patent would not serve the best interests of the community.¹

Section 133(2)(a) of the Patents Act provides that the court may make an order for the grant of a compulsory licence in favour of an applicant, where:

- (a) The applicant has tried for a reasonable period, without success, to obtain authorisation from the patentee to work the invention on reasonable terms and conditions; and
- (b) The "reasonable requirements of the public" are not being met with respect to a patented invention; and
- (c) The patentee has given no satisfactory reason for failing to exploit the patent.

Section 133(2)(b) provides that the court may make the order if the patentee has contravened or is contravening Part IV of the *Competition and Consumer Act 2010* (Cth) (CCA).

Section 135 sets out the circumstances in which the "reasonable requirements of the public" are taken not to have been satisfied.

A compulsory licence has never been granted in Australia. There have been three cases where an application has been made. There are several possible reasons for the limited number of compulsory licence applications:

- Compulsory licensing is a safeguard that is rarely needed;
- Compulsory licensing provisions may act as a deterrent against refusals to licence on voluntary terms; and/or
- Issues with the compulsory licensing provisions may be limiting their utilisation.

A number of reviews have raised issues with, and recommended amendments to, the compulsory licensing provisions, including:

- Intellectual Property and Competition Review Committee, 2000, *Review of Intellectual Property Legislation under the Competition Principles Agreement* (Ergas Report);
- Australian Law Reform Commission, 2004, Genes and Ingenuity: Gene Patenting and Human Health;
- Senate Community Affairs References Committee, 2010, Inquiry into Gene Patents; and
- Productivity Commission Inquiry Report, 2013, Compulsory Licensing of Patents

¹ Productivity Commission, Inquiry Report, *Compulsory Licensing of Patents*, 2013, p.47.

In its 2013 review, the Productivity Commission ("PC") made four recommendations in relation to the compulsory licensing provisions. In general terms, these recommendations would:

- Remove the competition test from the Patents Act and add it to the *Competition and Consumer Act 2010* (Cth) (Recommendation 6.1);
- Replace the reasonable requirements of the public test with a general public interest test (Recommendation 6.2);
- Repeal s.136 of the Patents Act, which prevents the court from making an order for a compulsory licence that is inconsistent with an international treaty (Recommendation 6.3); and
- Provide a plain English guide on compulsory licensing, jointly developed by IP Australia and the Australian Competition and Consumer Commission (Recommendation 10.1).

Problem

The PC identified three issues with the compulsory licensing provisions.

Issue One: Overlap with the Competition and Consumer Act 2010

Section 133(2)(b) of the Patents Act was introduced in 2006 in partial response to a recommendation in the Ergas Report. This provision provides that the court may issue a compulsory licence on the grounds that the patentee has contravened, or is contravening, Part IV of the CCA, which relates to anti-competitive conduct.

The PC argues that there is inconsistency and duplication between the Patents Act and the CCA because the CCA may already allow the court to make an order for a compulsory licence under the existing remedy provisions. For example, under s.80 of the CCA, the court can grant an injunction on the terms it considers appropriate, including "requiring a person to do an act or thing". Section 87 of the CCA gives the court broad powers to make any order it thinks appropriate if the order would compensate the applicant for the loss or damage suffered, or prevent or reduce the loss or damage.

In *NT Power v Power and Water Authority* (2004) 219 CLR 90 the High Court of Australia indicated that s.46 of the former *Trade Practices Act 1974* may create access regimes if an intellectual property owner refuses to licence intellectual property or only licences it on particular conditions.

Because of this, the PC argues that an applicant can seek a compulsory licence as a result of anticompetitive behaviour via two separate mechanisms: either under the remedy provisions of the CCA, or under s.133 of the Patents Act.

The PC suggests that this arrangement creates duplication and inconsistency, which, in the absence of clear guidance on which legislation prevails when the respective provisions are in conflict, leads to uncertainty. Potential inconsistencies raised by the PC include differences in who can apply for a compulsory licence, the timeframe for bringing an application, and differences in remuneration. Consequently, the PC recommended that the competition test be moved from the Patents Act to the CCA (Recommendation 6.1).

