# 8 Other forms of non-voluntary access in Australia

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| Key points |
| * There are several mechanisms, other than compulsory licensing and Crown use, for accessing patents without the authorisation of the patent holder. * Legislative exemptions for experimental use and for the purpose of obtaining regulatory approval have reduced uncertainty about accessing patented inventions without the consent of the patentee. * A foreshadowed exemption for the purposes of exporting pharmaceuticals to developing countries is expected to have limited implications for existing compulsory licensing and Crown use provisions. |
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The *Patents Act 1990* (Cwlth) (Patents Act) contains provisions allowing several forms of non-voluntary access to patents, in addition to compulsory licensing and Crown use and acquisition (chapter 1). This chapter examines the other provisions that are most relevant to this inquiry — exemptions from infringement for research and experimental use, and for the purpose of obtaining regulatory approval. A foreshadowed change to the Patents Act to provide an additional ground for issuing a compulsory licence — for the purpose of exporting pharmaceuticals to developing countries — is also discussed.

## 8.1 Experimental exemption

The *Intellectual Property Laws Amendment (Raising the Bar) Act 2012* (Cwlth) amended the Patents Act to allow the use of a patented invention for experimental purposes without the authorisation of the patent owner through the insertion of s. 119C (box 8.1).

The exemption is intended to apply to research related to the subject of the patent, including follow‑on research. Follow-on research on the subject matter of a patent might be undertaken for a range of purposes. One such purpose is for comparison with a new invention, which might represent an alternative to the patented invention.

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| Box 8.1 The experimental purposes exemption |
| Section 119C of the *Patents Act 1990* (Cwlth) states that:   1. A person may, without infringing a patent for an invention, do an act that would infringe the patent apart from this subsection, if the act is done for experimental purposes relating to the subject matter of the invention. 2. For the purposes of this section, experimental purposes relating to the subject matter of the invention include, but are not limited to, the following: 3. determining the properties of the invention; 4. determining the scope of a claim relating to the invention; 5. improving or modifying the invention; 6. determining the validity of the patent or of a claim relating to the invention; 7. determining whether the patent for the invention would be, or has been, infringed by the doing of an act. |
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The exemption does not apply to research that uses, but is not related to, the subject of a patent. In other words, patented research tools are not intended to be covered by the exemption.

### Rationale and assessment

Prior to the ‘Raising the Bar’ reforms, several reviews of the patents system highlighted how the absence of a research exemption created uncertainty around patent infringement and inhibited research and innovation (ACIP 2005b; ALRC 2004). Australian Council for Intellectual Property (ACIP) (2005b) noted that granting rights over experimental use to the patent holder creates a disincentive to other parties undertaking follow-on research. Research involving patented inventions might not have been undertaken, or might have been postponed until the patent is expired. It was also argued by some that research may have shifted to countries with clearer research exemptions (Australian Government 2011b).

On the other hand, many researchers were not concerned about the lack of an explicit exemption, as they considered that an implicit exemption for infringement already existed under Australian patent law. Advice from the Australian Government Solicitor to ACIP stated:

We think it is likely that a court would find that, in some circumstances, use of a patented invention for experimental or research purposes would not constitute an infringement of a patent registered under the Act. (ACIP 2005b, p. 28)

The view of an implicit exemption for research was held by many in the medical research community (Nicol and Nielsen 2003). The Centre for Law and Genetics submitted that:

... our research has demonstrated there has long been a ‘practice based’ research exemption, meaning that there is an unwritten rule that patentees do not enforce their patent rights against research users. (sub. 3, p. 8)

The Australian Government acknowledged that there was no strong empirical evidence that patents had prevented downstream research in Australia. However, a lack of evidence does not preclude the possibility that patents were a barrier to follow-on research, or that they could be in future (Australian Government 2011b).

#### ‘Raising the Bar’ experimental exemption reform

The experimental exemption, introduced as part of the ‘Raising the Bar’ reforms, aims to clarify the rights and obligations of researchers, and reduce uncertainty around patent infringement related to the use of patented inventions in research. According to the explanatory memorandum, the exemption only applies to experimental research, and does not cover research undertaken for commercial purposes (Australian Government 2011b).

