Australian Government

Productivity Commission

Compulsory Licensing of Patents

Productivity Commission Inquiry Report

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The Productivity Commission is the Australian Government's independent research and advisory body on a range of economic, social and environmental issues affecting the welfare of Australians. Its role, expressed most simply, is to help governments make better policies, in the long term interest of the Australian community.

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28 March 2013

The Hon David Bradbury MP
Assistant Treasurer
Parliament House
CANBERRA ACT 2600

Dear Assistant Treasurer

In accordance with Section 11 of the *Productivity Commission Act 1998*, we have pleasure in submitting to you the Commission's final report into Compulsory Licensing of Patents.

Yours sincerely

Alison McClelland
Presiding Commissioner

Dr Warren Mundy
Commissioner

Terms of reference

I, David Bradbury, Assistant Treasurer, under part 3 of the *Productivity Commission Act 1998*, hereby request that the Productivity Commission undertake an inquiry into the compulsory licensing provisions in the Patents Act 1990.

Background - balancing access to technology and innovation

The compulsory licensing provisions in the *Patents Act 1990* are a key safeguard, which may be invoked where the exercise of the exclusive rights conferred by a patent are not meeting the reasonable requirements of the public or constitute anti-competitive conduct.

In Australia, these provisions are used rarely and there are opposing views on their effectiveness. Infrequent use is attributed to significant barriers to accessing the provisions, or as a result of the deterrent effect of the provisions, which induces patent holders to enter into voluntary licences for their patented inventions.

Australia is a net importer of technology. Of the 14,557 patents granted in 2010, 1,178 (8 per cent) were granted to Australian residents. Overall, the likely benefit of these provisions is their use as a deterrent in licensing negotiations between a foreign patent holder and potential licensee in Australia, in order to ensure domestic access to technology and technology diffusion.

In November 2011, the Government's Response to recommendation 12 of the Senate Community Affairs References Committee's *Gene Patents* Report November 2010 and recommendation 27-1 of the Australian Law Reform Commission, *Genes and Ingenuity: Gene Patenting and Human Health* (ALRC 99, 2004) Report, endorsed a review of the operation of the compulsory licensing provisions in the *Patents Act 1990*, including measures to raise awareness of these provisions.

Compulsory licensing is an increasingly sensitive issue internationally, particularly in the context of access to affordable healthcare, and concerns that gene patents may prevent equitable access to medical advice that relies on the identification and use of gene sequences related to human health and disease. Other areas of sensitivity include climate change mitigation, food security and alternative energy

technologies, and technical standards essential patents (e.g. in telecommunication technologies).

Compulsory licensing provisions are a feature of many patent laws around the world, and are included in international agreements to which Australia is a party.

Scope of the inquiry

The Commission is requested to review the operation of the compulsory licensing provisions in the *Patents Act 1990,* in particular:

1. Assess whether the current Australian provisions can be invoked efficiently and effectively to deal with circumstances where reasonable requirements of the public are not being met or where the patentee engages in anti-competitive conduct. This includes, but is not limited to, consideration of concerns that gene patents may hinder access to affordable healthcare, including access to medical advice that relies on the identification and use of gene sequences related to human health and disease.
2. Advise on the frequency, and impact, of the issue of compulsory licences in comparable markets and the common features in such compulsory licenses.
3. Recommend any measures that may be required to efficiently and effectively exercise these safeguard provisions and invoke their use in a manner consistent with Australia's international obligations, without limiting access to overseas technologies, technology transfer, research and development investments or substantially reducing the patent incentive for innovation.
4. Recommend any alternative mechanisms deemed necessary to ensure that the balance between incentives to innovate and access to technology best reflect objectives of ensuring reasonable access to health care solutions, maximising economic growth and growing the Australian manufacturing industry.
5. Recommend measures to raise awareness of these provisions and their purpose, including the specific challenges of raising awareness among small businesses and the healthcare sector.

In conducting the inquiry, the Commission should have regard to:

(a) the importance of incentives for industry and researchers to invest in research and development, and innovation;

(b) access to and transfer of technology, including climate change mitigation, food security, healthcare and alternative energy technologies, and standard essential patents in telecommunication technologies, particularly where multiple patentees are involved;

(c) affordable and equitable access to healthcare, including medical treatments and diagnostic tests in Australia;

(d) recent changes to the intellectual property system reflected in the *Intellectual Property Laws Amendment (Raising the Bar) Act 2012*, including the research exemption;

(e) other relevant parts of the intellectual property system, such as crown use provisions; and

(f) the range of international approaches.

The Commission will report within nine months of receipt of this reference and will hold hearings for the purpose of this inquiry. The Commission is to provide both a draft and a final report, and the reports will be published. The Government will consider the Commission's recommendations, and its response will be announced as soon as possible after the receipt of the Commission's final report.

DAVID BRADBURY
[Received 29 June 2012]

Contents

Abbreviations

Abbreviations

ABSDO	Accreditation Board for Standards Development Organisations
ACCC	Australian Competition and Consumer Commission
ACIP	Advisory Council on Intellectual Property
ADR	Alternative dispute resolution
AHMAC	Australian Health Ministers Advisory Council
ALRC	Australian Law Reform Commission
AUSFTA	Australia-United States Free Trade Agreement
CAL	Copyright Agency Limited
CCA	*Competition and Consumer Act 2010* (Cwlth)
CIPO	Canadian Intellectual Property Office
DOHA	Department of Health and Ageing
EPC	European Patent Convention
EPO	European Patent Office
FICPI	Australian Federation of Intellectual Property Attorneys
FRAND	Fair, reasonable and non-discriminatory
FTC	United States Federal Trade Commission
GTL	Genetic Technologies Limited
IAC	Industries Assistance Commission
IC	Industry Commission
IP	Intellectual property
IPCRC	Intellectual Property and Competition Review Committee
IPTA	Institute of Patent and Trade Mark Attorneys
JPO	Japan Patent Office
KIPO	Korean Intellectual Property Office

LOR	Licence of right
MBS	Medicare Benefits Schedule
MSAC	Medical Services Advisory Committee
NGO	Non-government organisation
NHMRC	National Health and Medical Research Council
OECD	Organisation for Economic Cooperation and Development
PBAC	Pharmaceutical Benefits Advisory Committee
PBPA	Pharmaceutical Benefits Pricing Authority
PBR	Plant breeders right
PBS	Pharmaceutical Benefits Scheme
PC	Productivity Commission
PCT	Patents Cooperation Treaty
PPH	Patent Prosecution Highway
PPI	Patented pharmaceutical invention
RCPA	The Royal College of Pathologists of Australasia
RIS	Regulation impact statement
SDO	Standards development organisation
SCARC	Senate Community Affairs and References Committee
SLCALC	Senate Legal and Constitutional Affairs Legislation Committee
TRIPS	Agreement on Trade-Related Aspects of Intellectual Property Rights
UK IPO	United Kingdom Intellectual Property Office
UNFCCC	United Nations Framework Convention on Climate Change
USPTO	United States Patent and Trademark Office
WEHI	Walter and Eliza Hall Institute of Medical Research
WHO	World Health Organisation
WTO	World Trade Organisation
WIPO	World Intellectual Property Organisation

Glossary

Blocking/dependent patent	A patent owned by another party that prevents a patentee from exploiting its own invention without authorisation of the other party.
BRCA genes	A class of tumour suppressor genes. Mutations of these genes are associated with breast, ovarian and prostate cancer.
Compulsory licence	A government- or court-issued order for a patentee to grant a licence to another party (which allows that party to exploit the patented invention).
Crown acquisition	Acquisition of a patented invention by the Crown under s. 171 of the *Patents Act 1990* (Cwlth).
Crown use	Use of a patented invention by the Crown or another party authorised by the Crown under ss. 163–170 of the *Patents Act 1990* (Cwlth).
Injunctive relief	A court order instructing the defendant to cease a specific behaviour (for example, selling of a product that infringes an existing patent).
Innovation patent	An exclusive right to exploit an invention, granted for a term of eight years. To be eligible for an innovation patent, an invention must be novel, useful and involve an innovative step.
Isolated gene sequence	A free-standing portion of genetic material that is isolated from the larger natural DNA molecule. The process of isolating a gene involves chemically altering the DNA. However, the genetic information contained in the isolated gene is identical to that in the gene's naturally occurring form.

Licence of right	A legally enforceable mechanism by which a patent holder voluntarily chooses to provide access to a patented invention to anyone who is willing to accept the licence conditions.
Patent	A legally enforceable right to exclude others from exploiting an invention — a device, substance, method or process — that is new, inventive, and useful at the time the patent is granted.
Patent holdup	Where a new technology unknowingly infringes a patent and is not made aware until large scale production has commenced or is about to commence. In such cases the patent holder can use its enhanced bargaining power to 'hold up' production and extract higher licensing fees.
Patent infringement	Use of a patented invention in a prohibited manner without the authorisation of the patent holder.
Patent thicket	An area of technology in which many overlapping patents exist. Commercialisation of new technology might require licence deals in relation to multiple patents and with multiple patent holders.
Patent troll (non-practising entity)	A patentee who holds a patent with the intention of pursuing infringement claims but no intention of working the patent itself.
Prior art	All information relevant to a patent claim that is publicly available at the priority date. A patent might not be granted if the invention is described in the prior art.
Priority date	The date at which the invention is assessed and compared to the prior art. The priority date might differ from the patent application filing date.
Royalty stacking	Refers to a situation where a single product infringes multiple patents and is thus subject to multiple royalty burdens. Each royalty burden can be 'stacked' to determine the total royalty burden.

Springboarding	Springboarding allows firms to use patented inventions prior to the patent expiration for the sole purpose of gaining regulatory approval. Pharmaceuticals are an example of a product that requires regulatory approval.
Standard essential patent	A standard essential patent is a patent on an invention that is required to practise an industry standard (for example, 3G mobile internet technology).
Standard patent	An exclusive right to exploit an invention, granted for a term of 20 years. To be eligible for a standard patent, an invention must be novel, useful and involve an inventive step.
Subject matter exclusions	Exclusion from patent eligibility for particular fields of technology.

OVERVIEW

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.

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).

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)

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.

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.

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.

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**

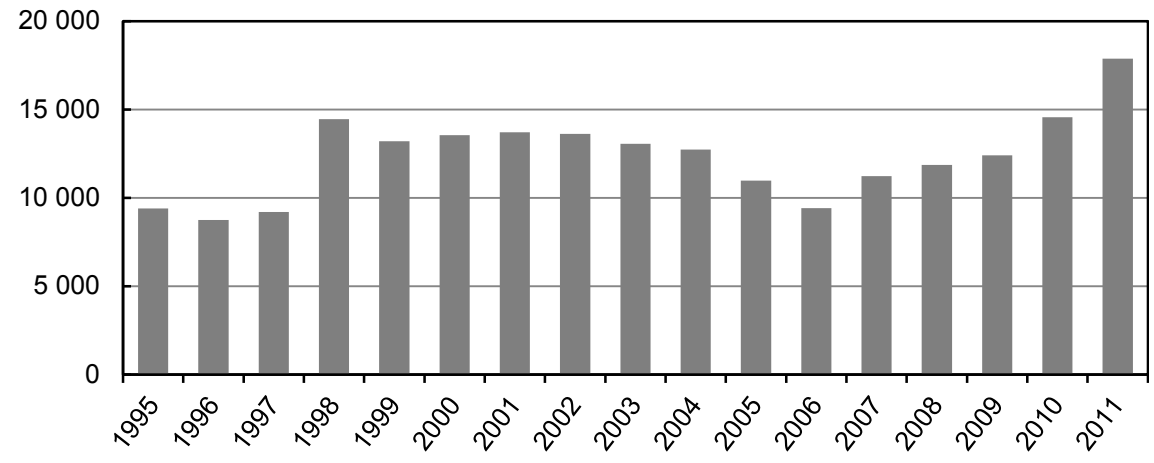


Table 1 **Nationality of parties granted Australian patents, 1995 to 2011**

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.

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)

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.

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.

