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Overview

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| Key points |
| * Like most countries, Australia has legislated a system of compulsory licensing so that patent owners can be compelled to license their inventions to others in a limited range of circumstances. * Survey data and participants’ comments confirm that this is a safeguard which only needs to be invoked in exceptional cases. In response to surveys, patent owners indicate that often they would prefer to license more than they do. * There have been few applications for a compulsory licence in Australia, and none have been successful. While this is consistent with its status as a rarely needed safeguard, another factor may be the costly and time-consuming process involved in obtaining a compulsory licence order from the Federal Court. * There are no clear alternatives to the Federal Court that would make compulsory licence applications significantly less costly and time consuming, without also raising concerns about the quality of outcomes and scope for appeals. * There is, however, a clear case to reform the criteria for a compulsory licence. * There are currently provisions in both the *Competition and Consumer Act 2010* (Cwlth) and *Patents Act 1990* (Cwlth) to address anticompetitive behaviour. To remove overlap and inconsistency, when a patent is used to engage in unlawful anticompetitive conduct, a compulsory licence should only be available under the Competition and Consumer Act. * A public interest test should replace existing criteria based on the ‘reasonable requirements of the public’ in the Patents Act.This would provide an access regime when greater use of a patented invention would deliver a substantial net benefit to the community. * To reduce uncertainty about international treaty obligations on compulsory licensing, the existing general requirement in the Patents Act to satisfy such obligations should be deleted, and the obligations should be incorporated directly into the Patents Act or its subordinate legislation. * To improve awareness of compulsory licensing, IP Australia and the ACCC should jointly develop a plain English guide and make it available on their websites. * The Patents Act contains a less costly and time-consuming alternative to compulsory licensing — termed ‘Crown use’ — that can be invoked when an invention is used for the services of a government. Two key reforms are proposed in this regard. * To reduce uncertainty about the scope of Crown use, the Patents Act should be amended to make it clear that Crown use can be invoked for the provision of a service that the Australian, State and/or Territory Governments have primary responsibility for providing or funding. * To improve transparency and accountability, governments should be required to first seek a negotiated outcome, and publicly state the reasons for invoking Crown use in advance, except in emergencies. Governments should in all cases be required to obtain Ministerial approval to invoke Crown use, and be subject to the same pricing principles as for compulsory licensing. |
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# Overview

Like most countries, Australia has legislated a system of compulsory licensing so that patent owners can be compelled to license their inventions to others in a limited range of circumstances. The right to maintain such arrangements is enshrined in international agreements on intellectual property (IP). This was originally to provide a default remedy against failure to produce and market an invention locally. Many countries had previously relied on the harsher penalty of patent forfeiture. Over time, countries have expanded the grounds for granting compulsory licences beyond promoting local industries.

In Australia, patent owners can be ordered to grant a compulsory licence if they fail to satisfy the ‘reasonable requirements of the public’ for their invention, or their behaviour in connection with the patent is contrary to the competition law. Several past reviews of the patents system have questioned the clarity of these criteria and their implementation, particularly as a means to address cases where gene patents unduly restrict access to healthcare. The effectiveness of the provisions has also been questioned because there have been few applications for a compulsory licence, and none has been successful (box 1).

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| Box 1 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 (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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Compulsory licensing is also rarely used in other countries. The most prominent recent examples have occurred in developing countries — particularly Brazil, India and Thailand — whose governments sought to access patented medicines at lower prices. Among developed countries, compulsory licensing appears to occur most frequently in the United States, particularly to remedy anticompetitive conduct and patent infringement. This is despite the United States being one of the few countries not to have compulsory licensing provisions in its patents legislation. Instead, US competition and sector-specific laws provide for measures analogous to compulsory licences. The US Government also makes use of other powers to gain access to patented inventions for defence and other national security purposes.

## What has the Commission been asked to do?

In response to the concerns raised in past reviews, the Australian Government has asked the Commission to examine the compulsory licensing provisions of the *Patents Act 1990* (Cwlth). Specifically, the Commission has been directed to:

* assess whether Australia’s 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 healthcare, maximising economic growth and growing the Australian manufacturing industry
* recommend measures to raise awareness of the compulsory licensing provisions.

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 broadly. 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 (such as the 3G standard for mobile phones).

## Why have compulsory licensing and other safeguards?

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 2). These are essentially safeguards to be invoked in exceptional cases where enforcing a patent would not serve the best interests of the community as a whole. To understand the rationale for such safeguards, it is necessary to consider what a patent entails.

A patent is a legally enforceable right to exclude others from exploiting a device, substance, method or process that is new, inventive, and useful at the time the patent is granted. Most countries have created this type of property right to encourage welfare-enhancing innovations that might not otherwise occur because innovative ideas tend to be non-excludable and non-rival. That is, without patents, innovators may struggle to earn a sufficient return to warrant their efforts, since others cannot be excluded from using innovative ideas they did not pay for, and one person’s use of such ideas does not diminish the ability of others to also use them.