Issue Two: Uncertainty within the reasonable requirements of the public test

Under s.133(2)(a)(ii) of the Patents Act, the court must be satisfied that the reasonable requirements of the public with respect to the patent have not been met, before it can make an order for a compulsory licence. Section 135(1) of the Patents Act outlines the circumstances in which the reasonable requirements of the public are taken not to have been satisfied.

The PC found that this term was not used elsewhere in Australian legislation or case law, in contrast to the more commonly used notion of the public interest. Additionally, there was limited case law to provide

guidance on its interpretation. As a result, the PC argued, the language used in the provisions creates significant uncertainty.² This uncertainty may reduce the incentive to apply for a compulsory licence, and may be one of the reasons that the provisions are so rarely used.

Another issue identified by the PC with the reasonable requirements of the public test is that it appears to conflate the interests of the broader public with the interests of individual industries. Section 135(1)(a) of the Patents Act provides that the reasonable requirements of the public are not satisfied if "an existing trade or industry in Australia, or the establishment of a new trade or industry in Australia, is unfairly prejudiced" by the lack of access to a patented invention.

The PC argues that the reasonable requirements of the public test should not protect the interests of a particular trade or industry if this comes at a net cost to the broader community. For example, there may be instances where providing a compulsory licence benefits a particular trade or industry today, but compromises community-wide welfare over time, by reducing the incentive of foreign firms to market their products in Australia. To the extent that protecting the interests of a particular industry is desirable for economic efficiency, the PC considered it more appropriate to consider this as part of a broader public interest test, than to treat the interests of an industry as an end goal.³

To address these issues, the PC recommended that the current test be replaced with a new public interest test (Recommendation 6.2). This test would focus on the criteria that Australian demand for a product or service is not being met on reasonable terms, and access to the patented invention is essential for meeting the demand.⁴ The PC also specified certain conditions that should be met. These included that the applicant must have tried for a reasonable period, without success, to obtain access from the patentee on reasonable terms (as required by the current Patents Act), and that there must be a substantial public interest in providing the applicant with access to the patent.

The PC also recommended that the terms of any compulsory licence, including the level of compensation to the patentee, be consistent with the public interest considerations outlined above.

Issue Three: Compulsory licence orders and international obligations

Section 136 of the Patents Act provides that the court must not make an order for a compulsory licence that is "inconsistent with a treaty between the Commonwealth and a foreign country". Australia's international obligations allow for compulsory licensing. Three agreements contain specific provisions on compulsory licensing:

- the Paris Convention for the Protection of Industrial Property;
- the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS); and
- the Australia-United States Free Trade Agreement (AUSFTA).

The PC considered s.136 to be problematic because it required the courts to interpret international agreements into domestic application and created uncertainty which may undermine the operation of the safeguard mechanism. The PC also considered that on a literal reading of the provision, the court would be required to apply international treaty provisions which had not been directly implemented in domestic legislation.⁵

The PC recommended that s.136 of the Patents Act be repealed, and that treaty obligations be implemented directly into legislation where necessary (Recommendation 6.3).

² Productivity Commission Inquiry Report, *Compulsory Licensing of Patents*, 2013, p.148.

³ Productivity Commission Inquiry Report, *Compulsory Licensing of Patents*, 2013, p.148.

⁴ Productivity Commission Inquiry Report, *Compulsory Licensing of Patents*, 2013, p.148.

⁵ Productivity Commission Inquiry Report, *Compulsory Licensing of Patents*, 2013, p.158.

Options for reform

Option 1: Public education and awareness

Under this option, IP Australia would undertake public education and awareness activities. For example, publishing an explanatory document that explains the scope of the reasonable requirement of the public test, and raise awareness of this document with relevant stakeholders. Alternatively, IP Australia may, in conjunction with the Australian Competition and Consumer Commission (ACCC), develop a plain English guide to the compulsory licensing provisions and publish it on both agency websites, in accordance with Recommendation 10.1 of the 2013 PC Report.