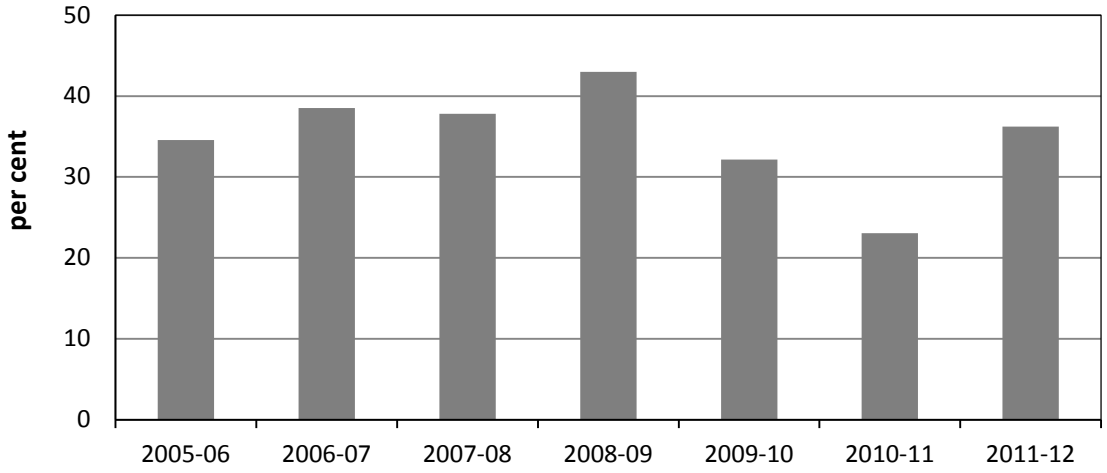
It is widely recognised that obtaining a compulsory licence would be costly and time consuming. This is largely because an application has to be made to the Federal Court for an order requiring the patent owner to grant a compulsory licence. The primary expense would be the legal costs to prepare and 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



[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).

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.

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.

1 Introduction

Key points

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

1.1 Focus of the inquiry

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

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

- assess whether the current compulsory licensing provisions can be invoked efficiently and effectively
- advise on the frequency, and impact, of compulsory licences in comparable markets and the common features of such licences
- recommend any measures that may be required to efficiently and effectively exercise Australia's compulsory licensing provisions

- recommend any alternative mechanisms deemed necessary to ensure that the balance between incentives to innovate and to access technology best reflects the objectives of reasonable access to health care, maximising economic growth and growing the Australian manufacturing industry
- recommend measures to raise awareness of the compulsory licensing provisions.

Box 1.1 **Non-voluntary access to patents**

There are currently seven mechanisms in the *Patents Act 1990* (Cwlth) that allow a patented invention to be exploited without the patentee's authorisation:

- compulsory licensing (ss. 133–140)
- Crown use (ss. 163–170)
- Crown acquisition (s. 171)
- for the purpose of obtaining regulatory approval (ss. 119A–119B)
- for experimental purposes related to the subject matter of the invention (s. 119C)
- when exploitation, or 'definite steps' (contractually or otherwise) to exploit, occurred immediately before the 'priority date' (date the patent became effective) (s. 119)
- use in or on foreign vessels, aircraft or vehicles temporarily in Australia (s. 118).

The 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.

The origins of this inquiry can be traced back to several past reviews of the patents system. In particular, the Australian Government (2011a) agreed to a review of compulsory licensing as part of its combined response to three reports.

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

All three reports rejected calls to exclude human genes from the patents system. They concluded that concerns about accessing patented inventions are better dealt with through other mechanisms, including compulsory licensing. However, the ALRC and SCARC also concluded that the patents legislation needed to be amended to clarify the conditions under which a compulsory licence would be granted, noting that the provisions had rarely been used. In addition, the ALRC recommended that a competition test proposed by the Intellectual Property and

Competition Review Committee (IPCRC 2000) be adopted as an additional ground for granting a compulsory licence. The Australian Government chose to implement a different type of competition test (detailed in chapter 6), which the SCARC subsequently recommended be reviewed.

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

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

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

1.2 Report structure and the Commission's approach

This report is structured as follows:

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

Matters the Commission was asked to have regard to

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

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

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

Efficiency and effectiveness

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

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

1 Affordable could be interpreted as meaning within a person's financial means, and equitable as being equally accessible for different individuals.

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

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

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

Box 1.2 **The limited use of Australia's compulsory licensing provisions**

There appears to have been only three applications for a compulsory licence order since this became available under Commonwealth legislation in 1903. None of the applications resulted in a compulsory licence.

Fastening Supplies Pty Ltd v Olin Mathieson Chemical Corp. [1969] HCA 61

This application was made under the *Patents Act 1952* (Cwlth), which required an applicant to first satisfy the Commissioner of Patents that there was a prima facie case that the 'reasonable requirements of the public' had not been satisfied. If a prima facie case was found, the matter had to be referred to the High Court (in its original jurisdiction).

Fastening Supplies sought a compulsory licence for a captive-bolt gun from Olin Mathieson, which had granted an exclusive licence in Australia to Ramset Fasteners.

(Continued next page)

Box 1.2 (continued)

The matter was referred to the High Court, which found that at the date of the application (December 1968) Ramset had not satisfied the reasonable requirements of the public. This was attributed to the difficulty of designing a gun of sufficient versatility and endurance to warrant large-scale manufacturing in Australia. The High Court also found that by the time of its decision (December 1969) Ramset was in the process of meeting Australian requirements, and that Fastening Supplies was not a suitable company to be granted a compulsory licence due to its limited capacity to undertake manufacturing or subcontract it to others. As a result, the application was denied.

Kenneth Mervin Lown v Wissen Pty Ltd [1987] APO 11

This case was also brought under the *Patents Act 1952* (Cwlth), but the Commissioner of Patents decided to dismiss the application.

Mr Lown sought a compulsory licence from Wissen for a device to prevent birds roosting on a surface. Mr Lown had sold the patent to Wissen in 1984 and at the same time made a non-exclusive licence with Wissen for a 'prestige model' made of metal. Wissen only sold a plastic version. Mr Lown claimed that his licence for the metal version had been terminated by Wissen and as a result a large proportion of demand for the device was not being met. The Commissioner of Patents found that Mr Lown's assertion of unmet demand was not supported by any evidence, whereas it was clear that Wissen was marketing a version of the device. As a result, the petition was dismissed.

Amrad Operations Pty Ltd v Genelabs Technologies Inc. [1999] FCA 633

This appears to be the only case made under current provisions in the *Patents Act 1990* (Cwlth), which require an application to be made to the Federal Court.

Amrad applied to the Federal Court for a compulsory licence order so it could manufacture a Hepatitis E virus diagnostic assay in Australia. It subsequently amended its application and statement of claim so that all the respondents — Genelabs, the US Government and Abbott Laboratories — were based in the United States, and sought leave to serve the application in that country. The Federal Court agreed to Amrad's requests without making a judgment in regard to the compulsory licence.

International perspective

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

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

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

When formulating recommendations, the Commission has also been mindful that Australia is a party to several international agreements that influence how Australia's intellectual property system operates (appendix D).

1.3 Consultation process for the inquiry

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

- At the commencement of the inquiry, a circular was sent to people and organisations that the Commission thought might be interested, inviting their participation. Subsequent circulars were sent to those who had expressed an interest in the inquiry to keep them updated on progress.
- The inquiry was also advertised in major national newspapers and promoted on the Commission's website.
- The Commission met with a cross-section of interested parties to identify relevant issues and sources of information.
- An issues paper was released in August 2012 to assist interested parties in preparing submissions to the inquiry.
- A draft report was released in December 2012, with an invitation for interested parties to provide feedback through further written submissions.
- Public hearings were held in Melbourne in February 2013.

The Commission thanks inquiry participants for meeting with the Commission, lodging written submissions and providing other assistance. A total of 52 submissions were received from a variety of groups. Appendix A provides details of the individuals and organisations that participated in the inquiry.

2 Rationale for patents and associated safeguards

Key points

- Without public intervention, inventors may have inadequate incentives to undertake the level of innovation that is optimal from society's viewpoint.
  - This can occur if those producing innovations are unable to capture sufficient benefits from their inventions to cover their costs.
- Measures to address this problem include establishing property rights (the issuance of patents), subsidies for research and development, and research prizes.
- A patent is a legally-enforceable right to exclude others from utilising a device, substance, method or process that is new, inventive, and useful at the time the patent was granted.
- In the design of a patents system, there is a tradeoff between encouraging innovation on the one hand, and facilitating adoption of inventions on the other.
  - 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 can also hinder adoption of the invention.
- In cases where there are no near substitutes for an invention, a patent could also facilitate monopolistic and/or anticompetitive behaviour. Safeguards are typically built into a patents system to limit its potential shortcomings. They can be divided into two broad groups.
  - Ex ante safeguards are applied before a patent is granted, and include a threshold test (that seeks to restrict patents to truly innovative ideas) and a fixed patent duration (to limit the time that people can be excluded from using inventions). Limited technological exemptions also exist.
  - Ex post safeguards (which include compulsory licensing) apply after a patent is granted, and are generally invoked in exceptional circumstances where patent exclusivity is inconsistent with upholding the general interests of the community.

2.1 Why have a patents system?

In the absence of public intervention, private incentives to undertake innovation could be inadequate, due to the 'public good' characteristics of innovative activity (Arrow 1962; PC 2007). The implication for economic policy is that mechanisms

such as patents are required to allow innovators to capture a sufficient amount of the benefits to the community from their activity.

Innovative ideas are regarded as having the characteristics of a public good because they are 'non-rival', meaning that their use by one entity does not diminish the amount that can be consumed by other potential users (Gans, Williams and Briggs 2004). For instance, one car manufacturer's use of the internal combustion engine does not impinge on the ability of other car manufacturers to use internal combustion engines in their cars. By contrast, use of a 'rival' good or service by one person, such as consuming a can of drink, reduces the amount of that good available for use by others.

An additional consideration is that of 'non-excludability'. If a firm or other producer of a good is unable to exclude others from using it, then the good may be described as 'non-excludable'. Innovative ideas that are in the public domain are typically regarded as possessing this characteristic, given the difficulty of preventing others from benefitting from them (in the absence of legal rights to prevent use unauthorised by the originator) (Encaoua, Guellec and Martinez 2006).

The optimal degree of innovation from society's perspective occurs when the expected social benefits from additional innovation equal the expected social costs. If, however, innovators are unable to appropriate sufficient benefits from their activity, innovation may be less than socially optimal (Besen and Raskind 1991). This might occur, for instance, if new products could be easily replicated by rival producers, or if products (such as books and music) could be readily copied by consumers.

As detailed below, patents are one means of encouraging innovation that would not otherwise occur due to its public good characteristics. Patents systems have existed for a number of centuries in different parts of the world. A patents system existed in Venice in the fifteenth century. In England, the formal development of a patents system culminated in the Statute of Monopolies of 1623, which provided the first patents law of a modern nation. In the sixteenth and seventeenth centuries, the granting of exclusive rights to inventors was widespread in parts of central and western Europe. In the 1790s, patents legislation was introduced in France and the United States. The nineteenth century saw significant international growth in patents systems, with countries such as Austria, Russia, Belgium, Spain and Sweden all introducing patent laws in the first half of the century (Machlup and Penrose 1950).

In Australia, the first patents legislation was introduced in New South Wales in 1852, and came into force in 1854. The colony of Victoria introduced its own

patents legislation in 1854 (State Library of Victoria 2012). The first national patents legislation was the *Patents Act 1903* (Cwlth), which was subsequently replaced by the *Patents Act 1952* (Cwlth) and then the current *Patents Act 1990* (Cwlth).

2.2 Options to foster innovation

Public policy options to mitigate potential obstacles to innovation include establishing property rights (especially by issuing patents), and policies such as subsidised R&D, prizes for research activity, and research contracts (collectively referred to as rewards).

Establishing property rights

The traditional means used to provide individuals with the ability to appropriate at least some of the benefits of creative activity is to establish a system of intellectual property (IP) rights. IP relates to creations of the mind, including industrial and other innovations, creative works (literary and visual) and software, as well as symbols, images, names and designs used in business (WIPO nd). It thus differs from other forms of property primarily on the basis of its intangibility, in that it embodies thoughts and knowledge created by people (Aoki and Small 2004; PC 2007). A property right over IP gives its owner the exclusive right to use the property covered by that right.