A further rationale for a patents system is that inventors no longer need to keep their ideas secret in order to prevent others from using them. Indeed, patent owners are required to publicly disclose details of their invention as a quid pro quo for being granted an exclusive property right. This benefits the community by reducing the likelihood of wasteful duplication of research effort, and by enabling others to improve on existing ideas.

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| Box 2 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 Australian 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. |
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A patents system involves a tradeoff between encouraging innovation and facilitating access to new technologies. In particular, the right to exclude others from using a patented invention is central to providing innovators with a means to benefit financially from their efforts, but it also has the potential to hinder the community’s access to new technologies. A patent that provides a greater reward than needed to induce an invention could reduce the invention’s net benefit to the community as a whole, and result in a greater share of the benefits going to the patent owner. In cases where there are no substitutes for the invention, a patent could also facilitate monopolistic and/or anticompetitive behaviour.

Safeguards are typically built into a patents system to limit these potential shortcomings. They can be divided into two broad groups:

* pre-grant (ex ante) safeguards — most notably, patent applications are subject to a threshold test that seeks to limit patents to truly innovative ideas; and patents are available for a fixed duration (typically 20 years from the grant of the patent) to limit the period that people can be excluded from using inventions
* post-grant (ex post) safeguards — these are invoked after a patent is granted if exercise of the exclusive right is considered not to be in the interest of the community as a whole. This includes compulsory licensing and the other mechanisms listed in box 2, as well as general application of competition law.

Some of the safeguards in Australia’s patents legislation were recently amended as part of a major package of changes, collectively known as the ‘Raising the Bar’ reforms. In particular, exemptions from patent infringement when inventions are used for experimental purposes or to gain regulatory approval were clarified and strengthened. However, the compulsory licensing provisions were unchanged.

## Is there evidence that compulsory licensing is needed?

A substantial number of inventions are patented in Australia each year (figure 1), with most of the patents being granted to non-residents (table 1). The benefit to the Australian community from new technologies is, therefore, likely to depend significantly on how accessible they are under the patents system, especially when owned by non-residents. The Commission has reviewed Australian and overseas evidence to identify what, if any, problems arise with accessing patented inventions.

Figure 1 Patents granted in Australia, 1995 to 2011

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Table 1 Nationality of parties granted Australian patents, 1995 to 2011

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| Nationality | 2011 | 1995–2011 average |
|  | % | % |
| Australia | 7 | 8 |
| Canada | 2 | 2 |
| France | 3 | 4 |
| Germany | 7 | 7 |
| Japan | 9 | 9 |
| Netherlands | 3 | 2 |
| Republic of Korea | 2 | 2 |
| Sweden | 2 | 3 |
| Switzerland | 5 | 4 |
| UK | 4 | 6 |
| USA | 42 | 43 |
| Other | 14 | 10 |
| Total | 100 | 100 |

### General issues with accessing patented inventions

After a patent has been granted, the owner may decide to manufacture the product itself, or a product that uses the patented invention as an input, and market it accordingly. Alternatively, the owner could sell the patent to another party, as occurs with other property. Another option is to license out the patent, either on an exclusive or non-exclusive basis. An exclusive licence is more likely to raise concerns about accessing an invention than a non-exclusive licence, but no more so than the original patent right itself.

Patent owners may prefer to license a patent, rather than work it themselves, for a number of reasons. They might not have the capacity to manufacture or use an invention themselves, to supply it to customers in all geographic regions, to scale up existing production facilities to meet increased demand, or to bear the risk associated with manufacturing and marketing the invention. There are also various reasons why licensees enter into a licensing agreement, including a belief that they have the skills to commercialise an invention, or that they need it as part of another product.

Patent licences are commercially sensitive documents, and so their contents are rarely made public. Inquiry participants stressed that there is no such thing as a typical licence agreement, as many different matters can be covered, and the agreed terms can be very case specific.

There is limited information on the extent to which inventors use their patents in‑house, sell them to others, or license them out. Survey data from Europe, Japan, and the United States suggest that only a small proportion of patents (roughly 10 per cent) are licensed to others. These data also suggest that around half of patents are used solely by their owner, and roughly 40 per cent are unused (with around half of these because the patent was used to block a competitor). The magnitudes vary markedly across different types of organisations. For example, research bodies are more likely to license out patents, and less likely to use them internally.

A low rate of licensing does not necessarily indicate that patent owners typically deny access to technologies on reasonable terms. On the contrary, surveys of patent owners indicate that they do not license as much as they would like to. The survey evidence shows that the primary reasons why patent owners license is to earn revenue, have a mutually beneficial exchange of technologies (through cross licensing), and to establish their invention as a de facto industry standard.

