# 1 Introduction

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| Key points |
| * Compulsory licensing is one of several safeguards in the *Patents Act 1990* (Cwlth) that allow a patented invention to be exploited without the authorisation of its owner. * The Commission has been asked to assess current compulsory licensing arrangements and, if necessary, recommend improvements and alternatives. * While this inquiry was largely initiated in response to past reviews of gene patenting, the inquiry focuses on the operation of compulsory licensing. * The Commission has taken account of a range of factors mentioned in the terms of reference, including the need to strike a balance between providing incentives to innovate and making inventions accessible, the goal of affordable and equitable access to healthcare, and lessons from international approaches. The Commission’s overall assessment is based on what set of arrangements would give the best outcomes for the Australian community as a whole. |
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## 1.1 Focus of the inquiry

The Commission has been asked to report on the compulsory licensing provisions in the *Patents Act 1990* (Cwlth) (Patents Act). Compulsory licensing is one of several mechanisms in the Patents Act that allow a patented invention to be used without the authorisation of its owner (box 1.1 and detailed further in later chapters). It is intended to be a safeguard that may be invoked when the exclusive rights conferred by a patent are not meeting the reasonable requirements of the public, or are being used to facilitate anticompetitive conduct.

The full terms of reference for the inquiry are provided at the front of this report. In summary, the Commission has been asked to:

* assess whether the current compulsory licensing provisions can be invoked efficiently and effectively
* advise on the frequency, and impact, of compulsory licences in comparable markets and the common features of such licences
* recommend any measures that may be required to efficiently and effectively exercise Australia’s compulsory licensing provisions
* recommend any alternative mechanisms deemed necessary to ensure that the balance between incentives to innovate and to access technology best reflects the objectives of reasonable access to health care, maximising economic growth and growing the Australian manufacturing industry
* recommend measures to raise awareness of the compulsory licensing provisions.

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| Box 1.1 Non-voluntary access to patents |
| There are currently seven mechanisms in the *Patents Act 1990* (Cwlth) that allow a patented invention to be exploited without the patentee’s authorisation:   * compulsory licensing (ss. 133–140) * Crown use (ss. 163–170) * Crown acquisition (s. 171) * for the purpose of obtaining regulatory approval (ss. 119A–119B) * for experimental purposes related to the subject matter of the invention (s. 119C) * when exploitation, or ‘definite steps’ (contractually or otherwise) to exploit, occurred immediately before the ‘priority date’ (date the patent became effective) (s. 119) * use in or on foreign vessels, aircraft or vehicles temporarily in Australia (s. 118).   The Government has foreshadowed amendments to the Patents Act that would add a further mechanism for the manufacture and export of patented pharmaceutical inventions to developing countries experiencing health crises (Carr and Emerson 2011). |
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The origins of this inquiry can be traced back to several past reviews of the patents system. In particular, the Australian Government (2011a) agreed to a review of compulsory licensing as part of its combined response to three reports.

* Two of the reports — prepared by the Australian Law Reform Commission (ALRC 2004) and the Senate Community Affairs References Committee (SCARC 2010) — examined the issue of gene patenting.
* The other report — by the Advisory Council on Intellectual Property (ACIP 2010c) — looked at the scope of patentable subject matter more broadly.

All three reports rejected calls to exclude human genes from the patents system. They concluded that concerns about accessing patented inventions are better dealt with through other mechanisms, including compulsory licensing. However, the ALRC and SCARC also concluded that the patents legislation needed to be amended to clarify the conditions under which a compulsory licence would be granted, noting that the provisions had rarely been used. In addition, the ALRC recommended that a competition test proposed by the Intellectual Property and Competition Review Committee (IPCRC 2000) be adopted as an additional ground for granting a compulsory licence. The Australian Government chose to implement a different type of competition test (detailed in chapter 6), which the SCARC subsequently recommended be reviewed.

A number of other developments have also been relevant to the inquiry, including:

* concurrent reviews of Australia’s system of innovation patents (ACIP 2011) and pharmaceutical patents (IP Australia 2012i)
* court cases in Australia and the United States regarding the patentability of genes associated with specific types of cancer (chapter 5)
* a Bill to amend the Patents Act so that patented pharmaceutical inventions can be manufactured and exported to developing countries experiencing health crises without a patentee’s authorisation (chapter 8).

While this inquiry was largely initiated in response to past debates about the patenting of genes, the focus of the inquiry is on the operation of compulsory licensing. As noted in the terms of reference, compulsory licensing could also be relevant to a number of other areas, including climate change mitigation and alternative energy technologies, food security, and standard essential patents (chapter 5).