Gans, Williams and Briggs (2004) identified three key basic elements required for an effective system of property rights: establishment, enforcement, and exchange. Establishment refers to the ability of the legal framework to identify those in possession of property rights, while enforcement relates to the presence of a system able to enforce those rights (for example, through courts). Exchange concerns the ability of individuals to exchange property rights within the system at a non-prohibitive cost. The presence of such a system enables trade to take place, and provides individuals and firms with the required incentives to create socially valuable assets (Gans, Williams and Briggs 2004).

With the ability to exclude others from using their creations, producers of IP may be able to capture sufficient benefit from their work to encourage productive activity. However, there is also potential for the creation of exclusive property rights to facilitate monopolistic or anticompetitive behaviour (Boldrin and Levine 2002; Romer 2002). This raises the issue of whether an IP rights system achieves a

sufficient balance between facilitating creation on the one hand, and allowing IP to be sufficiently disseminated on the other (Besen and Raskind 1991; PC 2007).

A number of researchers have cautioned against the notion of automatically equating property rights with market power. Kitch (2000), for example, noted that the assumption that IP rights confer monopoly power on their owners is only true if those rights prevent others from providing substitute goods with the same functional characteristics as those protected by the IP rights. For instance, a pharmaceutical patent would only confer a monopoly on the patent holder if there were no alternative treatments available for the medical condition(s) in question. Kitch (2000, p. 1731) thus concluded that 'whether a right or combination of rights, confers an economic monopoly is an empirical question'.

Similarly, Gans, Williams and Briggs (2004) concluded that assignment of IP rights, by itself, is unlikely to create monopoly power. They argued that monopoly problems may arise where the idea covered by strong IP rights is required as an input for the production of a distinct good. However, this requires the possibility of 'demand-side' substitution to be ruled out (as noted by Kitch (2000) above). Furthermore, Gans, Williams and Briggs (2004) observed that 'supply-side' substitution, whereby alternative inputs to the one with exclusive rights are available for production, can help to reduce the extent to which any market power conferred by rights can be exercised.

Where the assignment of exclusive rights over an invention does create market power, the primary concern from the standpoint of public policy is not the existence of such power, but rather whether it is exercised to the detriment of economic efficiency and the community more generally. These issues were given significant consideration in the Hilmer report on National Competition Policy (Hilmer, Rayner and Taperell 1993). The *Competition and Consumer Act 2010* (Cwlth) contains provisions relating to the misuse of market power and remedying anticompetitive conduct. Remedying anticompetitive conduct requires anticompetitive purpose in addition to the exercise of market power (chapter 6).

There are three main types of commonly used IP rights — patents, copyright, and trade marks. These are discussed below, in addition to IP rights provided for designs and plant breeders.

Patents

A patent is 'a right that is granted for any device, substance, method or process that is new, inventive, and useful', that is legally enforceable, and gives the patent holder an exclusive right to 'commercially exploit' the innovation for the duration

of the patent (IP Australia 2012i, p. 1). By creating an exclusive right over an invention, a patent is intended to overcome the 'free riding' problem associated with non-excludability of innovative activity. In return for excludability, patent holders are required to disclose details of their invention. This benefits the community by reducing the likelihood of duplication of research effort, and facilitating improvements on the patented invention by others. As the Institute of Patent and Trade Mark Attorneys and the Australian Federation of Intellectual Property Attorneys observed of the rationale for patents:

> … it is generally accepted that the patent system provides public benefits by stimulating investment in innovation and the commercialisation of the results of innovation. It does this by creating a piece of property comprised of specific exclusive rights with a limited life … In short, the grant of a patent stops or can be used to stop others from 'free riding' on the investment made for a limited period of time. (sub. 18, pp. 1–2)

The Patents Act establishes the conditions under which an invention may be eligible for a patent in Australia. The Australian patents system is discussed further in chapter 3 and appendix B.

A patent holder has a legal right to exclude innovations identical to its own from being produced and marketed.

Use of a patented innovation usually requires the permission of the patent holder, and such use can involve the payment of royalties to the party holding the patent. There are, however, often safeguards that allow a patented invention to be used without the owner's permission in limited circumstances, including compulsory licensing (discussed below). When the term of a patent expires, the invention covered by the patent enters the public domain and can be used without the permission of the initial patent holder.

Not all patented inventions are commercially successful. This has implications for the pricing of inventions. A firm may need to set the price of its successful innovations at a level that recoups the cost of both successful and unsuccessful innovations.

Copyright

Copyright is another measure used to address IP-related market failures. Its basic characteristics are described here, but are not discussed further, given the focus of this inquiry on patent issues.

Copyright focuses on artistic, musical, literary, software and dramatic works, often covering products such as films, books, and music. In Australia, copyright is

automatic the moment an idea or creative concept is documented, and is covered by the *Copyright Act 1968* (Cwlth). Copyright protection does not protect an originator against the creation of similar work, but does give the copyright holder the exclusive right to license others in the matters of copying, performing, broadcasting, publishing and making adaptations of the protected work (IP Australia 2011a).

Trade marks

A trade mark is 'a right that is granted for a letter, number, word, phrase, sound, smell, shape, logo, picture and/or aspect of packaging' (IP Australia 2012m, p. 1). It confers an exclusive right to commercially use, license, or sell the goods and services that the trade mark is registered under.

The primary function of trade marks is to provide consumers with an ability to identify products and their sources, and thus facilitate an orderly process of marketing (Besen and Raskind 1991). Trade marks have developed as a form of indirect consumer protection by allowing purchasing decisions to be made on the basis of marks that identify products and their source. Trade marks are not discussed in further detail in this report, given its focus on matters related to the patent system.

Designs

Design concerns the appearance of products, and is another variety of IP right. IP Australia defines a design as referring to 'features of shape, configuration, pattern, ornamentation, which gives a product a unique appearance' (IP Australia 2012d). Designs can be registered, providing the owner with the exclusive ability to use, license, or sell the design.

In order to be eligible for registration, a design must be 'new', such that it cannot be identical to any design previously disclosed anywhere in the world, nor any design previously used in Australia. Furthermore, the design must be 'distinctive', in that it must not be 'substantially similar in overall impression' to previously published designs (IP Australia 2012a, p. 1).

Plant breeder rights

Similar to patents, plant breeder rights provide an incentive to create new plant varieties that may not otherwise occur due to the public good characteristics of innovation. In Australia, this is codified in the *Plant Breeder's Rights Act 1994* (Cwlth).

The patents system was considered unsuitable for plants for several reasons:

- lower levels of newness and inventiveness involved in traditional breeding methods
- difficulty in reliably reproducing plant varieties from standard technical descriptions
- the importance of plants as a basic resource, especially for food (ACIP 2010a).

As a result, the criteria used to grant a plant breeder's right differ from those used for patents. There is also a separate compulsory licence regime (chapter 5).

Reward-based systems

A number of reward-based tools exist that may be utilised to stimulate research and other innovative activity, and can act as an alternative to assigning property rights. These include measures such as subsidies for undertaking R&D, and prizes for successful research. A key difference between these instruments, and assigning property rights, is that no exclusive right is established for innovations; once produced they enter the public domain and can be freely utilised.

These instruments may provide incentives for increasing the level of R&D, and hence, innovative activity. Prior to considering the use of these instruments, however, it is necessary to consider whether the targeted activities would generate greater benefits to the community as a whole with public intervention (PC 2007).

A body of literature has compared the functioning of, and incentives provided by, reward-based systems to those offered by patents. For example, Wright (1983) contrasted prizes awarded for successful research, research contracts, and patents. This author regarded the imbalance in information about the costs and benefits of research between those undertaking it and those potentially funding it as one of the key advantages of patents over other tools to encourage research. This was balanced against the costs of limited diffusion of innovations that may result from patents. Wright (1983) concluded that, if the social costs of limited technological diffusion associated with patents was greater than the social costs associated with raising an equivalent amount of taxation, prizes and contracts would be socially preferable to patents.

A later work by Shavell and van Ypersele (2001) contrasted the patents system with a reward system whereby innovators received payment for their innovations directly from government. In their analysis, they assumed that the grant of a patent led to market distortions, thus imposing a social cost, a concept common to much economic analysis of patents. The incentive for an inventor to innovative is thus

given by the price they would be able to receive through commercial exploitation, which would exceed the price of a competitive market due to the patent holder's exercise of market power. By comparison, under a reward-based system, the incentive an inventor has to innovate is determined by the reward they can expect to receive. An innovation, once created, is made available at marginal cost, avoiding the distortions associated with the use of market power to affect pricing. However, in Shavell and van Ypersele's (2001) framework, it was assumed that an inventor knew what the demand for a particular innovation would be before investing in research, whereas the government did not have this information.

Given this imperfect information, Shavell and van Ypersele (2001) make the point that incentives to invest under a reward system could be either insufficient or excessive, depending on the actual state of demand for an innovation, and the size of the reward offered by the government. In their analysis, neither system clearly dominates in all possible circumstances.

There are several other important differences between patents and other policies, such as subsidies, that aim to encourage innovation. For instance, under a patents system, decision making typically lies with individual innovators who are likely to have greater information on the private costs and benefits of their activity than the government. As noted by Encaoua, Guellec and Martinez (2006), this delegation of research activity discourages innovators from taking risks that they know are unlikely to be commercially successful. Hall (2007) stated that policies such as prizes and research contracts were of limited use when the objectives of innovative activity are unknown, or difficult to identify prior to the completion of research. Scotchmer (1991) argued that if a government knew all the costs and benefits associated with research, it could select the research projects that delivered net social benefits and the patent system would be unnecessary. This places large informational requirements on government for all possible research projects however, making the actual realisation of such a system likely to be infeasible. As Thomson and Webster (2009, p. 57) noted:

> Unfortunately, government supply of R&D is subject to enormous information requirements which are, in part, a product of the fundamental uncertainty inherent in technological progress. Efficient allocation requires identifying the most valuable research projects, determining who should tackle them, knowing how much resources are required and how investment should be spread over time. … Good innovation policy should therefore supplement public R&D grant schemes with policies that decentralise decision making and harness market forces to allocate resources to research.

This discussion highlights the fact that there are advantages and disadvantages associated with each of the public policy instruments designed to encourage innovation. A single instrument is not necessarily preferable to another in a general

sense; rather, which one is utilised depends largely on the specifics of a given situation. Hence, there is a role for patents and subsidies in the suite of government approaches to provide incentives for innovation.

Other mechanisms for promoting innovation

Government assignment of property rights and subsidies are not necessarily the only way to promote innovation. A number of other potential mechanisms exist, and have been discussed in various contexts over time. For instance, the maintenance of trade secrets is one means by which inventors can try to protect their IP from unauthorised use, and in doing so, retain sufficient incentives to innovate. Trade secrets prevent the disclosure and diffusion of inventions, and thus can allow firms to recoup the costs of innovating. However, trade secrets can be wasteful from the perspective of the whole community as they may lead to duplication of research effort and hinder efforts to improve on things that have already been invented. They also do not exclude others from using the innovation once it enters the public domain (Aoki and Small 2004).

In the context of financial innovations, Herrera and Schroth (2004) examined the possibility that informational advantage provides sufficient incentive for innovation to occur in the absence of property rights mechanisms such as patents. With specific reference to investment banks, they suggested that product innovators that engage in initial transactions with clients obtain more precise information about the characteristics of clients than do rival firms. Although rival firms can freely imitate new financial products, the innovating firm has an informational advantage provided by their initial period of dealing, allowing them to recoup the costs associated with innovating.

Boldrin and Levine (2002) distinguished between two components of property rights: the right of first sale, and downstream licensing. The first relates to the right to own and sell ideas, inherent in all property rights. The second relates to the right to control the use of ideas after sale, which Boldrin and Levine (2002, p. 209) argued was 'economically dangerous'. In their view, the right of first sale could provide sufficient incentives to innovate, and so make policy instruments such as patents unnecessary.[1] However, this result depends on assumptions made by the authors in their analysis, which are open to question (Encaoua, Guellec and Martinez 2006).

[1] In a later work, Boldrin and Levine (2012) called for the abolition of patents, based on their concerns about lobbying and rent seeking.

2.3 Patent design

Patents, and the economic issues they give rise to, have long been discussed in the economic literature. A number of relatively early contributions in the modern literature, beginning with Nordhaus (1969), began to focus on optimal patent design. In subsequent years, this work has been added to, and more complex elements of the issues raised by patents have been analysed.