There are many potential barriers that patent owners face in licensing their inventions. These include difficulties in identifying licensing partners; the cost and complexity of drafting and negotiating licence contracts; an invention not being a viable commercial proposition; the cost of supporting a licensee; and concerns about reputational damage if the licensee implements an invention poorly or discloses commercially sensitive information. Compulsory licensing is not a solution to these problems.

### Specific concerns about patent access

The terms of reference identify several specific areas — genes, standard essential patents, food security, climate change mitigation and alternative energy technologies — where the existence of patents has raised sensitive issues that could potentially be addressed through compulsory licensing.

#### Gene patents and access to healthcare

Australia, like other developed countries, has granted patents for ‘isolated and purified’ human genes, and associated testing methods. This has been criticised by some as restricting access to affordable healthcare. The behaviour of a US company and its Australian licensee with respect to patents over the BRCA1 and BRCA2 genes is typically cited as evidence (box 3). This prompted legal challenges to the validity of the BRCA patents in Australia and the United States. In Australia, the Federal Court recently ruled that the BRCA1 patent met the requirements of the Patents Act because an isolated gene is an artificially created state of affairs that has economic significance. The US legal system has similarly upheld patents on the processes used to isolate the BRCA genes. However, appeals have been lodged in both countries against these judgements.

The BRCA case was also the catalyst for several reviews of gene patenting in Australia, all of which rejected calls to exclude isolated and purified human genetic material from the patents system. Instead, they concluded that any concerns that arise after a patent is granted would be better addressed by other measures, including provisions for compulsory licensing and Crown use.

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| Box 3 The BRCA1 and BRCA2 gene patents |
| The BRCA1 and BRCA2 genes belong to a class of genes known as tumour suppressors. The normal BRCA1 and BRCA2 genes help prevent uncontrolled cell growth. Mutation of these genes has been linked to the development of breast, prostate and ovarian cancer. A US company, Myriad Genetics Incorporated (Myriad), holds the patents relating to methods and processes used to isolate and detect mutations of the BRCA1 and BRCA2 genes. In 2002, Genetic Technologies Limited (GTL) obtained an exclusive licence from Myriad to perform diagnostic testing for BRCA1 and BRCA2 genes in Australia.  In 2002-03 and 2008, GTL attempted to enforce its rights over diagnostic testing of the BRCA1 and BRCA2 genes in Australia. However, following community opposition, in both instances GTL subsequently announced that it would no longer seek to enforce its rights and would allow other laboratories in Australia to freely perform testing.  The actions of Myriad and GTL have raised concerns in relation to access to affordable genetic testing, and prompted legal action in both Australia and the United States.  In the United States, court proceedings were initiated in 2009 by the American Civil Liberties Union (ACLU) and the Public Patent Foundation against several respondents, including Myriad and the US Patent and Trademarks Office. The US District Court for the Southern District of New York ruled that the BRCA1 and BRCA2 patents were invalid as they represented discoveries and not inventions. An appeal was lodged to the US Federal Court by Myriad in 2010. The Federal Court ruled that the patents on the processes used to isolate the BRCA1 and BRCA2 genes were valid but the method claims to analysing or comparing the genes were invalid (due to obviousness). In 2011, the ACLU appealed to the US Supreme Court, which sent the case back to the Federal Court for review because of the Supreme Court’s recent ruling in a related case (Mayo Collaborative Services v. Prometheus Laboratories Inc). Following this hearing the Federal Court reaffirmed the validity of Myriad’s patents on the BRCA genes themselves. However, it invalidated a method patent based on comparing DNA sequences. This decision has again been appealed and the US Supreme Court will hear the case in its current session.  (Continued next page) |
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| Box 3 (continued) |
| In Australia, Cancer Voices Australia and Yvonne D’Arcy launched legal action against Myriad and GTL over the legality of the BRCA1 patent in 2010. The lawyers for Cancer Voices Australia and Yvonne D’Arcy argued that an isolated and purified gene from the human body is a discovery, rather than an invention, and therefore is not patentable. In February 2013, the Federal Court ruled that Myriad’s patent was valid because the isolated BRCA gene involves a ‘manner of manufacture’ — that is, an artificially created state of affairs which has economic significance — and so is not a discovery in the manner argued. An application to appeal this decision has been lodged with the Federal Court. |
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The BRCA case does not appear to be representative of the behaviour of gene patent owners. Critics rarely refer to any other examples, and preliminary results from a recent survey of testing laboratories suggest that patents are not currently hindering access to genetic tests. Furthermore, like other early gene patents, the BRCA patents will expire soon (from August 2015 to December 2016 in Australia).