Public education and awareness activities were undertaken for Crown use provisions in March 2009. This involved the then Minister for Innovation, Industry, Science and Research writing to relevant Commonwealth, State and Territory Ministers to raise awareness of rights and obligations under the provisions, and the development of a factsheet for public consumption. These actions did not appear to alleviate all concerns about those provisions.

Option 1 alone is not preferred, as it provides only a partial response to the issues that have been raised. Although this option would increase awareness of the existing provisions and may provide some clarification of how they are to be applied, it will also leave key issues unaddressed. Stakeholders are likely to continue to raise issues with the provisions. However, development of a plain English guide as set out in Recommendation 10.1 would be useful, were it to be progressed together with legislative solutions outlined below.

Option 2: Implement the Productivity Commission's recommendations in full

Under this option, the Patents Act will be amended to implement the recommendations of the PC Report. Option 2 is not preferred.

Recommendation 6.1: move competition test into the Competition and Consumer Act 2010

IP Australia does not agree with the PC that the competition test should be moved to the CCA. Currently, s.133(2)(b) of the Patents Act provides a clear and transparent statement that a compulsory licence is available under the Patents Act as a remedy for anti-competitive conduct.

The relationship between the provisions in the Patents Act and the CCA was recognised at the time s.133(2)(b) was implemented. During introduction of the competition test into section 133, a Parliamentary inquiry into the implementing Bill heard evidence that the CCA (then the *Trade Practices Act 1974*) already contained an alternative mechanism for compulsory licensing of patents. The suggestion was that although use of intellectual property is excluded from the operation of Part IIIA of the CCA's provisions regulating access to services, the courts had "attempted to bridge this gap" through Part IV of the CCA – specifically s.46, which concerns misuse of market power.⁶

Under the CCA remedy provisions, the court may grant an injunction in such terms as it deems appropriate to remedy a misuse of market power,⁷ which could conceivably take the form of a compulsory licence. As noted above, the High Court has said that the market power provisions could be used to create access regimes for the supply of intellectual property.⁸ However, the CCA does not include a specific provision under which a person can directly apply to the court for a compulsory licence.

⁶ Professor Stephen Corones, *Submission on Compulsory Licensing of Patents*, Senate Economics Legislation Committee, 28 July 2006, pp 6-8.

⁷ *Competition and Consumer Act 2010* (Cth), s. 80.

⁸ In non-binding commentary: *NT Power Generation Pty Ltd v Power and Water Authority* (2004) 219 CLR 90 at 122.

As the Further Explanatory Memorandum to the 2006 Bill made clear, section 133(2)(b) is intended to complement the remedies available under the CCA, and is not intended to limit the court's powers under that Act. It is intended to clarify that a compulsory licence is available under the Patents Act for any breach of Part IV of CCA. This is in addition to any other remedies available under the CCA.

There is insufficient evidence of particular problems that would be specifically resolved by implementing Recommendation 6.1. It may also have the unintended consequence of reducing the court's powers under the CCA. As it stands, the current provision in the Patents Act provides a clear statement that a compulsory licence is available as a remedy for anti-competitive conduct relating to a patent.

Recommendation 6.2: public interest test

IP Australia does not agree with all elements of Recommendation 6.2 – but does agree that the reasonable requirements of the public test should be replaced with a new public interest test. IP Australia also agrees that the references to the protection of trade and industry in s.135 of the Patents Act should be removed. This follows a series of earlier reviews which have recommended that s.135 be replaced or clarified, including:

- ALRC, Report 99, Genes and Ingenuity, June 2004, Recommendation 27-1; and
- Senate Standing Committee on Community Affairs, Report, *Inquiry into Gene Patents*, November 2010, Recommendation 12.