This section gives a brief outline of some of the key (theoretical) literature that has informed economic discussion of aspects of patent design. The specific design of the Australian patents system is considered in chapter 3 and appendix B.

The tradeoff between exclusivity and diffusion

Although patents may address incentives to innovate (discussed above) by assigning property rights, they also come with the risk of facilitating anticompetitive behaviour. As noted earlier, if granting a patent to one producer prevents others from providing similar products to consumers, and prevents possibilities for substitution, a monopoly may be conferred on the producer in possession of the patent. A great deal of the economic literature on patents focuses on market power issues (for example, Denicolo 1996; Nordhaus 1969, 1972; Scherer 1972; Vaughan 1948; Wright 1983).

Thus, a patents system typically involves striking a balance between providing sufficient incentives to encourage innovation on the one hand, and encouraging the diffusion of new technologies and processes on the other. Indeed, a system with a large number of innovations that are not widely used may be less beneficial to society than one with less innovation overall, but greater diffusion of new technology (Besen and Raskind 1991).

Disclosure and limited duration

While a patent confers exclusive rights to commercial exploitation on its holder, in return, the holder must also publicly disclose information relevant to the invention. This disclosure plays an important role in facilitating the diffusion of knowledge to other potential users of technology (Scotchmer and Green 1990), even though their ability to actively utilise that technology may be limited for the duration of the patent. A patent might be socially beneficial due to this aspect alone, even if it is not required for innovation. If an innovation can easily be kept secret, granting a patent, through its information disclosure provisions, may help to ensure that the

innovation is diffused and ultimately provides broader public benefits that would not occur had it remained secret (Encaoua, Guellec and Martinez 2006).

There are also other benefits that arise from the information disclosure aspect of patents. Among them, parallel independent discoveries of identical processes and creation of technologies may be prevented. Resources not utilised in duplicating the efforts of others are then free to be directed to other, more valuable purposes, including other innovative activities.

In addition, the information disclosure requirements inherent in patents can aid in the creation of subsequent innovations in the future. Subsequent innovations might be either complements or substitutes to the initial one: regardless, a great deal of research is cumulative in nature. This raises a dynamic issue, namely, that of providing adequate incentives to encourage first-stage innovation, and yet also ensuring that those innovations are eventually available to society more widely to enable second-stage innovation.

This issue is addressed by one of the key features of patents, namely, that they have a limited duration, after which the innovation covered by the patent enters the public domain. In Australia, the exclusivity period for a standard patent is 20 years subject to the payment of annual renewal fees (up to 25 years for pharmaceutical products), with fees increasing over the life of the patent (IP Australia nda).

'Optimal' patent duration and breadth

Over time, a large body of economic literature has developed on the question of how to design patents to yield the greatest possible net benefit to society. Much of this work has analysed the effects of different choices of patent duration. Duration affects the amount of time revenue can be derived based on the presence of a patent. Patent breadth is another concept that has been the subject of discussion in the literature. Unlike patent duration, there is no universal definition of patent breadth. Encaoua, Guellec and Martinez (2006) noted that, in principle, breadth is determined by the claims accorded by patent examiners to a patentee, which establishes the elements of IP to be protected by a patent. In the economic literature, the term breadth has been used to refer to diverse concepts, such as the costliness of imitating an innovation, and the degree to which differentiated products possess similarities without infringing each other's patents (Denicolo 1996).

Another body of literature has developed that considers the 'strength' and 'quality' of patents systems in various countries. The definition of strength incorporates patent duration and breadth, with strength also typically considered to include patent coverage, enforcement mechanisms available to patent holders, and

safeguards. The concept of quality normally relates to the stringency and transparency of patent systems. This literature is discussed in more detail in appendix B.

The balance between providing adequate incentives for innovation and the desire to enable access to inventions to the wider public led to a focus on analysing the perceived tradeoff between patent duration and breadth in the economic literature.

However, there is a difficulty in drawing general conclusions for policy from the literature. For example, although much has been written on patent breadth (Denicolo 1996; Gallini 1992; Gilbert and Shapiro 1990, Klemperer 1990, and Tandon 1982, among others), authors have often used different concepts of patent breadth, and chosen different economic frameworks in which to consider them. In some cases, conclusions reached by one author have stood in contrast to those reached by another. The main implications that arise from the economic literature are that the effects of changing patent duration and breadth are dependent on the economic environment in which they occur. This includes the type of innovations that are patented and the degree to which they may reduce production costs, as well as the structure of the markets in which final products are sold (such as how many competitors an innovating firm faces). Also important is the degree to which innovations are isolated, or instead build on one another. For instance, a wider patent breadth (though perhaps desirable for some reasons) could make it more difficult to improve on an innovation, or invent around it. Also, a longer patent length could provide a greater incentive for other inventors to imitate or build on an initial innovation (although a longer patent life could have adverse effects of its own).

In conclusion, considerations of patent duration and breadth involve a complex interaction between instruments of policy, their effects on innovation, and the market structures that firms face. As a matter of practicality, Australia and many other countries have ultimately settled on a patent life of 20 years for most types of innovations.

2.4 Compulsory licensing and other safeguards

While a patent generally gives its owner an exclusive right over an innovation, safeguard mechanisms also typically exist to limit the extent of the patent holder's right to exclusive use. These mechanisms can be grouped into two categories: ex ante and ex post safeguards.

Ex ante safeguards are applied prior to the granting of a patent. They include a threshold test that seeks to limit patents to truly innovative ideas, and a time limit on the duration of patents (typically 20 years from the grant of the patent) to limit the period that people can be excluded from using an invention without the consent of the patent owner. The stringency of these safeguards has a significant bearing on the tradeoff made between encouraging innovation and facilitating access to technologies, as discussed above.

Ex ante safeguards have the advantage of being fully known by the patentee at the time the patent is granted, thus exposing the holder to no additional uncertainty regarding these aspects of the design of the patent.

Ex post safeguards are invoked in exceptional circumstances after a patent is granted when exercising the exclusive right associated with the patent is not in the interest of the community as a whole. For instance, in times of pandemic, a government may find it desirable to have a means to limit the exclusive rights of a patentee in order to ensure that adequate production of pharmaceuticals takes place. Non-use of a patented innovation may also prompt a government to invoke ex post safeguards to ensure that the benefits of the innovation are realised by the community.

Adequacy of ex ante safeguards

Some submissions to this inquiry raised questions about the adequacy of ex ante safeguards, and a small number also discussed concerns with the patents system generally (which is outside the terms of reference for this inquiry). In particular, Dwyer Lawyers (sub. 1) and Dr Hazel Moir (sub. 31, sub. DR46) questioned the argument that patents are needed because inventors would otherwise be unable to earn a sufficient return for their efforts. Dr Moir argued that this view was only plausible for large, lumpy investments and where followers can enter a market very quickly. She claimed that many patents systems typically have a low requirement for inventiveness, which has led to many patents being granted for trivial variations on existing innovations. The Commission supports Dr Moir's view that patents should only be granted where they lead to worthwhile innovations that would not otherwise occur. An assessment of Australia's threshold test for granting a patent is beyond the terms of reference for this inquiry. However, the Commission notes that this was recently subject to review and subsequent amendments as part of the 'Raising the Bar' reforms, which are due to come into full effect in April 2013.

The result is intended to be the application of a higher threshold test, reflecting concerns identified in the review process:

> Concerns have been raised that the thresholds set for the grant of a patent in Australia are too low, suppressing competition and discouraging follow-on innovation. Particular concerns have been raised that patents are granted for inventions that are not sufficiently inventive … (Australian Government 2011b, p. 8)

These reforms involved a number of changes to the Patents Act. For instance, a requirement was inserted that a 'specific, substantial and credible use' for an invention must be disclosed in a patent specification (IP Australia 2013, p. 3). According to IP Australia (2013, p. 3):

> These amendments will strengthen the test for usefulness and prevent the claiming of speculative inventions that would require further experimentation to put the invention into practice.

Examples of further changes included expanding the grounds for consideration of standard patent applications during examination, re-examination of standard and innovation patents, and opposition of an innovation patent, to include usefulness and prior use. Furthermore, higher standards of the balance of probabilities are expected to be applied when considering criteria for patentability during examination and re-examination of patents, as well as for opposition proceedings (IP Australia 2013).

The 'Raising the Bar' reforms were subject to an extensive public consultation process. This included the release of a draft Bill and associated regulations, accompanied by an invitation for submissions from the public.

Ex post safeguards

Ex post safeguards include government use or acquisition, remedies under competition law, and compulsory licensing. Government acquisition provides for a patent, or an invention that is the subject of a patent application, to be acquired by a government. Competition law remedies sometimes include a direction by the judiciary to grant licences to work a patented invention (on competition-related grounds, in relation to certain characteristics of competition law) (chapter 6). The validity of a patent itself can also be subject to challenge (for instance, on the grounds of inventiveness) in court in a number of jurisdictions, including Australia.

Compulsory licensing, the focus of this inquiry, is an ex post safeguard that exists in most countries. It compels a patent owner to license its innovation to another party (usually on a non-exclusive basis) in certain circumstances. The precise grounds for

issuing a compulsory licence vary between countries, but usually includes underutilisation of an invention that could benefit the community (appendix C).

Like government acquisition or use, and provisions of competition law, compulsory licensing could, if used inappropriately, blunt the incentive to innovate. As a form of forced patent use, compulsory licensing permits a patent holder to retain their ownership rights over the innovation. By contrast, government acquisition does not allow a patent holder to retain their ownership rights. Both instruments usually allow for the payment of compensation to patent holders.

The appropriate conditions or circumstances that warrant the use of compulsory licensing has been examined by a number of researchers over time, in various contexts. In a relatively early discussion in the economic literature, Vaughan (1948, p. 226) argued that compulsory licences should be provided to allow the 'conjoint use of important improvements and basic inventions, to prevent the suppression of worthwhile patents, to restore competition and at the same time lessen the conflict in the use of the latest technology'. By way of example, Vaughan (1948) suggested a situation where most of the important patents in an industry are owned by one or a few companies. This, in his view, could be remedied by requiring the patent owner(s) to offer licences to other firms on a royalty basis, with the reasonableness of terms judged by the number of resulting licensees and competitors.

In a similar vein to Vaughan (1948), a much later contribution by Aoki and Small (2004) also raised compulsory licensing as a possible remedy to anticompetitive activity. Indeed, they regarded it as one of the two reasons for the very existence of the provision. The other reason noted was the use of compulsory licensing for reasons such as ensuring the adequate provision of pharmaceuticals to those with insufficient income to afford the products in their own right.

The origins of compulsory licensing date to the International Convention for the Protection of Industrial Property 1883 (the Paris Convention). This Convention included a provision that obligated patentees to 'work' a patent in accordance with the laws of the country in which patented innovations were introduced. Failure to do so could result in the forfeiture of patent rights by the patentee. Legally, countries could require patent holders to work a patent within a certain period of time, and also require them to do so locally, generating manufacturing and distribution activity in the country in which the patent was granted. In 1925, the Convention was altered to essentially oblige countries to attempt to rectify patent 'abuses' via the use of compulsory licensing, prior to using the stricter remedy of patent forfeiture (appendix D; Reichman and Hasenzahl 2003).

While there has been some discussion and debate about the circumstances in which compulsory licensing ought to be used, empirical analysis of its effects is quite limited. One example is an analysis by Moser and Voena (2009) of the impact of compulsory licensing in the United States in the aftermath of the passing of the Trading with the Enemy Act of 1917. By the conclusion of the First World War, the Act provided for the confiscation of all enemy patents, and by February 1919, German-owned patents were systematically licensed to US companies. In order to test the effects of this on US innovation, Moser and Voena examined changes in domestic invention between 1875 and 1939 of chemicals affected by the Act. The majority of patents covered by the Act were licensed between 1919 and 1924, with most licenses granted in 1920 and 1921. Moser and Voena found that, in the chemical industries affected, domestic innovation increased by almost 20 per cent following the introduction of the Act. However, the relevance of this result to compulsory licensing generally is questionable, given the war-related circumstances under which patents were confiscated.