It is also notable that there appears to have been a significant decline in the number of broad patents granted over individual genes, reflecting a trend by patents offices to apply a more stringent novelty test as genetic technologies become more widespread. Moreover, the human genome project has made much information about genes freely available, thus ensuring it cannot satisfy the novelty requirement for a patent. These developments suggest that gene patenting has peaked as a concern.

Nevertheless, the Commission supports the conclusion of past reviews that there is an in-principle case for compulsory licensing and other safeguards to address concerns such as those raised by the BRCA case. While such cases are currently rare, concerns about gene patents may become more pronounced in the future if healthcare increasingly depends on emerging (newly patented) genetic technologies and personalised medicine that requires the testing of multiple genes.

#### Other specific concerns

Standard essential patents cover inventions that are used in an industry standard, such as the 3G standard for mobile phones. Standards development organisations typically secure a commitment from the owners of such patents to license on ‘fair, reasonable and non‑discriminatory’ (FRAND) terms. However, disputes can arise over the interpretation of what constitutes FRAND, which in some cases may be due to the patent owner abusing its market power. If such anticompetitive behaviour were to occur in Australia, it could conceivably be addressed by granting a compulsory licence.

Compulsory licensing has also been suggested as a means to address developing countries’ concerns about food security and access to technologies for climate change mitigation and alternative energy. Whether a compulsory licence is granted in such cases is a matter for individual developing countries to determine, since international IP law requires a compulsory licence to be predominantly for the supply of a domestic market. It is unlikely to be an effective option for developing countries that do not have local capacity to exploit the relevant technology. Developed countries, such as Australia, assist less-developed nations through other mechanisms, including aid programs.

## Reforming Australia’s compulsory licensing provisions

Inquiry participants had differing views on why Australia’s compulsory licensing provisions have been rarely used. In essence, three different reasons were proposed, and only one of these provides a case for reform.

* The compulsory licensing provisions are such an effective deterrent against refusals to license on reasonable terms that they almost never need to be invoked by a potential licensee.
* Compulsory licensing is a safeguard that is only needed in exceptional circumstances, since it is generally in a patent owner’s interest to license.
* The process for granting a compulsory licence is so costly and time consuming that a potential licensee rarely finds it a viable option.

It is almost impossible to ascertain whether the compulsory licensing provisions have been a deterrent against refusals to license, given that commercial negotiations are rarely made public. That said, the Law Council of Australia submitted three examples to support the deterrence effect, without naming the parties.

The view that compulsory licensing is a safeguard only to be invoked in exceptional circumstances is consistent with the previously mentioned evidence, which suggests that relatively few cases arise where a compulsory licence is warranted.

It is widely recognised that obtaining a compulsory licence would be costly and time consuming. This is largely because an application has to be made to the Federal Court for an order requiring the patent owner to grant a compulsory licence. The primary expense would be the legal costs to prepare and present a case to the court, rather than any fees charged by the court itself. Inquiry participants estimated that the cost could range from roughly $100 000 for a relatively straightforward application to more than $1 million for a pharmaceutical patent that is vigorously contested by the patent owner.

Federal Court statistics indicate that it is not uncommon for matters to take longer than 12 months to finalise (figure 2). However, it should also be recognised that the Federal Court has taken steps to employ various case management strategies to improve the efficiency of its processes, and so the high cost and time involved in resolving matters would, at least in part, reflect the complexity of cases that come before it.

Figure 2 Timeliness of Federal Court judgments**a**

Per cent of outstanding matters aged over 12 months, at 30 June

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a Excludes appeals and related matters.

### Alternatives to the Federal Court

There are no clear alternatives to the Federal Court that would make compulsory licence applications significantly less costly and time consuming without also raising concerns about the quality of outcomes and scope for appeals.

* Alternative dispute resolution involving mediation or conciliation is unlikely to have much impact because the Patents Act already requires applicants to attempt to negotiate for a ‘reasonable’ period before seeking a compulsory licence. Moreover, Federal Court processes already include the option of referring cases to alternative dispute resolution.
* The more interventionist approach of ordering binding arbitration by a private arbitrator depends on whether the arbitrator has sufficient expertise to minimise successful appeals. A further complication is that both the patent holder and prospective licensee would have to consent to binding arbitration by a private arbitrator. Moreover, the costs incurred by the parties may not be substantially less than for an application to the Federal Court.
* Moving decision making to another body is difficult to justify because existing alternatives have limitations. For example, IP Australia does not have expertise in commercial dispute resolution or remedying anticompetitive behaviour; the Copyright Tribunal would find there is limited synergy between copyright and patent issues; the Administrative Appeals Tribunal lacks jurisdiction; and the Federal Magistrates Court may not have the necessary expertise or be much less costly and time consuming. The cost of creating a new body just for compulsory licensing would outweigh the benefits.