## 1.2 Report structure and the Commission’s approach

This draft report is structured as follows:

* relevant background — the rationale for patents and associated safeguards, including compulsory licensing (chapter 2); key features of the patents system in Australia and comparable markets (chapter 3)
* examination of whether patent access has been a problem — current utilisation of patents in Australia and comparable markets, including through voluntary licences and non-voluntary mechanisms (chapter 4); specific concerns about accessing patented inventions related to genes, climate change mitigation and alternative energy, food security, and standard essential patents (chapter 5)
* assessment of current mechanisms for accessing patented inventions without the owner’s authorisation — compulsory licensing (chapter 6); Crown use and acquisition (chapter 7); other forms of non-voluntary access to patented inventions (chapter 8)
* consideration of new initiatives — new alternative mechanisms (chapter 9); and awareness-raising measures (chapter 10).

### Matters the Commission was asked to have regard to

The terms of reference requested the Commission to have regard to:

* the need to strike a balance between providing incentives for innovation on the one hand, and facilitating access to, and transfer of, technology on the other (discussed in chapter 2)
* recent changes made in the *Intellectual Property Laws Amendment (Raising the Bar) Act 2012* (Cwlth), including broadening the extent to which research can be conducted without the permission of patent owners (chapters 3 and 8)
* the goals of affordable and equitable access to healthcare[[1]](#footnote-2), maximising economic growth, and growing the manufacturing industry (chapter 5 onwards)
* other relevant parts of the intellectual property system, such as Crown use provisions (particularly chapters 7 and 8)
* international approaches (chapters 3–9 and appendices B–C).

The above included consideration of the interests of specific groups and industries, particularly those that patent inventions or wish to access them. That said, the Commission ultimately sought to take account of the community-wide impacts, including the effects on other businesses, consumers, and the broader Australian community. Hence, the Commission has based its overall assessment on what set of arrangements would give the best outcomes for the Australian community as a whole.

### Efficiency and effectiveness

Two key criteria that the Commission was asked to apply in its assessment of existing and proposed arrangements were efficiency and effectiveness.

Efficiency, in its broadest sense, refers to how well resources are used to benefit the wellbeing of the community as a whole. This broad interpretation, known as ‘economic efficiency’, has three components — the degree to which outputs are produced at least possible cost (productive efficiency), how resources are allocated across different uses so as to generate the greatest community wellbeing at a given point in time (allocative efficiency), and to achieve the greatest possible wellbeing over time (dynamic efficiency).

A patents system can be an important determinant of economic efficiency, given its influence on the incentive for innovation and use of inventions. This includes compulsory licences, which if issued too liberally could discourage innovation or, if too restrictively, may reduce the benefits to the community as a whole from new inventions. These have been important considerations for the inquiry. A further consideration has been the efficiency of the process for obtaining a compulsory licence itself, which includes both the financial cost and timeliness.

Effectiveness refers to how successful a policy is in meeting its objectives. The objectives of Australia’s compulsory licensing provisions are not explicitly stated in the Patents Act. However, the Government has indicated in the terms of reference that the provisions are a safeguard to be invoked when the exercise of exclusive rights under a patent is not meeting the reasonable requirements of the public or constitutes anticompetitive conduct. This reflects the current grounds on which a compulsory licence order can be issued under the Patents Act (chapter 6). The clarity of current objectives and their appropriateness are matters considered further in later chapters.

An important consideration in assessing the efficiency and effectiveness of existing arrangements has been the small number of applications for a compulsory licence order in Australia, and that none have resulted in a compulsory licence (box 1.2). Whether this is evidence that the compulsory licensing provisions are inefficient and ineffective, or alternatively a sign that the provisions have successfully discouraged unwanted behaviour, is assessed in chapter 6.