Scherer (2000) also undertook an empirical study of compulsory licensing in the United States. He looked at the impact of compulsory licensing on the privately-financed R&D expenditures (undertaken in 1975) of more than 40 US companies that had been subject to mandatory patent licensing. One of the primary intentions of such an empirical investigation was to determine to what extent, if any, the exercise of compulsory licensing provisions affected the incentives of firms to innovate (discussed earlier).

Scherer concluded that there was no significant statistical evidence that the companies subject to compulsory licensing under antitrust decrees undertook less intensive R&D than other firms of comparable size and industry origin. He also concluded in a related statistical analysis that compulsory licensing had had no discernible effect on industry concentration. It should be borne in mind, however, that the conclusions obtained in this empirical study do not necessarily generalise for different companies, time periods, or indeed, different countries.

3 Key features of patents systems in Australia and comparable markets

Key points

- Under the *Patents Act 1990* (Cwlth), an invention is eligible for a patent if it meets patentability criteria, including that it is a 'manner of manufacture', is novel, involves an inventive step and is useful.
- Australia and all comparable markets are signatories to key international intellectual property agreements, which condition patents systems. As a result, there are many similarities between patentability criteria, patent application processes and patent terms and conditions.
- There have been many reforms of patents systems in Australia and comparable markets in recent years. Common themes include: raising the threshold for patentability; further harmonisation of patents systems; and cooperation and sharing of resources between patents offices.
- Compulsory licensing provisions are a feature of patents systems in Australia and comparable markets. The specific grounds for a compulsory licence vary across countries, but typically include non-working of a patent, dependent patents, public interest and anticompetitive conduct.
- As in Australia, compulsory licences are rarely granted in most countries. Among developed countries, compulsory licensing appears to have occurred most frequently in the United States, particularly to remedy anticompetitive conduct and patent infringement. The US Government has also invoked government use provisions to gain access to patented inventions for defence and other national security related purposes.

This chapter provides an overview of key features of patents systems in Australia and comparable markets. This includes mechanisms that allow non-voluntary access to patents, such as compulsory licensing. More detailed information on patents systems is provided in appendices B and C.

What constitutes a comparable market is a complex issue that depends on a range of factors, such as a country's industrial structure, geography, form of government, human and physical capital, and the purpose of the analysis at hand. Like many other developed countries, the fact that Australia grants the majority of patents to non-residents is particularly relevant for this inquiry. For example, in 2010,

91 per cent of patents granted in New Zealand and 90 per cent in Canada were to non-residents (WIPO 2012a). Australia's status as a developed economy is also relevant, given the importance that places on attracting suppliers of advanced technologies. Hence, the United States is included in the comparison. Australia's significant trading relationship with Asian countries, such as China, has been a further consideration.

3.1 Key features of patents systems

Patents systems in Australia and comparable markets are broadly similar. For example, comparable markets provide intellectual property (IP) protection, have patents legislation and have a patents office. These similarities are largely because comparable markets are typically signatories to key international IP agreements, such as the Agreement on Trade-Related Aspects of Intellectual Property Rights 1994 (TRIPS), and efforts have been made in recent years to further harmonise patents systems. Similarities are also due to the common genesis of many patents systems. For example, Australia's patents system was influenced by the patents system in the United Kingdom and other countries.

The *Patents Act 1903* (Cwlth) established a national patents system in Australia. This Act was subsequently replaced by the *Patents Act 1952* (Cwlth) and most recently by the *Patents Act 1990* (Cwlth) (Patents Act). Under the current system, patents are granted by a statutory officer, the Commissioner of Patents, and IP Australia is the government agency with responsibility for administering the patents system. The Patents Act sets out the criteria for patentability of an invention. To be patentable, an invention must be a 'manner of manufacture', be novel, involve an inventive step and be useful. These requirements are discussed in more detail in appendix B.

In addition to patents, copyright and trademarks, Australia has a separate system of IP rights under the *Plant Breeder's Rights Act 1994* (Cwlth) for new varieties of plants that are distinguishable, uniform and stable. This is beyond the terms of reference for this inquiry, and so is not discussed further in this chapter (chapter 2 contains a brief discussion).

There are two types of patents available in Australia — standard and innovation patents. The TRIPS agreement requires signatories to provide standard patent protection for a minimum of 20 years. Consistent with this requirement, standard patents have a maximum term of 20 years in Australia, except patents for pharmaceuticals, which can be granted a 5-year extension, taking the maximum term to 25 years. Standard patents in comparable markets also have a 20-year

maximum term. Some comparable markets also allow extensions for pharmaceutical patents, including many members of the European Union, Japan, Korea and the United States. Extensions also exist for agricultural chemicals and veterinary products in some countries.

Innovation patents have a maximum term of eight years in Australia, and provide patent protection to inventions that do not meet the inventive threshold required for standard patents. These patents were introduced in 2001, and were intended to provide inventors with a relatively quick and inexpensive way to obtain patent protection for an incremental advance on existing technology, rather than a ground-breaking invention.

In most comparable markets, inventions can be protected under a 'utility model', equivalent to innovation patents in Australia. Utility model patents have a maximum term of: 6 years in France; 10 years in Germany; 10–15 years in Japan; and 15 years in Korea. In these markets, like Australia's innovation patents, utility model patents have less stringent requirements for patentability, lower fees and a more streamlined application process.

Application process

Standard patents

In Australia, applications for a standard patent must disclose sufficient information, such that a person skilled in the relevant field could replicate the invention. Prior to submitting an application, an inventor may undertake a search to determine if a similar invention has been patented, which will affect the likelihood of a patent being granted. An inventor may also engage a patent attorney to represent them. Applications accepted by IP Australia are published in the *Australian Official Journal of Patents* 18 months after the date the application was filed. Once an application is published, third parties have three months to start 'opposition proceedings' and challenge the validity of the patent application.

Australia, like all comparable markets, has a 'first-to-file' system, where the right to the grant of a patent lies with the first person to file a patent application. Until recently the United States had a 'first-to-invent' system, but moved to a first-to-file system in March 2013 as part of changes made under the America Invents Act, which was passed into law in 2011.

Accepted applications are subject to mandatory examination (assessment against patentability criteria). Applicants must request examination within five years of filing an application. Within 12 months of requesting examination, IP Australia

advises applicants whether their application meets the patentability requirements. Applicants can modify and resubmit their application. Once an application has passed examination and opposition proceedings have been resolved, a patent is granted. Annual renewal (maintenance) fees are payable from four years after grant and increase steeply over the term of the patent. A request for re-examination can be made once a patent is granted, subject to narrower grounds than for opposition proceedings.

Pre- or post-grant patent review provisions exist in most comparable markets. Opposition proceedings are available in some comparable markets subject to time limits, which are similar in Australia. However, they have been abolished in a number of countries. For example, in Japan, opposition proceedings were abolished in 2004 because they were considered redundant since patent invalidation proceedings were also available (Okuyama 2007). Other review procedures exist for challenging patents in comparable markets. For example, in the United States, a request for re-examination of a patent can be made by anyone at any time during a patent's term.

It is difficult to compare the cost of obtaining a patent in Australia with comparable markets because application processes differ, translation requirements might exist and fees are charged in the local currency. Costs change regularly, in part due to patents reforms, which also makes comparison more difficult. Park (2010) compared the costs of applying for a patent of specific complexity across countries. He found that it cost about US $20 000 to obtain a patent in Australia, which was about 50 per cent higher than in Germany and Japan, and between 10 and 20 per cent lower than in Canada, China, the United Kingdom and the United States. The mix of fees also varied, with the United States having the highest proportion of application fees and the lowest proportion of renewal fees.

Innovation patents

In contrast with a standard patent, innovation patents can be registered (or granted) without substantive examination. An innovation patent will be examined only if requested, as examination is not a requirement, unless the patent holder requires that the patent be enforceable. Examination of an innovation patent can only happen after it is granted (IP Australia nda). Some comparable markets with utility models, equivalent to innovation patents, have substantive examination requirements. The Advisory Council on Intellectual Property (ACIP 2011) is currently investigating the effectiveness of innovation patents.

In the past decade, applications for innovation patents in Australia have been stable, and small, relative to standard patents (less than 10 per cent). In contrast, utility

model applications worldwide have grown rapidly in recent years. Applications received by the Chinese IP Office make up most of these applications (83 per cent in 2010). Worldwide, the proportion of utility model applications made by domestic applicants is higher than for standard patents. This is particularly the case in China where, in 2010, 99 per cent of applications were made by domestic applicants (WIPO 2012a).

International applications

Many Australian inventors apply for a patent overseas as well as in Australia. They do so because an Australian patent only provides protection in Australia. Patent owners have two options for an international application.

- Patent Cooperation Treaty application — this allows an applicant to file a patent application with IP Australia and opt for protection in over 100 countries.
- Paris Convention application — if protection is only sought in a few countries, it might be cost effective for an applicant to make separate patent applications in each country.

Foreign inventors can apply for a patent in Australia. In 2011, about 93 per cent of patents granted in Australia were to non-residents. Statistics on patents, including country of origin of patent grantees, are presented in chapter 4.

Subject matter exclusions

Exclusions from patentability for particular types of subject matter exist in Australia and in comparable markets. Many are health related. Australia's Patents Act states that 'human beings, and the biological processes for their generation, are not patentable inventions' (s. 18(2)). With respect to innovation patents, the Patents Act states that 'plants and animals, and the biological processes for the generation of plants and animals, are not patentable inventions' (s. 18(3)).[1]

Most comparable markets have similar subject matter exclusions. Chapter 9 discusses health-related subject matter exclusions in more detail. Other typical subject matter exclusions in comparable markets include discoveries, scientific theories or mathematical methods, inventions contrary to public policy or morality, business methods and methods of medical treatment and diagnosis. Subject matter exclusions are discussed in more detail in appendix B.

[1] The exclusion for the purposes of an innovation patent does not apply if the invention is a microbiological process, or a product of such a process (Patents Act s. 18(3)).

Patent strength and quality

In recent decades, a number of authors have compared the 'strength' or 'quality' of patents systems across countries (for example, Ginarte and Park 1997; Park 2008; Rapp and Rozek 1990; de Saint-Georges and van Pottelsberghe 2011; Tiwari 2012). Strength tends to relate to the degree of protection provided by patents, whereas quality relates to the rigour and transparency of the patent application process (a more detailed discussion of patent design is contained in chapter 2).

This literature has consistently found that developed countries have stronger patents systems than developing countries. Park (2008) and Tiwari (2012) both found that Australia had a strong patents system, but its system was not as strong as systems in some EU member countries, Japan and the United States. De Saint-Georges and van Pottelsberghe (2011) examined the quality of patents systems in 32 mostly developed countries. Australia was ranked as medium-low behind the European Patent Office, Japan and the United Kingdom but was ranked ahead of the United States. These rankings do not take account of recent reforms in Australia and comparable markets. Patent strength and quality is discussed in more detail in appendix B.

Recent patents reforms

Australia, like most countries, has undertaken significant reforms to its patents system in recent years. The latest package of reforms in Australia — titled 'Raising the Bar' — led to extensive changes. A key rationale for these reforms was to raise the threshold for granting patents so that it is consistent with higher standards overseas. More specifically, the reforms aimed to raise standards by:

- requiring more information to be provided in patent applications and specifications, and that the patent has a credible use consistent with the information provided
- increasing the threshold for inventiveness, including by taking into account common general knowledge from overseas
- ensuring that a consistent standard of proof is applied by the Commissioner of Patents.

The compulsory licensing provisions were untouched by the 'Raising the Bar' reforms, and no significant changes have been foreshadowed at this stage. The 'Raising the Bar' reforms are discussed in more detail in appendix B.

Reforms in comparable markets have also been oriented to 'raise the bar'. Other common themes of recent reforms include moves to harmonise patents systems and

to increase cooperation and share resources between patents offices. For example, the five largest patents offices established a forum aimed at 'the elimination of unnecessary duplication of work among the offices [and the] enhancement of patent examination efficiency and quality' (Five IP Offices 2012).[2] Key recent reforms in Australia and comparable markets are discussed in more detail in appendix B.