The benefit from such changes is likely to be small, given that compulsory licensing is a rarely needed safeguard. The lack of jurisprudence on, and potential complexity of, compulsory licensing provides a further reason for the Federal Court to retain its current role.

### Improving the criteria for granting a compulsory licence

There is a clear case to strengthen the criteria for granting a compulsory licence, and to remove overlap and inconsistency across different pieces of legislation. As noted above, there are essentially two grounds for a compulsory licence — the reasonable requirements of the public have not been satisfied, or the patent has been used to engage in unlawful anticompetitive behaviour.

The Patents Act defines the reasonable requirements of the public in a way that focuses on promoting domestic trades and industries (box 4). This could potentially lead to a compulsory licence being issued when it is not in the interests of the community as a whole. The Commission has, therefore, proposed that a public interest test be used instead. The intention is to provide an access regime for cases where greater use of a patented invention would deliver a substantial net benefit to the community, and this opportunity arises for reasons other than unlawful anticompetitive conduct.

There should be general pricing principles that explicitly recognise the balance between providing access to inventions and ensuring patent owners receive a return commensurate with the commercial and regulatory risks they face.

Introducing an objects clause into the Patents Act could also assist by clarifying the context for compulsory licensing and the considerations that should guide a court. The Australian Government has agreed to introduce such a clause in response to a recommendation made by the Advisory Council on Intellectual Property (ACIP).

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| Box 4 The ‘reasonable requirements of the public’ |
| Section 135(1) of the *Patents Act 1990* (Cwlth) states that:  (1) … the reasonable requirements of the public with respect to a patented invention are to be taken not to have been satisfied if:  (a) an existing trade or industry in Australia, or the establishment of a new trade or industry in Australia, is unfairly prejudiced, or the demand in Australia for the patented product, or for a product resulting from the patented process, is not reasonably met, because of the patentee’s failure:  (i) to manufacture the patented product to an adequate extent, and supply it on reasonable terms; or  (ii) to manufacture, to an adequate extent, a part of the patented product that is necessary for the efficient working of the product, and supply the part on reasonable terms; or  (iii) to carry on the patented process to a reasonable extent; or  (iv) to grant licences on reasonable terms; or  (b) a trade or industry in Australia is unfairly prejudiced by the conditions attached by the patentee (whether before or after the commencing day) to the purchase, hire or use of the patented product, the use or working of the patented process; or  (c) if the patented invention is not being worked in Australia on a commercial scale, but is capable of being worked in Australia. |
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The Patents Act defines the other ground for a compulsory licence  
 — anticompetitive behaviour — as a contravention of Part IV of the *Competition and Consumer Act 2010* (Cwlth) in connection with a patent. This creates overlap and inconsistency because different remedies against such behaviour are also available in the Competition and Consumer Act itself (including effectively a compulsory licence). Moreover, there are differences between the two Acts in the rights afforded to prospective applicants and the potential litigation avenues and process. It is proposed that the competition provisions be taken out of the Patents Act, and that the Competition and Consumer Act be amended to explicitly state that compulsory licences are available as a remedy for breaches of Part IV.

Some aspects of IP are exempted from certain provisions of Part IV. The rationale for the exemption is unclear. It has been scrutinised in past reviews, including by the National Competition Council, which effectively recommended removing it. The Australian Competition and Consumer Commission (ACCC) has also called for its removal on the grounds that IP rights should be treated the same as other property. The Productivity Commission is mindful that the exemption addresses a range of IP issues, but with respect to access to patents sees no reason why it should not be repealed.

### Clarifying international treaty obligations

Rather than incorporate all relevant international treaty obligations into the compulsory licensing provisions, the Patents Act simply states that a compulsory licence order must not be made if it ‘is inconsistent with a treaty between the Commonwealth and a foreign country’ (s. 136). This has led to a situation where the provisions of the Patents Act may no longer be consistent with international agreements. In particular, there is a widely held view among interested parties that the Australia–United States Free Trade Agreement (AUSFTA) does not permit a compulsory licence to be granted on the grounds that the reasonable requirements of the public are unsatisfied. It could be similarly argued that the Commission’s proposed alternative of a public interest test breaches AUSFTA.

However, the Australian Government has publicly stated that the existing compulsory licensing provisions are compliant with AUSFTA (in which case, the Commission’s proposed public interest test should also be compliant). To remove any doubt, the clause in the Patents Act requiring compulsory licence orders to be consistent with international treaties should be removed. Current and future treaty obligations with respect to compulsory licensing should be incorporated directly into the Patents Act or its subordinate legislation. While this could raise the cost of implementing treaties on intellectual property, it will be outweighed by the benefit of having treaty terms translated into standard legislative language and scrutinised more thoroughly by the Parliament. It would also be consistent with how Australia has implemented treaties on other matters, such as the environment, human rights and arms control.