Recommendation 6.2 specified that a compulsory licence would be available under the new test if the following legislated conditions were met:⁹

- Australian demand for a product or service is not being met on reasonable terms, and access to the patented invention is essential for meeting this demand.
- The applicant has tried for a reasonable period, but without success, to obtain access from the patentee on reasonable terms and conditions.
- There is a substantial public interest in providing access to the applicant, having regard to
 - benefits to the community from meeting the relevant unmet demand;
 - commercial costs and benefits to the patent holder and licensee from granting access to the patented invention; and
 - other impacts on community wellbeing, including those resulting from greater competition and from the overall effect on innovation.

The availability of a compulsory licence should focus on whether Australian demand for a product or service is not being met, and whether access to the patent is necessary in order to address this demand. Broader considerations concerning Australian trade or industry could be considered as part of a public interest test.

However, the threshold proposed by the PC – a "substantial" public interest – should not be adopted. This would create a significant barrier for applicants to overcome in applying for a compulsory licence. It would raise the threshold above what is currently required, noting that the proposed test already specifies that access to the patent must be essential to meet demand.

Further, the introduction of the word "substantial" will increase the level of uncertainty. It is unclear what would constitute a "substantial" public interest, and judicial interpretation of the term "substantial" varies widely. In IP Australia's view, adding the word "substantial" would only increase uncertainty and introduce a further disincentive to apply for a compulsory licence.

⁹ Productivity Commission, Inquiry Report, *Compulsory Licensing of Patents*, 2013, p.24.

IP Australia also agrees that the PC recommendations on the terms of a licence be implemented. Recommendation 6.2 included provisions for the Federal Court to set the terms of the compulsory licence – where the parties cannot reach agreement – "consistent with the public interest", having regard to the rights of:

- *the patentee* to obtain a return on investment commensurate with the regulatory and commercial risks involved; and
- *the public* to the efficient exploitation of the invention.

In addition, IP Australia would propose retaining the current requirement that the court take into account the economic value of the licence.

The proposed legislative amendment would require the court to explicitly refer to these two factors in determining the appropriate level of remuneration (and other terms) for the compulsory licence, where the parties are unable to agree on negotiated terms. This would not be an exhaustive list and would not prevent the court taking other relevant factors into account. The PC noted that its factors are based on the pricing principles in Part IIIA of the CCA.¹⁰

Recommendation 6.3: repeal s.136 of the Patents Act

IP Australia does not agree with the PC's recommendation that s.136 of the Patents Act should be repealed. The provision provides certainty that a court will not issue compulsory licences in circumstances which are inconsistent with Australia's international obligations.

Section 136 has been included in its current wording since the introduction of the *Patents Act 1990*. Prior variations were also included in the *Patents Act 1952* and the *Patents Act 1903*.¹¹ The provision provides certainty that a court cannot make an order that is inconsistent with Australia's international law obligations.

The PC is correct in saying that it is ordinary practice for Australia's international obligations to be implemented through specific amendments to domestic legislation. However, it is not unusual for legislation to refer to international agreements in a similar manner to s.136. There are a considerable number of other legislative regimes with similar provisions which restrict decision-makers from exercising powers inconsistently with international agreements.¹²

Option 3: Implement a refinement of Recommendation 6.2 only

Under this option Recommendations 6.1 and 6.3 would not be implemented, and the Patents Act would be amended to implement Recommendation 6.2 only, but with a "public interest" test, rather than a "substantial public interest" test. This option is otherwise identical to Recommendation 6.2, both in terms of the application of the test for the issue of a compulsory licence, and the determination of the terms of the licence.

The new test would focus on whether there is unmet demand for a product or service, which would be remedied by access to the patent. It would also require the court to consider whether access to the patent would be in the public interest.

¹⁰ These are the principles to which the ACCC must have regard in making determinations on essential infrastructure access for services: see *Competition and Consumer Act 2010*, s.44ZZCA.

¹¹ Section 111 of the *Patents Act 1952* and section 87A of the *Patents Act 1903* introduced by Act No 17 of 1909.