The intention of the reforms is ‘ … to give broad and clear protection to research and experimental activities in order to maximise the potential for research in Australia’ (Australian Government 2011b, p. 9). To the extent that the experimental exemption increases the quantity and quality of research, there are flow‑on social benefits. For instance, if the exemption increases the level of follow‑on research, this may improve the quality of patents and increase the level of competition in the market.

That said, several inquiry participants, while generally supportive of the reforms overall, highlighted concerns that it may be difficult to determine if the research exemption applies when there is overlap between experimental and commercial research. Thus, Civil Liberties Australia expressed a concern that the exemption may not cover all types of research undertaken at Australian universities and research institutes:

The new experimental use exemption represents an important safeguard against corporate efforts to stifle researcher freedom. However CLA is not convinced that ‘Raising the Bar’ eliminated all threats to academic speech ... the exemption may only cover ‘blue‑sky’ or basic research. It might not cover applied research, especially where that research has a commercial goal. (sub. 12, p. 4)

Civil Liberties Australia (sub. 12) provided several examples of circumstances in which the exemption may not apply to the use of gene patents, including when:

* a researcher uses a patented gene sequence to test a multi-gene screening test, with the goal of commercialisation
* university-based researchers outsource gene profiling to universities with better facilities, as this may be considered a commercial service
* a university uses patented gene sequences as part of a teaching program, which is not likely to be considered experimental use.

The Generic Medicines Industry Association submitted that research on genetic therapies is not within the scope of the research exemption (sub. 34). However, subsequent correspondence with the Generic Medicines Industry Association clarified that their concern is that the exemption may not cover research that is undertaken with a view to possible commercialisation of resulting therapies.

The Department of Health and Ageing (DOHA) was similarly concerned that the exemption may not cover all types of medical research:

... the Department has reservations about the extent to which the research exemption will permit all research. While this will permit health related research to be conducted it does not address the problem of patent holders using monopoly rights to block access to an individual’s own health information, for example through screening and diagnostic testing involved in research. (sub. 22, p. 10)

However, other inquiry participants (including DOHA) expressed support for the research exemption introduced as part of the ‘Raising the Bar’ reforms:

The various changes encoded under *Raising the Bar* will serve to increase the quality of patents that are granted and to allow others to freely conduct research on gene sequences set out in patents granted and published by IP Australia without infringing those patents. (Department of Health and Ageing, sub. 22, p. 10)

The research exemptions in the recent ‘Raising the Bar’ reforms appear to be adequate for accessing patents for research purposes, and there has been no need to invoke a compulsory licence. (Association of Australian Medical Research Institutes, sub. 17, p. 3)

Section 119C [of the Patents Act] was introduced to clarify the situation regarding experimental use of patented inventions. The section makes clear that such use is not infringement and must satisfy the concerns of researchers and others who had voiced concerns over whether patents were inhibiting the conduct of research in Australia. (Institute of Patent and Trade Mark Attorneys, sub. 18, p. 7)

... the introduction of free access to patented inventions for research (known as ‘research exemption’) provides a level of certainty to health and medical research in Australia. (National Health and Medical Research Council, sub. 33, p. 3)

It has been suggested that it may fall on courts to clarify what types of research are covered by the exemption. Australian Life Scientist, paraphrasing patent attorney Joe Seisdedos stated:

While the research exemption opens up more possibilities for genuine exploratory research involving patented subject matter, it will take some time before we know precisely where the lines are drawn, and it will likely take the courts to do just that … . (Dean 2012)

While in practice it is always going to be difficult to precisely differentiate between experimental and commercial research (ALRC 2004), the reforms provide a clear benefit to (at least some) researchers, who are now more likely to undertake research involving a patented invention due to the reduced risk of infringement. The reforms may also partially reduce research costs because researchers may be less likely to need legal advice on the possibility of infringement (particularly with respect to non‑commercial research).

In light of views that there existed an implicit research exemption prior to the ‘Raising the Bar’ reforms, and that the research exemption simply formalises this, the Commission considers that there are unlikely to be issues in accessing patented inventions for research purposes (provided research is not related to commercialisation of the patented invention itself). Moreover, given the recent enactment of the ‘Raising the Bar’ reforms, the Commission considers that it is simply too soon to form a view on their effectiveness in practice.