### Dependent patents

If a compulsory licence is granted for an invention that cannot be worked without infringing another (dependent) patent, the court can order the dependent patent holder to also grant a licence. Some inquiry participants argued that the presence of a dependent patent should be a standalone ground for a compulsory licence. The Australian Law Reform Commission considered this option in a 2004 review and concluded that it was unnecessary because the circumstances in which a dependent patent situation may arise are already covered by the reasonable requirements of the public test. Similarly, the Productivity Commission considers that its recommended competition and public interest tests — in combination with the existing provisions on dependent patents — would make a separate dependent patent ground redundant.

## Alternative mechanisms

As requested by the Government, the Commission has also considered existing and potential alternatives to compulsory licensing. The focus of this analysis has largely been on how to facilitate access to healthcare, as this is where the key concerns exist. In its consideration of different options, the Commission has supported the long-held position of successive Australian Governments, and the view put by most inquiry participants, that it is generally desirable for the patents system to be technology neutral.

### Crown use and acquisition

The Patents Act contains specific provisions for the Australian and State Governments and their agencies (including local governments) to use a patented invention (Crown use) or acquire it (Crown acquisition) without the owner’s authorisation. Only two cases of Crown use have been contested in a court, both of which were allowed — use of a central bearing structure for rail carriages by the NSW Government in 1964, and a water meter assembly by Brisbane City Council in 1994. While governments may have acquired patents on a voluntary basis, to the Commission’s knowledge they have never compulsorily acquired a patent through the Crown acquisition provisions. This is probably because Crown use is sufficient to exploit an invention and is less costly, since the patent holder does not have to be compensated for a loss of earnings from using the patent itself and licensing it to third parties. The Commission has, therefore, focused on Crown use.

Governments will generally find Crown use to be a less costly and time-consuming option than compulsory licensing. There is currently no requirement to first attempt to negotiate with the patent owner and, if unsuccessful, apply to the Federal Court for authorisation to use an invention. A patent owner can apply for a court determination on the compensation it receives but, unlike compulsory licensing, there is currently no explicit requirement for this to be ‘just and reasonable’.

Moreover, it appears that Crown use can be applied to healthcare-related patents, given that governments have a major role in providing healthcare. However, inquiry participants were uncertain about this for several reasons.

* The Patents Act states that Crown use can only be used ‘for the services of’ a government, which the courts could interpret narrowly to exclude healthcare. Conversely, it could be argued that this is unlikely, given that Crown use has previously been allowed for railways and domestic water supply.
* Healthcare services are sometimes supplied by non-government organisations — such as privately owned testing laboratories and not-for-profit bodies — which some participants considered to be outside the scope of Crown use. An alternative view is that non-government providers can be included because the Patents Act allows a government to authorise other parties to undertake Crown use on behalf of that government.
* Genetic samples taken in one state are sometimes tested by a laboratory in another state. Some participants questioned whether states can apply Crown use outside their borders in such cases. Some were also concerned that states have to invoke Crown use individually, rather than coordinate their actions. An alternative view is that the Patents Act does not limit the geographic location of Crown use, or interjurisdictional coordination.

The Commission proposes that such uncertainty be addressed by clarifying the scope of Crown use. In particular, the Patents Act should be amended to make it clear that Crown use can be invoked for the provision of a service that the Australian, State and/or Territory Governments have primary responsibility for providing or funding.

It is the Commission’s intention that the primary responsibility test would take account of all providers of similar services. This would, for example, mean that genetic testing undertaken by private providers for private patients would be included in an assessment of whether governments have primary responsibility for providing or funding such testing. Given that governments are responsible for providing or funding the vast majority of genetic tests, they would be found to have primary responsibility. As a result, genetic testing would be eligible for Crown use, including when it is undertaken by private providers for private patients. The private providers could be authorised to exercise Crown use on behalf of a government, as is already allowed under s. 163(1) of the Patents Act.

The introduction of the primary responsibility test should not remove the existing right of individual government bodies to exploit a patented invention under Crown use, regardless of their share of the relevant market.

There is also a case for improving the protection of patentees’ rights under Crown use. Governments are currently subject to a low standard of transparency and accountability. A review by ACIP in 2005 received submissions that this had facilitated abuse — such as threats to invoke Crown use in order to achieve   
one-sided agreements unfavourable to a patent holder — and uncertainty about whether quasi-government organisations had the authority to invoke Crown use themselves. ACIP made various recommendations to address the concerns, but the Australian Government chose not to implement them, reflecting a lack of specific evidence and limited utilisation of Crown use.