International agreements

Australia is a party to several international agreements which, in addition to establishing patentability criteria, impose conditions on Australia's right to authorise non-voluntary access to patents (including compulsory licences). These agreements can influence Australia's patents system. The agreements most relevant to this inquiry are the Paris Convention for the Protection of Industrial Property 1883 (Paris Convention); the TRIPS Agreement; and the Australia–United States Free Trade Agreement (AUSFTA) (these agreements are further discussed in chapter 6 as they relate to compulsory licensing, and in appendix D in greater detail).

3.2 Non-voluntary access to patents

As mentioned in chapter 1, there are currently seven mechanisms in the Patents Act that allow a patented invention to be exploited without the patentee's authorisation. Such mechanisms are essentially safeguards to be invoked in exceptional cases where the outcome associated with a patent would not serve the best interests of the community as a whole (chapter 2). This section provides an overview of the relevant mechanisms in Australia and their equivalents in comparable markets.

Compulsory licensing

Sections 133–140 of the Patents Act allow a person to apply to the Federal Court for an order requiring a patentee to grant the applicant a non-exclusive licence to 'work' a patented invention.[3] There are two grounds for the granting of a

[2] The five largest patents offices are: European Patent Office; Japan Patent Office; Korean Intellectual Property Office; State Intellectual Property Office of the People's Republic of China; and United States Patent and Trademark Office.

[3] 'Work' means: to make or import a product, where the invention is a product; or to use the method or process to make or import a product, where the invention is a method or process. Parties can apply for a compulsory licence order only after three years have passed since the patent was granted (*Patents Regulations 1991*, r. 12.1).

compulsory licence. An applicant must satisfy either a 'reasonable requirements of the public' test or demonstrate that certain offences under competition law have, or are going to, occur (chapter 6). Compensation must be provided to the patentee. This has to be an amount negotiated by the patentee and applicant, or an amount determined by the Federal Court as just and reasonable, having regard to the economic value of the licence and the desirability of discouraging anticompetitive behaviour (s. 133(5)). There appears to have only been three applications for a compulsory licence in Australia, and none were granted (chapter 1).

A third ground for compulsory licensing has been foreshadowed. In 2011, the Australian Government announced its intention to implement a TRIPS Protocol which will allow compulsory licensing for the purpose of exporting pharmaceuticals to developing countries (Carr and Emerson 2011). A draft of the Bill was released in August 2012. This mechanism is discussed in more detail in chapter 8. A number of comparable markets have already implemented the TRIPS Protocol, including Canada, which has issued one compulsory licence for the export of an AIDS drug to Rwanda. At the time of writing, no other country had issued such a compulsory licence.

Compulsory licensing provisions exist in almost all comparable markets, and have similar features to Australian provisions, in part because these countries, like Australia, are signatories to a number of international IP agreements. The US system stands in contrast to other systems, as it does not have compulsory licensing provisions in its patents legislation. However, provisions similar to compulsory licensing are contained in the Clean Air Act, Atomic Energy Act of 1954 and a number of other pieces of legislation. Compulsory licensing is also available to remedy antitrust violations and can be ordered in patent infringement cases.

Among comparable markets, despite its absence from patents legislation, compulsory licensing appears to have been used most frequently in the United States, particularly to remedy anticompetitive conduct, and more recently in patent infringement cases. Compulsory licensing in comparable markets is discussed in more detail in appendix C. Table 3.1 compares key features of compulsory licensing provisions in Australia and selected comparable markets.

Of the four grounds for compulsory licensing in patents legislation listed in table 3.1, all are contained in Australia's Patents Act. Most countries allow at least one of these grounds for compulsory licences in their patents legislation (with the exception of the United States, as mentioned). While competition grounds for compulsory licensing exist in most comparable markets, the features of these provisions differ. For example, in Australia the Patents Act makes reference to breaches of the *Competition and Consumer Act 2010* (Cwlth). In contrast, US

competition grounds are based on case law, rather than explicit provisions in either US patents or competition legislation. Among the countries listed in table 3.1, compulsory licences have been granted in the past decade in Canada, Malaysia and the United States.

Table 3.1 **Features of compulsory licensing in patents systems in selected countries**

	Grounds for compulsory licensing in patents legislation[a]				*Competition grounds for use of compulsory licensing*[b]	*Use of compulsory licensing in past decade*
	Non-working of patent	*Dependent patent*	*Patent abuse*	*Public interest*		
Australia	✓	✓	✓	✓	✓	×
Canada	×	×	✓	×	✓	✓
China	✓	✓	✓	✓	✓	×
France	✓	✓	×	✓	✓	×
Germany	✓	✓	×	✓	✓	×
Japan	✓	✓	×	✓	×	×
Korea	✓	✓	✓	✓	×	×
Malaysia	✓	✓	✓	×	✓	✓
New Zealand	✓	×	×	×	×	×
United Kingdom	✓	✓	✓	✓	✓	×
United States	×	×	×	×	✓	✓

[a] In this table, a cross means that the relevant ground is not *explicitly* provided for in patents legislation. [b] A competition ground for compulsory licensing might exist in patents or competition legislation or have its basis in case law.

Sources: WIPO (2010a), (2011b); national legislation.

Government use and acquisition

The Crown use provisions of the Patents Act (ss. 163–170) provide for the Australian, State and/or Territory Governments, or a person or organisation authorised by them or their agencies, to use a patent with protection from legal action for patent infringement. Such use is only permissible where the use is for the services of the Australian, State and/or Territory Governments. If this provision is invoked, the patent holder is entitled to remuneration under s. 165 of the Act. If the parties do not agree to terms, the Federal Court can determine them. There are two reported cases in which Crown use has been contested in court (discussed in more detail in chapter 7).

Crown acquisition is also available to governments. In addition to the Commonwealth acquiring a patent from a willing seller on agreed terms, the Patents Act (s. 171) provides for the Governor-General to direct that a patent, or an invention that is the subject of a patent application, be acquired by the Commonwealth with all rights in respect of the patent or invention transferred to the Commonwealth. In this case, reflecting s. 51(xxxi) of the Australian Constitution, the Commonwealth must pay compensation to the patent holder on agreed terms or, in the absence of agreement, on terms determined by a prescribed court. While governments may have acquired patents on a voluntary basis, to the Commission's knowledge they have never compulsory acquired a patent. Crown use and acquisition is discussed in more detail in chapter 7.

Government use provisions also exist in comparable markets. The provisions in Canada, New Zealand and the United Kingdom are most similar to Australia's. It appears that most comparable markets have rarely invoked their government use provisions. A notable exception is the United States, which has relied on such provisions predominantly for defence and national security purposes (Reichman 2006).

Research and regulatory approval exemptions

Two exemptions from patent infringement were clarified and strengthened in Australia's Patents Act as part of the 'Raising the Bar' reforms.

- A regulatory approval exemption for activities undertaken for the purpose of obtaining information required for regulatory approval to market or manufacture a patented technology. The exemption applies to all regulated technologies with the exception of regulatory activities relating to pharmaceutical patents, which were already exempt (s. 119B).
- A research exemption for experimental activities that applies to all research activities where the predominant purpose of those activities is to gain new knowledge, or test a supposition or principle about the invention, or improve on or modify the invention (s. 119C) (IP Australia 2012b).

Unlike other parts of the 'Raising the Bar' reforms, these changes came into effect immediately after the legislation was passed. They aimed to address particular areas of concern for which compulsory licensing might have been used as a remedy.

Many comparable markets have research exemptions and almost all have regulatory approval exemptions. These are similar in nature to Australian exemptions. The Australian exemptions are discussed in more detail in chapter 8. Research and

regulatory approval exemptions in comparable markets are discussed in more detail in appendix C.

Other mechanisms

Australia's Patents Act also allows use of a patented invention without the owner's authorisation in cases of prior use and temporary presence.

The prior use exemption covers cases when exploitation of a product, method or process, or 'definite steps' (contractually or otherwise) to exploit, occurred immediately before the 'priority date' (filing date of the patent application) (s. 119). This exemption does not apply when exploitation of a patent had stopped or been abandoned. The prior use exemption ensures that the grant of a patent does not prevent parties other than the patentee continuing research and development activity already underway, and avoids researchers having to continually monitor the patents register to check that they are not infringing patents. Broad prior use exemptions exist in comparable markets. In the United States, the prior use exemption was recently expanded from business method patents to all patents, as part of the America Invents Act.

The temporary presence exemption covers use on board or in the construction of foreign vessels, aircraft or vehicles, temporarily or accidentally in Australia (s. 118). This exemption has its origins in nineteenth century English law, and is common in contemporary patents legislation around the world. The exemption was adopted by the United States and later internationally through the Paris Convention. Courts interpreting this exemption have found that it covers cases where a party is 'entering for a period of time of finite duration with the sole purpose of engaging in international commerce'. There are arguments that this exemption is exploited by vessels choosing 'flags of convenience' to avoid patent infringement. There have been proposals to establish an international patent register to address this problem (Jonas Anderson 2008).

4 Current utilisation of patents in Australia and comparable markets

Key points

- The Commission has reviewed evidence from Australia and overseas to identify any problems with accessing patented inventions.
- A substantial number of inventions are patented in Australia each year. Most are granted to non-residents. The benefit the Australian community receives from new technologies is, therefore, likely to depend on the extent of their accessibility in Australia.
- There are essentially three routes through which the community can access patented inventions — a patent owner manufactures the product itself, sells the patent to another party, or licenses it.
- Survey data from Europe, Japan, and the United States suggest that, among organisations that own patents, around half of patents are used solely by their owner, roughly 40 per cent are unused, and only a small proportion (roughly 10 per cent) are licensed to others.
- The low rate of licensing does not necessarily indicate that patent owners intend to deny access to their technologies. Survey evidence and comments from inquiry participants suggest the reverse — that patent owners do not license out as much as they would like.
- Further research is required about the impediments faced by patent owners in licensing their inventions. Potential barriers discussed in the literature — such as difficulties in identifying licensing partners — would not be addressed by compulsory licensing.
- Where 'patent thickets' occur, the private sector has mostly been able to address access issues through use of patent pools and clearinghouses. These can benefit the community as a whole, provided competition laws prevent patent owners from using them as vehicles to reduce competition.

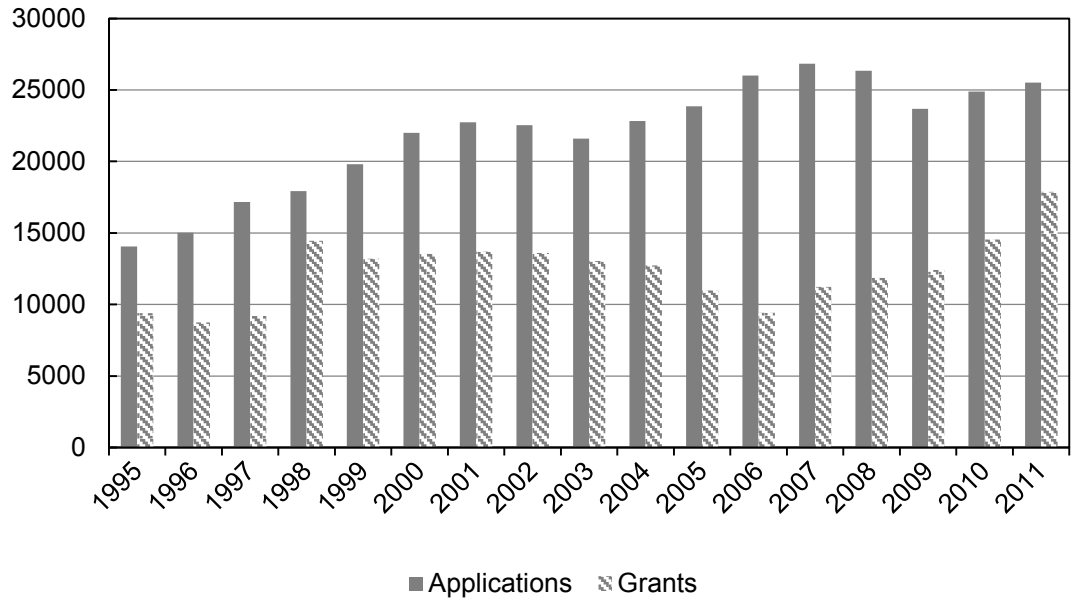
A substantial number of inventions are patented in Australia and other industrialised economies each year. Hence, the benefit that the community receives from inventions is likely to significantly depend on how they can be exploited under the patents system, and the extent to which this is occurring. This chapter reviews the available literature and evidence in order to identify what, if any, problems

generally exist with accessing patented inventions. The next chapter examines issues specific to accessing particular technologies, such as gene patents.