#### Interaction with other forms of non-voluntary access

Prior to the experimental exemption, if a researcher was unable to obtain authorisation from the patent holder to conduct experimentation on the subject matter of a patent, one option, other than infringing the patent, may have been to apply for a compulsory licence. An application could have been made on grounds that the patent holder failed to satisfy the reasonable requirements of the public (s. 135 Patents Act). Specifically, a researcher could rely on s. 135 in arguing that an existing trade or industry in Australia, or the establishment of a new trade or industry was unfairly prejudiced because of the patent holder’s failure to grant a licence on reasonable terms. Even though there is no evidence of any such application, the experimental exemption provides a partial substitute for at least one of the hypothetical circumstances in which a compulsory licence might have been sought.

This view was shared by the Institute of Patent and Trade Mark Attorneys:

IPTA and FICPI [Australian Federation of Intellectual Property Attorneys] cannot see that there would be any need to invoke the compulsory licensing provisions where the [regulatory and research] exemptions now apply. (sub. 18, p. 7)

Crown use may provide an alternative option for a researcher to access a necessary patent, however, it is questionable how useful this provision is for researchers. In particular, the definition of the Crown in the Patents Act is vague (chapter 7). Research undertaken by Australian, state and territory agencies (for example, the CSIRO), may have previously been able to gain an exemption from infringement under the Crown use provisions, but this was not certain. Additionally, there is uncertainty about whether publicly funded research institutes (for example, universities) are an authority of the Crown (ALRC 2004). The Commission has recommended changes to the Patents Act that aim to remove uncertainty on the Crown use provisions (chapter 7). Nonetheless, the new exemption removes such uncertainty for experimental use and gives public and publicly funded research bodies an alternative option to Crown use. That said, in the case of public institutions, the existing Crown use provisions remain an option for accessing patented inventions.

## 8.2 Regulatory approval exemption

In 2006, the Patents Act was amended to include an exemption from infringement for use of patented pharmaceutical products for the purposes of regulatory approval from the Therapeutic Goods Administration (s. 119A). The ‘Raising the Bar’ reforms extended the exemption to all products, processes or methods that require approval by law of the Commonwealth, state or territory (s. 119B) (box 8.2). Examples of products that require regulatory approval are pharmaceuticals (by the Therapeutic Goods Administration), agricultural and veterinary chemical products (Australian Pesticides and Veterinary Medicines Authority) and industrial chemicals (National Industrial Chemicals Notification and Assessment Scheme). The exemptions do not allow generic manufacturers to stockpile the patented product prior to the expiry date of the patent.

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| Box 8.2 Regulatory approval exemption |
| Section 119A of the *Patents Act 1990* (Cwlth) states:   1. The rights of a patentee of a pharmaceutical patent are not infringed by a person exploiting an invention claimed in the patent if the exploitation is solely for:    1. purposes connected with obtaining the inclusion in the Australian Register of Therapeutic Goods of goods that: 2. are intended for therapeutic use; and 3. are not medical devices, or therapeutic devices, as defined in the Therapeutic Goods Act 1989; or    1. purposes connected with obtaining similar regulatory approval under a law of a foreign country or of a part of a foreign country. 4. Subsection (1) does not apply to the export from Australia of goods for purposes described in paragraph (1)(b) unless the term of the patent has been extended under Part 3 of Chapter 6 and the goods consist of or contain: 5. a pharmaceutical substance per se that is in substance disclosed in the complete specification of the patent and in substance falls within the scope of the claim or claims of that specification; or 6. a pharmaceutical substance when produced by a process that involves the use of recombinant DNA technology, that is in substance disclosed in the complete specification of the patent and in substance falls within the scope of the claim or claims of that specification.   Note: Part 3 of Chapter 6 provides for the extension of the term of standard patents claiming pharmaceutical substances.   1. In this section:   pharmaceutical patent means a patent claiming:   1. a pharmaceutical substance; or 2. a method, use or product relating to a pharmaceutical substance, including any of the following: 3. a method for producing a raw material needed to produce the substance; 4. a product that is a raw material needed to produce the substance; 5. a product that is a pro-drug, metabolite or derivative of the substance. |
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| Box 8.2 continued |
| Section 119B of the *Patents Act 1990* (Cwlth) states:   1. A person may, without infringing a patent, do an act that would infringe the patent apart from this subsection, if the act is done solely for:    1. purposes connected with obtaining an approval required by a law of the Commonwealth or of a State or Territory to exploit a product, method or process; or    2. purposes connected with obtaining a similar approval under a law of another country or region. 2. This section does not apply in relation to a pharmaceutical patent within the meaning of subsection 119A(3). |
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### Rationale and assessment

Use of a patented invention, prior to the expiry of the patent, to gain regulatory approval is commonly referred to as ‘springboarding’. Approval is gained by demonstrating the equivalence of the generic product with the patented invention. Springboarding is done in anticipation of the patent expiring, and allows generic manufacturers to bring their products to market sooner.

