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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. Rather than having to be compelled to license, patent owners often 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 a clear case to reform the criteria for granting a compulsory licence. * When a patent is used to engage in unlawful anticompetitive conduct, a compulsory licence should only be available under the *Competition and Consumer Act 2010* (Cwlth). * A public interest test should replace existing criteria based on the ‘reasonable requirements of the public’ in the *Patents Act 1990* (Cwlth). For cases other than those relating to unlawful anticompetitive conduct, this would provide an access regime when greater use of a patented invention would deliver a net benefit to the community. * To reduce uncertainty about international treaty obligations on compulsory licensing, such obligations should be incorporated directly into the Patents Act or its subordinate legislation. * To improve awareness of the compulsory licensing provisions, IP Australia should develop a plain English guide and make it available on its website. * 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, obtain Ministerial approval to invoke Crown use, and publicly state the reasons no less than 14 days before such use occurs. These requirements should be able to be waived in emergencies. In all cases, governments should be required to pay just and reasonable compensation. |
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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 more affordable prices. Among developed countries, compulsory licensing appears to occur most frequently in the United States, particularly to remedy anticompetitive conduct and patent infringement. 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 commercially 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 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 will 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.

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 2010

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Table 1 Nationality of patent grantees in Australia, 1995 to 2010

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| Country | 2010 | 1995–2010 average |
|  | % | % |
| Australia | 8 | 9 |
| USA | 41 | 43 |
| Japan | 8 | 9 |
| Germany | 7 | 7 |
| Switzerland | 5 | 4 |
| UK | 4 | 6 |
| Other | 27 | 22 |
| 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 rights. 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 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 have 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 sought 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 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.

There is an in-principle case for compulsory licensing and other safeguards to address concerns such as those raised by the BRCA case. However, this case does not appear to be representative of the behaviour of gene patent owners (critics rarely refer to any other examples). Furthermore, like other early gene patents, the BRCA patents will expire soon (from August 2015 to December 2016 in Australia).

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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.  In Australia, Cancer Voices and Yvonne D’Arcy launched legal action in 2010 against four biotech companies (including Myriad and GTL) over the legality of the BRCA1 patent. They argue that an isolated and purified gene from the human body is a discovery, rather than an invention, and so is not patentable. The parties are now waiting for a judgement from the Federal Court. |
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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. However, patents may continue to raise concerns 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. Developed countries such as Australia assist   
less–developed nations through other mechanisms, including aid programs.

## Reforming Australia’s compulsory licensing provisions

There are three different views on why Australia’s compulsory licensing provisions have been rarely used.

* 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 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.
* The process for granting a compulsory licence is so costly and time consuming that a potential licensee rarely finds it a viable option.

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.

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

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 employs 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 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 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. Rather than attempt to harmonise the two Acts, 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 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 consistency with international treaties should be removed. Current and future treaty obligations should be incorporated directly into the Patents Act or its subordinate legislation. This also has the advantage of subjecting the terms of any future treaties to more comprehensive scrutiny by the Parliament, and requiring the terms to be expressed in standard legislative language.

## 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 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. To the Commission’s knowledge, Crown acquisition has never been used. 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 provided by non-government organisations, such as privately owned testing laboratories, 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 its behalf.
* 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.

There is also a case for improving the transparency and accountability of Crown use. A review by ACIP in 2005 recommended that government agencies be required to first seek a negotiated outcome, obtain Ministerial approval to invoke Crown use, and (as currently required for compulsory licensing) pay just and reasonable compensation to the patent owner. The Australian Government chose not to implement these requirements because there was no evidence of a problem.

While ACIP’s recommended reforms would reduce (but not eliminate) the cost and time advantage of Crown use compared to compulsory licensing, the Commission has proposed similar changes to improve transparency and accountability. This includes using the same pricing principles that the Commission has recommended for compulsory licensing. It is also proposed that governments be required to publicly state the reasons for invoking Crown use no less than 14 days before such use occurs. Concerns about timeliness could be addressed by allowing the recommended requirements (except for 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 very 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. Most genetic tests are currently provided and funded by state and territory health departments. While the Commission has only identified five genetic tests in the Medicare Benefits Schedule (MBS), the latest available data indicate that these account for 40 per cent of tests conducted. 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 would address cases where 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, it appears that existing privacy laws already give people the right to see their test results, irrespective of any restrictions in the Patents Act.
* *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, Switzerland 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. Nevertheless, there may be merit in Australia adopting a licence-of-right mechanism to facilitate voluntary licensing. The Commission requests further input on this issue.
* *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 includes the provision of written guides on its website for issues such as Crown use and the process for obtaining a patent.

In light of the above, it is recommended that IP Australia develop a plain English guide to the compulsory licensing provisions and make it available on its website.