4.1 Patenting of inventions

In Australia, the annual number of standard patents applied for and granted is somewhat volatile (figure 4.1). In the past decade, however, growth in (standard) patent applications and grants has been moderate. From 2001 to 2011, applications rose by about 12 per cent, while grants rose by about 30 per cent. Over the same period, Australia's real GDP (in chain volume terms) increased by around 35 per cent (ABS 2012).

Figure 4.1 **Patent applications and grants in Australia, 1995 to 2011[a]**



a Data are for standard patents only. The difference between standard and innovation patents is discussed in chapter 3.

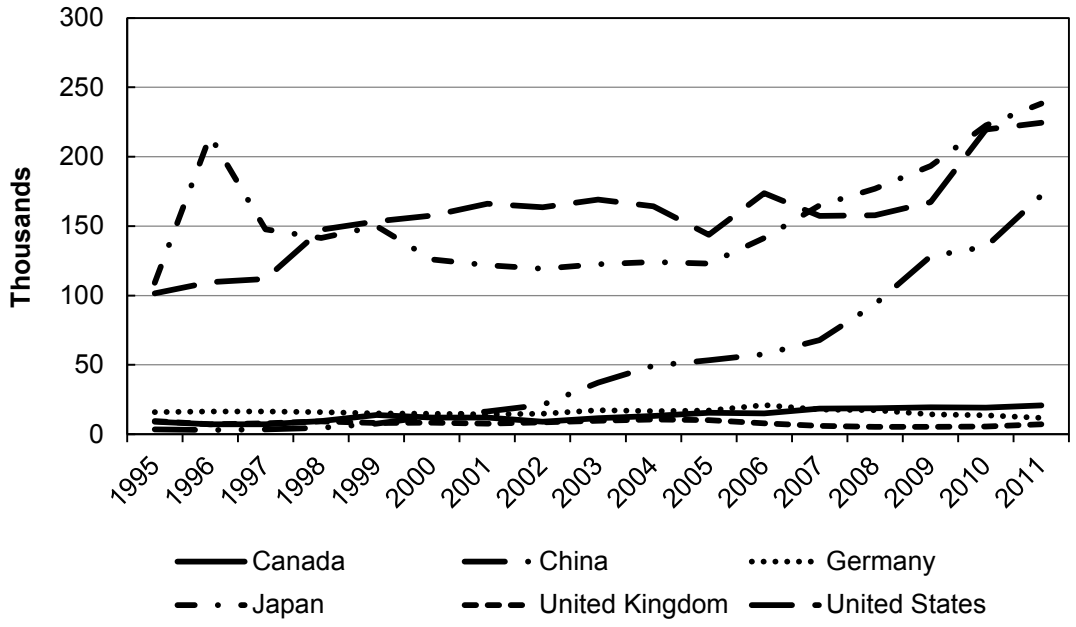
Source: WIPO (2012b).

There are a number of possible explanations for the difference between patent applications and patent grants, including the threshold required for an innovation to be patented. Some innovations for which inventors have submitted a patent application would not meet the threshold and, hence, would not be granted a patent.

Over the past 15 years, annual patent grants in a number of other economies have also increased. For instance, in 1995, patent grants in Japan totalled approximately 110 000, and had risen to nearly 240 000 by 2011 (figure 4.2). Similarly, in the United States, the number of patents granted increased from just over 100 000 in

1995 to about 220 000 in 2011. China, in particular, has seen a significant rise in the number of patent grants, from approximately 3000 in 1995 to about 172 000 in 2011. A notable exception to rising patent grants has been the United Kingdom, where grants fell to a little over 7000 in 2011, down from over 9000 in 1995.

Figure 4.2 **Patents granted in selected countries, 1995 to 2011**



Source: WIPO (2012b).

The majority of patents granted in Australia are to non-residents. For example, out of the total of 17 877 patents granted in 2011, 1267 of these were granted to residents. Nearly 7500 (42 per cent) of patents were granted to residents of the United States, with the next most significant foreign country being Japan, which received over 1600 patent grants (9 per cent) (table 4.1).

Besides being granted a patent in Australia, Australian residents may also be granted patents by overseas patent offices. In 2011, the total number of patents granted to Australian residents by overseas patent offices was 4895. This represents significant growth on earlier overseas grants to Australian residents. For example, in 1995, the number of patents granted to Australians by overseas patent offices totalled 1421 (WIPO 2012b), representing an increase of about 8 per cent per annum from 1995 to 2011.

Table 4.1 **Nationality of parties granted Australian patents, 1995 to 2011**

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
United Kingdom	4	6
United States	42	43
Other	14	10
Total	100	100

Source: WIPO (2012b).

The World Intellectual Property Organisation collects information on the field of technology in which patent applications were made. Over the period from 1997 to 2011, the most significant field of technology in which patents were applied for in Australia was civil engineering, accounting for roughly 8 per cent of the total share of patent applications, followed by medical technology and pharmaceuticals (table 4.2).

Canada has a number of similarities with Australia, including being a net importer of technology. In 2011, about 7 per cent of Australian patents were granted to residents, and in Canada it was around 10 per cent (WIPO 2012e). There are also some similarities with Australia with respect to the technology fields in which patents are granted. For instance, civil engineering accounted for a similar proportion of patent applications in both countries.

By contrast, the United States is a much larger economy and it grants many more patents. The number of US patents granted to residents has been slightly exceeded by those granted to non-residents in recent years. However, US residents are also granted a large number of patents in other countries (WIPO 2012b). In common with Canada, the most important field of technology for US patent applications is computer technology. Unlike Australia and Canada, civil engineering does not feature as a prominent field of technology.

Table 4.2 **Patent applications by field of technology, 1997 to 2011**

Percentage share of total patent applications[a]

Australia		*United States*		*Canada*	
Field of technology	*Share*	*Field of technology*	*Share*	*Field of technology*	*Share*
Civil engineering	8	Computer technology	10	Computer technology	8
Medical technology	7	Medical technology	8	Digital communication	7
Pharmaceuticals	6	Pharmaceuticals	6	Civil engineering	7
Biotechnology	5	Electrical machinery, apparatus, energy	4	Pharmaceuticals	6
Computer technology	5	Organic fine chemistry	4	Telecommunications	5
Textile and paper machines	5	Digital communication	4	Other special machines	5
Other special machines	4	Biotechnology	4	Transport	4
Handling	4	Measurement (instruments)	4	Medical technology	4
Furniture, games	4	Telecommunications	4	Biotechnology	4
Measurement (instruments)	4	Audio-visual technology	3	Electrical machinery, apparatus, energy	4
Other	49	Other	48	Other	46

[a] Columns may not sum to 100 due to rounding.

Sources: WIPO (2012d, 2012e, 2012f).

4.2 Exploitation of patents by the innovator

After an organisation has created a new innovation, applied for a patent, and the patent has been granted to them, they would typically seek to commercially exploit the innovation. The party that has created the innovation might itself decide to be the sole manufacturer of the patented product, or a product that uses the patented good as an input, and market these accordingly. For example, the pharmaceutical company Merck & Co., Inc. has a patent on Zostavax, a vaccine for shingles (Merck & Co., Inc. 2012), a drug which the company also manufactures.

Where the patentee is solely responsible for commercialisation, they retain the exclusive rights to the innovation that are afforded by the patent, and seek to realise the full returns anticipated from the development of the product.

If an innovator fails to work a patent, however, and allows it to remain dormant, there are mechanisms available to ensure that the patented innovation reaches the public, where the public interest suggests such action might be warranted. Compulsory licensing is one of these mechanisms — the 1925 Hague revision of

the Paris Convention incorporated compulsory licencing in order to address the absence of effective exploitation of a patent by a patentee (chapter 2; Gontijo 2005).

There are a number of reasons why a patent holder may decide not to 'work' a patent. For instance, some innovations protected by patents may simply offer limited opportunity for commercial development, and hence, patentees may not carry the innovation forward to the stage of commercialisation. This might occur if, for example, anticipated demand for a final product based on the innovation was so low as to make such a product unprofitable.

There is some empirical evidence that sheds light on the purposes for which companies and other organisations use their patents. A group of European researchers undertook a wide-ranging survey of the inventors of approximately 9000 inventions patented in Europe (Giuri et al. 2007). The patents included in the survey had been granted between 1993 and 1997, to inventors in France, Germany, Italy, the Netherlands, Spain, and the United Kingdom.

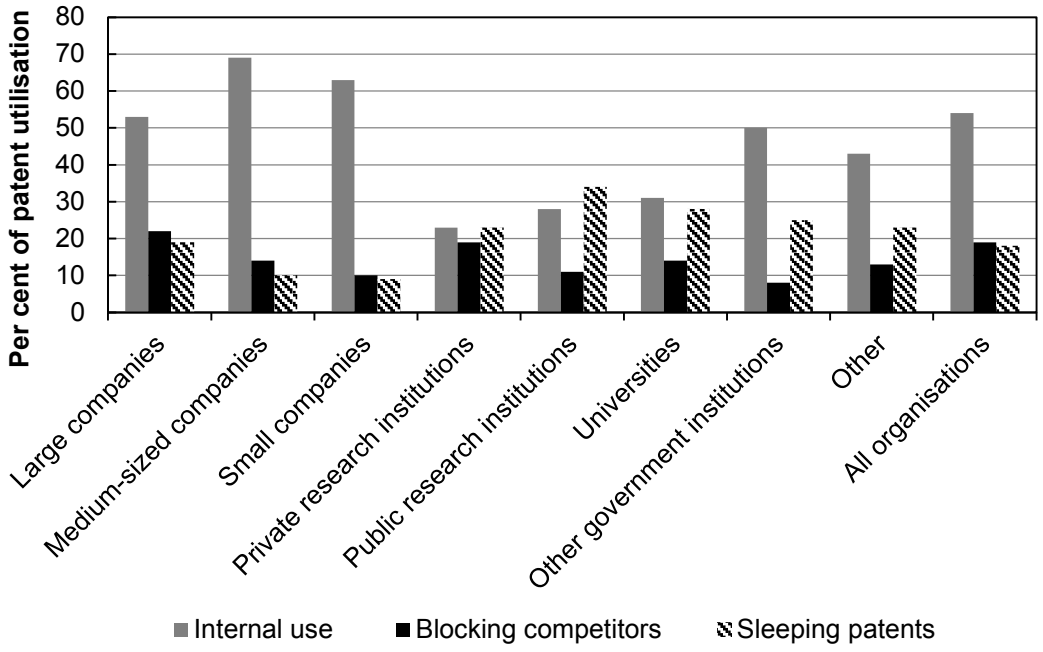
The researchers asked survey respondents how their patents were utilised — for example, whether they were used internally for commercial and industrial purposes, or were instead licensed-out to other parties, or used to 'block' competitors. The survey indicated that large companies used roughly half of their patents internally. Medium and small-sized companies used a greater fraction of their patents internally than large firms (figure 4.3).

Sleeping patents — those that were not commercially exploited by the owner, were not licensed, or were not used for blocking purposes (whether or not specifically sought for such purposes) — appeared to be correlated with the size of European companies. The study indicated that larger firms had a higher proportion of sleeping patents than smaller-sized companies. Blocking patents also appeared to be correlated with firm size, with larger companies exhibiting a greater use of blocking patents than medium-sized and smaller companies. Somewhat surprisingly, public and private research institutions, as well as universities, reported using blocking patents. This behaviour would appear, prima facie, to be inconsistent with the objective of creating and disseminating new knowledge.

According to Giuri et al. (2007), the reason why larger companies had a higher fraction of blocking and sleeping patents than smaller organisations may stem from their lower incremental costs of patenting. Larger companies are more likely to possess specialised divisions dealing with issues related to patents, making the additional costs of applying for a patent relatively low compared with smaller companies. As a result, larger companies may patent more 'minor' innovations

which are unlikely to be commercially exploited, resulting in a greater proportion of unused patents than smaller companies.