The regulatory approval exemption aims to reduce the length of, or remove entirely, any unintended extension of the patent term that may have otherwise been created by the regulatory approval process. Without an exemption for springboarding, generic manufacturers may have delayed research on the patented invention until after the expiry of the patent to avoid infringement. This in turn may have delayed regulatory approval of the generic product, effectively providing the patent holder with a de facto extension of the patent term and potentially leading to higher prices for consumers over the period of the extension. For instance, there is evidence from the pharmaceutical market suggesting that the price of generic medicines are, on average, substantially lower than the price of the equivalent branded product (Beecroft 2007). The period of this de facto extension could be considerable because regulatory approval can be a time‑consuming process, ranging from several weeks to years.

The circumstances in which the exemption applies appear reasonably clear and to follow standard practice in other countries. For instance, in 2002 the New Zealand Government amended its Patents Act to exempt third parties from patent infringement for purposes related to gaining regulatory approval (ACIP 2005b). In the United States, only generic pharmaceutical companies have a research exemption, provided through the Hatch-Waxman Act (Thomas 2012). Regulatory and research exemptions in comparable markets are discussed in more detail in appendix C.

The reforms are likely to increase competition in the initial period following the expiry of the patent. While the return to innovation (and the incentive to innovate) might be lower as a result of the regulatory use exemption, the de facto extension of the patent period was an unintended consequence of the regulatory approval process. If a patent term of 20 years is optimal, the community would be worse off as a result of any unintended de facto patent extension, and the reforms aim to correct this situation.

#### Interaction with other forms of non-voluntary access

The Australian Government envisaged that the regulatory approval exemption would not impact on a patent holder’s commercial interests during the term of the patent. In contrast, compulsory licensing and Crown use provisions relate to circumstances during the patent term, and so the regulatory approval exemption is unlikely to provide a substitute for these provisions. Given that a compulsory licence may be granted during the patent term when a patent holder engages in anticompetitive practices, the exemption complements the compulsory licensing provisions.

## 8.3 Compulsory licences for pharmaceutical exports

In 2011, the Australian Government announced its intention to introduce legislation to allow the issuing of compulsory licences in Australia, for the purposes of exporting pharmaceuticals to developing countries (Carr and Emerson 2011). A draft of the Bill was released in August 2012 (IP Australia 2012c), which contains proposed amendments to the Patents Act.

The reforms aim to provide the legislative framework for Australian courts to issue compulsory licences by allowing Australian generic manufactures to produce and export pharmaceutical products to eligible countries, in line with Australia’s rights and obligations under the agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS), and the TRIPS Protocol. The aim of the TRIPS agreement is to reduce distortions and impediments to international trade and ensure that intellectual property laws are not barriers themselves. The TRIPS Protocol amends the agreement to permit World Trade Organisation members, including Australia, to issue compulsory licences to produce patented pharmaceutical products for export to least‑developed and developing countries (IP Australia 2010). Appendix D contains more information on TRIPS.

### Proposed amendments

The proposed amendments, through the insertion of s. 136D in the Patents Act (box 8.3), will create two classes of compulsory licences, which are:

* general compulsory licences (the current provisions in the Patents Act)
* patented pharmaceutical invention (PPI) compulsory licences.

The draft Bill would also introduce provisions in the terms of a PPI compulsory licence, cross-licensing, and amendment and revocation of a PPI compulsory licence.