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| Box 1.2 The limited use of Australia’s compulsory licensing provisions |
| There appears to have been only three applications for a compulsory licence order since this became available under Commonwealth legislation in 1903. None of the applications resulted in a compulsory licence.  Fastening Supplies Pty Ltd v Olin Mathieson Chemical Corp. [1969] HCA 61  This application was made under the *Patents Act 1952* (Cwlth), which required an applicant to first satisfy the Commissioner of Patents that there was a prima facie case that the ‘reasonable requirements of the public’ had not been satisfied. If a prima facie case was found, the matter had to be referred to the High Court (in its original jurisdiction).  Fastening Supplies sought a compulsory licence for a captive-bolt gun from Olin Mathieson, which had granted an exclusive licence in Australia to Ramset Fasteners.  (Continued next page) |
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| Box 1.2 (continued) |
| The matter was referred to the High Court, which found that at the date of the application (December 1968) Ramset had not satisfied the reasonable requirements of the public. This was attributed to the difficulty of designing a gun of sufficient versatility and endurance to warrant large-scale manufacturing in Australia. The High Court also found that by the time of its decision (December 1969) Ramset was in the process of meeting Australian requirements, and that Fastening Supplies was not a suitable company to be granted a compulsory licence due to its limited capacity to undertake manufacturing or subcontract it to others. As a result, the application was denied.  Kenneth Mervin Lown v Wissen Pty Ltd [1987] APO 11  This case was also brought under the *Patents Act 1952* (Cwlth), but the Commissioner of Patents decided to dismiss the application.  Mr Lown sought a compulsory licence from Wissen for a device to prevent birds roosting on a surface. Mr Lown had sold the patent to Wissen in 1984 and at the same time made a non-exclusive licence with Wissen for a ‘prestige model’ made of metal. Wissen only sold a plastic version. Mr Lown claimed that his licence for the metal version had been terminated by Wissen and as a result a large proportion of demand for the device was not being met. The Commissioner of Patents found that Mr Lown’s assertion of unmet demand was not supported by any evidence, whereas it was clear that Wissen was marketing a version of the device. As a result, the petition was dismissed.  Amrad Operations Pty Ltd v Genelabs Technologies Inc. [1999] FCA 633  This appears to be the only case made under current provisions in the *Patents Act 1990* (Cwlth), which require an application to be made to the Federal Court.  Amrad applied to the Federal Court for a compulsory licence order so it could manufacture a Hepatitis E virus diagnostic assay in Australia. It subsequently amended its application and statement of claim so that all the respondents — Genelabs, the US Government and Abbott Laboratories — were based in the United States, and sought leave to serve the application in that country. The Federal Court agreed to Amrad’s requests without making a judgment in regard to the compulsory licence. |
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### International perspective

Examination of international evidence has been particularly important for this inquiry, given the limited use of compulsory licensing in Australia. Most other countries have a form of compulsory licensing and, in some cases, it has been used more extensively (chapters 3 and 6). The use of alternative mechanisms in other countries has also been relevant to the inquiry (chapter 9).

The most prominent examples of compulsory licensing in recent years have involved developing countries wishing to access patented products — particularly medicines — at a price that their governments consider affordable. In particular, there has been much debate about the compulsory licensing of AIDS medicines by Brazil and Thailand in 2007, and an anti-cancer drug by India in 2012 (Bond and Saggi 2012; ICGPDTM 2012).

Like many developing countries, Australia is a net importer of technology. The terms of reference posit that this means that the likely benefit of compulsory licensing is its use as a deterrent in licensing negotiations between foreign patent holders and potential licensees in Australia. However, like other developed economies, Australia has the human capital to exploit inventions, the capacity to afford them, and is able to create substantial valuable intellectual property in its own right. The Commission has therefore examined the use of compulsory licensing in a range of developed and developing economies.

When formulating draft recommendations, the Commission has also been mindful that Australia is a party to several international agreements that set boundaries within which the intellectual property system must operate (appendix D).

## 1.3 Consultation process for the inquiry

The terms of reference for this inquiry were received from the Assistant Treasurer on 29 June 2012. The Commission consulted and invited feedback from interested parties in the following ways.

* At the commencement of the inquiry, a circular was sent to people and organisations that the Commission thought might be interested, inviting their participation. Subsequent circulars were sent to those who had expressed an interest in the inquiry to keep them updated on progress.
* The inquiry was also advertised in major national newspapers and promoted on the Commission’s website.
* The Commission met with a cross-section of interested parties to identify relevant issues and sources of information.
* An issues paper was released in August 2012 to assist interested parties in preparing submissions to the inquiry. At the time of writing this report, a total of 35 submissions had been received from a variety of groups.

The Commission thanks inquiry participants for meeting with the Commission, lodging written submissions and providing other assistance. Appendix A provides details of the individuals and organisations that have participated in the inquiry to date.

Interested parties are invited to provide feedback on this draft report through further written submissions (due by 8 February 2013) and at public hearings to be held in mid-February 2013. More information about these consultation processes is provided at the front of this report.

The Commission’s final report will be submitted to the Government in March 2013, and subsequently published. The Government has indicated that it will consider the Commission’s recommendations and announce its response as soon as possible after receiving the final report.

1. Affordable could be interpreted as meaning within a person’s financial means, and equitable as being equally accessible for different individuals. [↑](#footnote-ref-2)