¹² For example, the *Civil Aviation Act 1988* (Cth) s.11: "CASA shall perform its functions in a manner consistent with the obligations of Australia under the Chicago Convention and any other agreement between Australia and any other country or countries relating to the safety of air navigation."

Benefits of Proposed Solution

A combination of Options 1 and 3 is the preferred solution. The proposal will:

- Ensure that s.133 of the Patents Act continues to provide a clear and transparent statement that a compulsory licence is available as a remedy for anti-competitive conduct;
- Increase certainty and clarity in s.133(2) and s.135 of the Patents Act by removing the reasonable requirements of the public test and replacing it with a public interest test;
- Balance the right of the patentee to obtain an appropriate economic return on their investment, and the rights of the public to the invention being exploited efficiently;
- Retain s.136 of the Patents Act, to maintain certainty that the grant of a compulsory licence will not be inconsistent with Australia's international legal obligations; and
- Communicate the legislative changes to the public, and clarify the intent and purpose of the provisions to patent owners and prospective licensees.

Questions for consultation

- CL1.1 Which approach to compulsory licensing of patents do you favour and why?
- CL1.2 What pros and cons have we not considered, including unintended or unforeseen consequences?
- CL1.3 What other options are there?
- CL1.4 Are there any particular aspects of compulsory licensing which should be a focus of public education and awareness efforts?

Part 2: Compulsory Licensing for Dependent Patent Owners

Stakeholders have identified an issue in the implementation of additional legislative requirements for applicants seeking a compulsory licence for a patent under the Patents Act in circumstances of patent dependency. These stakeholders have also suggested an amendment to the provision to correct this apparent error.

Background

"Patent dependency" refers to circumstances in which a patented invention (**the dependent patent**) cannot be worked without exploiting an earlier patented invention (**the original patent**). Examples of dependent patents include a patent which protects a novel process for the production of a product which is already protected by an original patent, or a patent granted in respect of a novel application of a product or a process protected by an original patent.

Subsection 133(3B) of the Patents Act provides additional conditions which must be satisfied where an applicant seeks a compulsory licence in order to work a dependent patent invention.

The provision requires that, if the dependent patented invention cannot be worked without infringing another patent (the original patent):

- (a) the court is to make the order only if the court is further satisfied that the [dependent] patented invention involves an important technical advance of considerable economic significance on the [original] invention; and
- (b) the court must further order that the patentee of the [original] invention:
 - (i) must grant a licence to the applicant to work the other invention insofar as is necessary to work the patented invention; and
 - (ii) is to be granted, if he or she so requires, a cross-licence on reasonable terms to work the [original] patented invention.

This cross-licensing requirement in paragraph 133(3B)(b)(ii) is intended to provide appropriate compensation for an original patent owner for the compulsory licence over their invention, in additional to remuneration terms of that licence. It effectively allows the original patent owner to benefit from the follow-on innovation which was facilitated by their original invention.

Subsection 133(3B) was introduced by the *Patents (World Trade Organization Amendments) Act 1994,* which made amendments to the Patents Act to ensure consistency with the TRIPS Agreement.¹³ Article 31(I) of the TRIPS Agreement prescribes additional conditions where member states provide for unauthorised use of a patent in circumstances of patent dependency. Subsection 133(3B) has never been tested in an Australian court, though it could be expected to have some influence on voluntary licensing negotiations between dependent and original patent owners.

¹³ Hansard, Second Reading Speech, *Patents (World Trade Organization Amendments) Bill 1994*, House of Representatives, 18 October 1994, p. 2185.

Problem

The Institute of Patent and Trade Marks Attorneys (IPTA) and the Law Council of Australia (LCA) contend that subsection 133(3B) of the Patents Act may create unintended and erroneous outcomes. They argue that the purpose of the provision should be to deal only with situations where an application for a compulsory licence is made by the <u>owner</u> of the dependent patent.¹⁴ On this view, the provision should provide that dependent patent owners may seek compulsory licences over original patents, only where their follow-on innovation involves an important technical advance of considerable economic significance on the original invention.