### Rationale and assessment

The reforms are chiefly motivated by concerns about access to medicines in developing countries, and reflect changes made to the TRIPS agreement through the TRIPS Protocol (appendix D). The regulatory impact statement (RIS) for the proposed amendments stated that:

Much of the world’s population is suffering from treatable diseases, with over 100 countries currently experiencing one or more serious epidemics. In 2009, an estimated 272 million people were infected with malaria, HIV/AIDS or tuberculosis causing 3.9 million deaths ... Many of the countries that are suffering such epidemics are developing or least‑developed countries with limited resources and manufacturing capabilities. Such countries have difficulty obtaining and distributing the necessary medicines. (IP Australia 2011b, p. 1)

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| Box 8.3 Proposed section 136D |
| 1. After hearing an application under section 136C, the Federal Court may, subject to this Part, make the PPI order sought if the court is satisfied of all of the following matters: 2. the application is made in good faith; 3. the pharmaceutical product is to be imported: 4. by the eligible importing country; or 5. on behalf of, and with the authorisation of, the eligible importing country; |
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| Box 8.3 continued |
| 1. the proposed use of the pharmaceutical product is to address a public health problem in the eligible importing country: 2. in circumstances of national emergency, or other circumstances of extreme urgency, in that country; or 3. in other circumstances—by the public non-commercial use of the pharmaceutical product in that country; 4. working the patented pharmaceutical invention is necessary to enable the import and proposed use of the pharmaceutical product as mentioned in paragraphs (b) and (c); 5. if subparagraph (c)(ii) applies: 6. the PPI order applicant has given the patentee a notice in the approved form seeking from the patentee an authorisation to work the patented pharmaceutical invention for public non-commercial use; and 7. during the 30 days beginning when the notice was given, the PPI order applicant has tried, without success, to obtain such an authorisation from the patentee on reasonable terms and conditions; 8. the notification requirements prescribed by the regulations in relation to the importation of the pharmaceutical product have been complied with; 9. the PPI order applicant and the eligible importing country will take reasonable measures to prevent a pharmaceutical product that is exported from Australia in accordance with a PPI compulsory licence from being used for a purpose other than the purpose of addressing the public health problem mentioned in paragraph (c).   Without limiting the matters that the court may take into account in 19 deciding whether it is satisfied of a matter mentioned in subsection (1), the court must take into account any matters prescribed by the regulations. |
| *Source*: *Intellectual Property Laws Amendment Bill 2012* (exposure draft). |
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The reforms aim to address issues in the patent system that may be partly responsible for the limited availability of affordable medicine in developing countries:

... issues arise where medicines are under patent, as some patent owners have shown themselves unwilling to practice price differentiation or to issue voluntary licences to generic manufacturers to the necessary extent. (IP Australia 2011b, p. 5)

The provisions should provide some benefit to developing countries. The RIS suggested that the main benefit to ‘developing and least-developed countries is an opportunity to purchase generic pharmaceuticals from Australia, and in a simpler and more efficient manner than in other jurisdictions which have adopted the TRIPS Protocol’ (IP Australia 2011b, p. 14). By reducing the costs associated with applying for this form of compulsory licence, the provisions in the draft Bill might result in more applications.

Also, the compulsory licensing provisions could further incentivise pharmaceutical companies to charge lower prices in eligible importing countries. Evidence from South Africa indicates that competition from generic manufacturers, and threats to issue compulsory licences, prompted several multinational pharmaceutical companies to lower the prices of HIV/AIDS medicines (Schoofs and Waldholz 2001). The World Health Organisation found that competition from generic manufacturers lowered the annual per patient cost of HIV/AIDS medication from over US$10 000 in 2002 to US$100 in 2010 (WTO 2010). According to Health Action International, the flexibilities provided by the TRIPS Protocol are an important strategy for bringing the price of vital medicines down and improving the availability and affordability of essential medicines (Ewen 2010).

Several other countries have already implemented the TRIPS Protocol, including the European Union and Canada. To date, only one licence has been issued (in Canada in 2007). IP Australia (2011b) suggested that reasons for this include:

* the process of applying for a licence places too high a burden on applicants and importing countries
* least-developed countries are not required to protect patent rights until 2016
* parallel importation from generic manufacturers in countries where pharmaceutical products are not protected by patents provides an alternative to the compulsory licensing provisions.

#### Interaction with other forms of non‑voluntary access

The new compulsory licensing mechanism serves a very different purpose from the existing compulsory licensing and Crown use provisions. As such, it is not a substitute, and has limited relevance to this inquiry.