While there may be little specific evidence of abuse to date, as a matter of principle governments should be held to higher standards than currently exist. It could be argued that the cost of initiating reforms solely for the Crown use provisions is not justified, given their limited use and lack of evidence of problems. However, in light of the previously mentioned recommendations requiring changes to the Patents Act, the Commission considers that beneficial changes to the Crown use provisions could be made concurrently at relatively low cost.

The Commission proposes that, except in emergencies, governments should be required to first seek a negotiated outcome, and publicly state the reasons for Crown use no less than 14 days before it occurs. In all cases, governments should be required to obtain Ministerial approval to invoke Crown use, and be subject to the same pricing principles as for compulsory licensing.

The proposed requirements would not significantly alter the cost and time advantage of Crown use over compulsory licensing. Governments are already obliged under the Patents Act to inform patent holders about Crown use as soon as practicable after it occurs, and under administrative review legislation can be directed to provide the reasons for Crown use. With respect to compensation, patent holders already have a right to seek adjudication by the Federal Court. Moreover, the proposed requirements would not remove the right of governments to invoke Crown use without having to obtain authorisation from the Federal Court. Finally, concerns about timeliness would be addressed by allowing the recommended requirements (except for Ministerial approval and compensation) to be waived in emergencies.

### Other alternative mechanisms

The Commission has considered various other alternatives to compulsory licensing and found that there is not a compelling case to change existing arrangements.

* *Exclusions and exemptions for healthcare* — excluding healthcare from the patents system, especially when it is based on genetic technologies, has been considered and rejected in several past reviews because it would reduce the incentives for health innovation, and there have been few cases where patents have been a barrier to healthcare. Similar concerns apply to medical‑practitioner exemptions from patent infringement.
* *A compulsory licensing regime specifically for public health* — Belgium, France and Switzerland adopted this in response to concerns that their generic compulsory licensing provisions were ineffective in the BRCA case. It appears that the new regimes have never been used. It is difficult to justify creating a similar arrangement in Australia, as it would also rarely be needed, and Crown use can be applied to healthcare. The Commission’s proposed changes to clarify the scope of Crown use should reduce any potential uncertainty about where it can be applied.
* *Use of government purchasing power in health* — several inquiry participants and past reviews have called for governments to use their purchasing power to ensure equitable and affordable access to gene-related healthcare. The majority of genetic tests are provided and funded by state and territory health departments. Only 23 distinct genetic tests are currently listed on the Medicare Benefits Schedule (MBS). However, the latest available data show that 40 per cent of the volume of genetic tests undertaken in 2007 attracted Commonwealth funding through Medicare. Moreover, it seems inevitable that the number of gene-related diagnostics and therapeutics covered by the MBS and Pharmaceutical Benefits Scheme (PBS) will increase over time. Indeed, over one-third of current applications for listing on the MBS relate to genetic tests and associated services. Thus, there is not a strong case for altering existing funding arrangements to address the very rare scenario where access to   
  gene-related healthcare has been an issue. Where the processes associated with listing on the MBS and PBS are considered too slow, governments can always resort to Crown use, particularly in emergencies. They could also consider changes to the approval and funding arrangements if necessary.
* *Legislating a right to personal genetic information* — this might be useful if a person cannot be given the results of a genetic test because it was conducted without the patent owner’s authorisation under a research exemption. However, the Commission was not presented with any evidence of this having occurred in Australia. Moreover, existing privacy laws may already give people the right to see their test results if such a situation was to arise. If privacy laws prove to be inadequate, then the most effective remedy is likely to be to reform those laws and/or the research exemption. Few individuals have the capacity to obtain a licence to work a patent themselves, and so measures to encourage greater licensing of patents would not give them a means to access their health records.
* *Non-voluntary licensing by a ‘collecting society’* — this currently exists for copyrighted works, such as written material, with Copyright Australia Limited authorised to license, collect royalties from users, and distribute the proceeds to copyright owners. It is not a suitable option for patents, because their use is much more diverse, and so less amenable to standardised licensing by a central body.
* *Licence-of-right mechanism* — patent owners can register a commitment with the patents authority to license to all parties who wish to do so. If the parties cannot agree on the terms of a licence, there is typically provision for this to be determined by arbitration. A number of countries currently have licence-of-right provisions — including Germany, New Zealand, Singapore and the United Kingdom — but it appears that the provisions are rarely used. Moreover, the voluntary aspect of such provisions means that they would not address cases where patent owners are unwilling to license widely.
* *Other measures to encourage voluntary licensing* — patent fee discounts and model licences are unlikely to encourage much more licensing because patent fees are relatively small and licences need to be tailored to diverse circumstances.

## Awareness-raising measures

The Commission has been asked to recommend measures to raise awareness of the compulsory licensing provisions, noting the specific challenges of raising awareness among small businesses and the healthcare sector.