However, as currently drafted, s.133 of the Patents Act allows an *applicant*, who may be a relevant patent owner or a third party, to apply for a compulsory licence over the original patent in order to work the dependent patent invention. This has the effect that a third party applicant may obtain a compulsory licence in respect of the dependent patent and the original patent in the one application. However, a third party applicant would only need to satisfy the grounds for obtaining the compulsory licence in s.133(2) in relation to the dependent patent – applying a different test for a compulsory licence over the original patent.

Furthermore, paragraph 133(3B)(b)(ii) provides that the owner of the original patent must be granted, if he or she requires, a cross-licence on reasonable terms to work the dependent patent invention. This provision has the effect that the original patent owner may require a cross licence on reasonable terms from the owner of the dependent patent, even where the applicant is a third party. This outcome has been criticised as illogical. It is the third party applicant who has sought access to the dependent patent, and it is the third party who is making use of the original invention, not the owner of the dependent patent. IPTA has argued that it is not equitable to require the owner of the dependent patent to compensate the owner of the original patent for the actions of a third party with the grant of a compulsory cross-licence. Where an applicant requires compulsory licences to more than one patent, these should arguably be treated as separate applications.

Options for reform

Option 1: Amend subsection 133(3B) so that it applies only to dependent patent owners

Option 1 is the preferred option.

This option adopts the suggestion of stakeholders that subsection 133(3B) be amended so that it applies only in circumstances where the owner of a dependent patent is seeking a compulsory licence over the original patent. This would remove the purported illogical outcomes from the legislation.¹⁵

This would have the effect of removing the ability of third parties to seek compulsory licences over both a dependent and original patent at the same time. Instead, third parties would need to seek separate licences over each patent. As a result, this option would clarify that the subsequent cross-license arrangements only apply between original and dependent patent owners.

¹⁴ IPTA submission to the 2016 Productivity Commission Inquiry, *Intellectual Property Arrangements*, p. 33, and LCA letter to IP Australia, 12 June 2013, p. 4.

¹⁵ IPTA, Response to Productivity Commission Inquiry into Australia's Intellectual Property Arrangements Chapter 7, 14 February 2017, at p 34.

Option 2: Repeal subsection 133(3B)

A further option is to repeal s.133(3B). Under this option, all compulsory licence applications would be governed by common requirements of s.133(2), with no special arrangements for circumstances of patent dependency. This option could be taken in response to the comments of the ALRC and the PC that subsection 133(3B) may be unnecessary, as subsection 133(2) may already effectively act to achieve the intended policy outcomes. That is, in applying the reasonable requirements of the public test, or a public interest test, a court would likely consider the importance and economic significance of the technological advance of a dependent patent before granting a compulsory licence over an original patent.

This option would have the benefits of simplifying compulsory licensing arrangements under a single set of requirements. It would also remove the illogical outcomes produced by the current provision in relation to third party applicants and cross-licensing.

However, it is not sufficiently certain that a court, in the absence of s.133(3B), would only order a compulsory licence to work a dependent patent which represents an "important technical advance of considerable economic significance" on the original patent. Accordingly, this option is not recommended.

Benefits of proposed solution

Option 1 is the preferred solution. The proposal will increase certainty and clarity of the operation of compulsory licensing provisions as they relate to dependent patents by eliminating illogical outcomes which arise when third party applicants seek a concurrent compulsory licence over dependent and original patents in the one application.

Whilst this option will require third applicants to make multiple applications in respect of the dependent and original patents where required – and to satisfy the requirements of s.133(2) in respect of each application – such applicants will no longer have to satisfy the requirements economic significance test applied to dependent patentee applicants.

Questions for consultation

- CL2.1 Which approach to compulsory licensing in circumstances of patent dependency do you favour and why?
- CL2.2 What pros and cons have we not considered, including unintended or unforeseen consequences?
- CL2.3 What other options are there?

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