The limited awareness of compulsory licensing in the community is likely to reflect the fact that very few people have any substantial involvement or interest in patent licensing. However, the Commission has found that people working in the field are aware of the provisions, and professional service providers are available to assist in these matters.

It would not be cost effective for awareness-raising measures to seek to engage directly with every small business and healthcare provider. Potential licensees will typically seek the advice of a patent attorney or other expert, who should be able to provide advice on compulsory licensing in the rare instances where this is warranted. Furthermore, many businesses may not have the capacity to ‘work’ a patent.

IP Australia is the main government body engaged in measures to raise awareness of the patents system. This has included the provision of written guides on its website for issues such as Crown use and the process for obtaining a patent. The ACCC has a similar role in informing the public about competition law.

In light of the above, it is recommended that IP Australia and the ACCC jointly develop a plain English guide to the compulsory licensing provisions — reflecting the public interest and competition grounds for compulsory licensing — and make it available on their websites.

Recommendations and findings

## Compulsory licensing provisions

Finding 6.1

While the cost and timeliness of the compulsory licensing process could be a barrier for its use by some parties, there are no clear alternatives that would significantly reduce its cost without also reducing the quality of the outcomes and increasing the scope for appeals.

Finding 6.2

The Australian Government has agreed to introduce a general objects clause recommended by the Advisory Council on Intellectual Property into the Patents Act 1990 (Cwlth). This could assist in clarifying the context for compulsory licensing and the considerations that should guide a court.

Recommendation 6.1

The Australian Government should seek to remove s. 133(2)(b) from the Patents Act 1990 (Cwlth), so that a compulsory licence order based on restrictive trade practices of the patent holder is only available under the Competition and Consumer Act 2010 (Cwlth). The remedy provisions in the Competition and Consumer Act should be amended to explicitly recognise compulsory licence orders to exploit a patented invention as a remedy under the Act. The new remedy provision should specify that an order must:

* not give the licensee, or a person authorised by the licensee, the exclusive right to work the patented invention
* be assignable only in connection with an enterprise or goodwill in connection with which the licence is used.

The new provision should also contain a clause specifying the basis for determining remuneration, which is identical to the corresponding clause in the Patents Act.

Finding 6.3

Section 51(3) of the Competition and Consumer Act 2010 (Cwlth) — which exempts certain types of conduct involving intellectual property from some provisions of the Act — is unlikely to promote efficient outcomes with respect to access to patented inventions. The Commission sees no reason why the exemption should continue to apply to patents, but any changes to s. 51(3) will need to be based on a consideration of the implications for all types of intellectual property, including those beyond this inquiry’s terms of reference.

Finding 6.4

The current language in s. 135 of the Patents Act 1990 (Cwlth), which conflates the reasonable requirements of the public with the interests of Australian industry, is inconsistent with promoting community-wide welfare.

Recommendation 6.2

The Australian Government should seek to amend the Patents Act 1990 (Cwlth) to replace the ‘reasonable requirements of the public’ test for a compulsory licence with a new public interest test. The new test should specify that a compulsory licence to exploit the patented invention would be available if the following conditions are met:

* 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
* other impacts on community wellbeing, including those resulting from greater competition and from the overall effect on innovation.

The new provisions should require the Federal Court to set the terms of the licence, including — where the parties cannot reach agreement — any remuneration, 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
* the public to the efficient exploitation of the invention.

Recommendation 6.3

The Australian Government should seek to repeal s. 136 of the Patents Act 1990 (Cwlth). Current and future international treaty obligations should be incorporated directly into the Patents Act or its subordinate legislation.

## Crown use provisions

Recommendation 7.1

The Australian Government should seek to amend s. 163 of the Patents Act 1990 (Cwlth) to make it clear that Crown use can be invoked for the provision of a service that the Australian, State and/or Territory Governments have the primary responsibility for providing or funding.

Recommendation 7.2

The Australian Government should seek to amend the Patents Act 1990 (Cwlth) to require:

* the Crown to attempt to negotiate use of the patented invention prior to invoking Crown use
* the Crown to provide the patentee with a statement of reasons no less than 14 days before such use occurs
* Crown use to be approved by a Minister (the relevant Federal Minister or State Attorneys-General)
* that in instances of Crown use, the patentee is entitled to remuneration determined on the same basis as that for a compulsory licence.

The first two requirements should be able to be waived in emergencies. However, in all cases patentees should be provided with immediate notice that their patents have been used, and a statement of reasons as soon as practical thereafter.

## Awareness raising

Recommendation 10.1

IP Australia and the Australian Competition and Consumer Commission (ACCC) should jointly develop a plain English guide on the compulsory licensing provisions. The guide should be available on both the IP Australia and ACCC websites.