Figure 4.3 **Patent utilisation in PatVal-EU survey, by organisation type**[a, b, c]



[a] Small companies are defined as those with less than 100 employees. Medium-sized companies are those with 100–250 employees, while large companies are defined as having more than 250 employees. [b] Based on 7556 observations. [c] 'Internal use' comprises the categories of 'internal use only' and 'licensing and use', which are disaggregated in table 4.5.

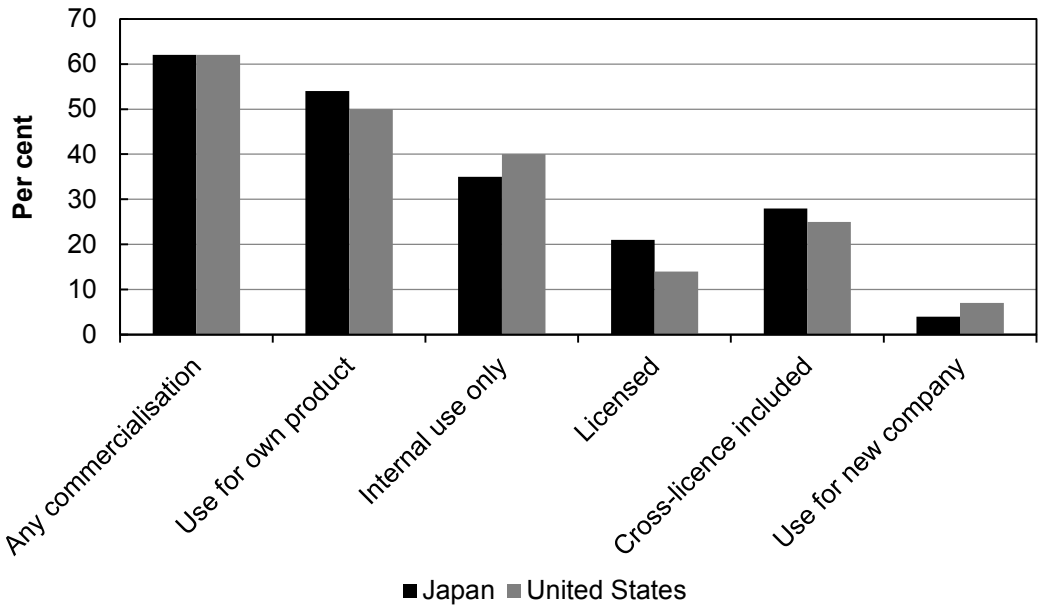
Source: Giuri et al. (2007).

The results of the PatVal-EU survey on patent utilisation provide a point of comparison with a similar study undertaken for Japan and the United States by Sadao and Walsh (2009). These researchers analysed a sample of 'triadic' patents (those for which a patent was granted by the US patent office and applied for at both the Japanese and European patent offices) through a survey conducted in 2007 (the RIETI-Georgia Tech survey). The Japanese stream of the survey yielded information on roughly 3700 patents, while the US survey utilised a sample of just over 1900 patents.

It was found that just over 60 per cent of triadic patents in Japan and the United States were used commercially in some form (figure 4.4), whether that be for the patentee's own products and processes, licensing, or use for a start-up by the inventor (note that these uses are not mutually exclusive). Similar to the PatVal-EU survey, the most important mechanism for commercialisation was in-house use (54 per cent in Japan and 50 per cent in the United States), although pure in-house use (use of the patent internally by the patentee only) was less extensive.

Internal commercialisation by patentees was found to be higher for smaller companies than larger ones, both in Japan and the United States. In Japan, 55 per cent of large companies (defined as those employing 500 or more people) commercialised internally, increasing to over 60 per cent for small companies (employing 101 to 250 people), and to 70 per cent for very small companies (employing 100 or less people). Reflecting a similar pattern, in the United States, 50 per cent of large companies commercialised internally, increasing to approximately 65 per cent for small firms, before declining slightly to 60 per cent for very small firms. Again, these results are broadly comparable with those obtained in the PatVal-EU survey.

Figure 4.4 **Commercialisation of inventions in RIETI-Georgia Tech survey**
Per cent of patents[a]



[a] Use for new company relates to use for start-ups.

Source: Sadao and Walsh (2009).

Sadao and Walsh (2009) also surveyed companies about their failure to commercially develop a proportion of their patents. Overall, 38 per cent of triadic patents were not commercialised in both Japan and the United States. In Japan, 6 per cent of patents were used for strategic holding and were not commercialised — that is, they were used either to block competitors from patenting similar technology, or to prevent competitors from inventing around a patentee's current technology. The remaining 32 per cent of triadic patents in Japan were non-commercialised purely for non-strategic reasons (for example, because of delayed development of complementary products, or business downsizing). In the United States, 14 per cent of not commercialised triadic patents were used for

strategic holding, while the remaining 24 per cent were not commercialised for non-strategic reasons.

One of the main conclusions that may be drawn from the PatVal-EU and RIETI-Georgia Tech surveys of patent use is that roughly half of all patents are used internally for commercial purposes by the owner (without licensing) across organisation types and across countries. In addition, there appears to be a negative correlation between internal commercialisation and company size, with smaller companies commercially exploiting more of their patents internally than larger companies.

These studies also indicate that a significant share of patents are not commercially exploited. For instance, in the PatVal-EU survey, across all organisation types, more than 35 per cent of patents were either used for blocking competitors or remained unexploited for other purposes. The share of unutilised patents was positively correlated with company size. Similarly, the results of the RIETI-Georgia Tech survey indicated that nearly 40 per cent of patents in Japan and the United States were not commercialised.

However, the extent to which general conclusions can be drawn from two overseas studies of patent use is somewhat limited. While possibly indicative of certain aspects of patent utilisation, greater empirical evidence, especially with regard to Australia, is necessary to draw definitive conclusions.

4.3 Patent sale

Like other property rights, patents can be bought and sold. Sale of a patent is often referred to as an assignment, as distinct from licensing (Mendes nd).

Aggregate data and other information on patent assignments are generally quite limited, in part due to the commercially sensitive nature of such transactions. Nevertheless, some information on assignments can be gleaned from national patent offices. For example, the US Patent and Trademark Office (USPTO) maintains a searchable database with patent assignment information dating back to August 1980. Users can search for assignment information by, for example, patent number, assignor name, or assignee name (USPTO 2012b).

A study of patent assignments in the United States was undertaken by Serrano (2010), using data sourced from the USPTO's assignment database. Serrano collected information on US utility patents (as opposed to, for example, design and plant patents) granted between 1 January 1983 and 31 December 2001, and analysed the extent to which these patents were traded. The data demonstrated

that, across various types of organisations, the transfer of ownership of patents was generally limited. Even the most active traders of patents — private inventors and small corporations — on average sold a little over 10 per cent of their patents. Large companies and government agencies traded an even smaller fraction of their patents (table 4.3).

Table 4.3 **US utility patents traded and untraded**[a, b]

	Traded	*Not traded*	*Total*	*Per cent traded*
Individually owned and unassigned[c]	28 044	276 043	304 087	9
Individually owned by private inventors	2 185	15 469	17 654	12
Small corporations	54 533	399 150	453 683	12
Medium corporations	53 359	513 722	567 081	9
Large corporations	31 540	534 042	565 582	6
Government agencies	809	24 574	25 383	3

[a] Data refer to US utility patents granted between 1 January 1983 and 31 December 2001. [b] Small corporations refer to those granted no more than five patents in a given year. Large corporations refer to corporations with more than 100 patents granted in a given year. Medium corporations constitute the remainder. [c] Refers to patents still owned by their original inventors at the time of patenting, and for which the inventors have not yet granted rights to the invention to a legal entity.

Source: Serrano (2010).

IP Australia provided the Commission with data on patent assignments in Australia from its AusPat system. As registering an assignment with IP Australia is optional, the resulting data do not constitute a complete record of patent assignments in Australia. The data consist of assignments made by patent applicants under s. 113 of the *Patents Act 1990* (Cwlth); assignments made by a patentee under s. 187 of the Patents Act, and r. 19.1 of the Patents Regulations (Cwlth); and requests for assignments.

In 2002, IP Australia changed its recording system for patent assignments. Prior to this time, data were recorded as assignments by applicants or assignments by patentees. Under the newer system data are recorded as requests for assignment (IP Australia pers. comm., 19 October 2012). Hence, there is a gradual reduction in assignments by applicants and assignments by patentees recorded over time, and an increase in requests for assignment (table 4.4).

Drawing definitive conclusions from these data presents challenges, given the voluntary registration of assignments. While fluctuations in the number of registered assignments may reflect underlying changes in patents bought and sold, it may also simply be a reflection of changes in the propensity for those entering into agreements to register them. This makes it difficult to discern the presence of trends in the data, and to determine why assignment figures vary from year to year.

Table 4.4 **Patent assignments and requests for assignments in Australia recorded by IP Australia[a]**

Year	Assignments by applicants[b]	Assignments by patentees[c]	Requests for assignment	Total
2000	1 226	1 984	..	3 210
2001	1 390	1 983	..	3 373
2002	1 522	2 105	38	3 665
2003	1 101	2 322	689	4 112
2004	608	2 156	1 204	3 968
2005	219	1 679	1 714	3 612
2006	72	1 855	3 232	5 159
2007	16	1 427	4 143	5 586
2008	13	1 321	2 905	4 239
2009	4	997	3 054	4 055
2010	2	1 105	2 763	3 870
2011	..	677	3 107	3 784
2012	..	596	2 958	3 554
Total	6 173	20 207	25 807	52 187

a These data under report patent assignments in Australia since registration of assignments with IP Australia is optional. **b** Assignments by applicants refer to those made under s. 113 of the Patents Act. **c** Assignments by patentees refer to assignments made under s. 187 of the Patents Act, and r. 19.1 of the Patents Regulations (Cwlth). **..** Not applicable.

Source: IP Australia (unpublished).

4.4 Licensing of patents

A patent holder may license exploitation rights to another party. The patent holder who provides the licence is referred to as the licensor, while the firm or individual acquiring the exploitation rights is referred to as the licensee. A patent licence normally constitutes a legal arrangement, and thus will have associated conditions that the licensee must adhere to in exploiting the patented innovation (Mendes nd). However, it is not necessarily the case that all licence agreements are formally documented. For example, with respect to the medical biotechnology sector, the Centre for Law and Genetics observed that:

> … patent licences are tacitly agreed on a frequent basis, so that there is no written agreement as such on the terms comprising the agreement. (sub. 3, p. 7)

The Walter and Eliza Hall Institute of Medical Research (sub. 13) noted that, rather than have a standalone licence after an invention is fully developed, biomedical research organisations often build licensing provisions into agreements with their development partners.

Exclusive, non-exclusive and sole licences

Parties may choose to enter into an exclusive licence, which gives the licensee (and persons authorised by the licensee) the ability to exploit the innovation covered by the patent, and excludes the patent holder from doing the same (IP Australia 2012n). Exclusive licences may be limited to particular territories, specified periods of time, or certain specified uses, enabling the patent holder to exploit the patent in other cases (ALRC 2004). 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.

Alternatively, a patent holder might decide to enter into in a sole licence with a licensee. In contrast to an exclusive licence, a sole licence allows for both the patent holder and the licensee to commercially exploit a patented innovation. It also prohibits a patent holder from licensing the patent rights to any other party (ALRC 2004).

A non-exclusive licence gives the patentee greater freedom than an exclusive or sole licence, because the patentee retains the right to exploit the invention and to license it to other parties.

Why license?

There are many reasons why organisations might engage in licensing agreements. An organisation that licenses out patented technology to another organisation may, for instance, be motivated by:

- a desire to earn revenue from royalty and other payments
- a limited capacity or desire to manufacture the patented product in commercial quantities
- the ability to establish and take advantage of business networks in foreign jurisdictions
- preventing or settling patent litigation, especially where cross-licensing may be involved (ALRC 2004)
- a need to establish collaborative research networks, including through cross-licensing
- a desire to spread the risk associated with commercialisation (Institute of Patent and Trade Mark Attorneys and the Australian Federation of Intellectual Property Attorneys, sub. 18).

Reasons for licensing have also been put forward in the economic literature, and these mainly deal with strategic interactions among firms (for example, Gallini 1984; and Rockett 1990). Shepard (1987) argued that licensing could expand the industry-wide demand for a patented product by inducing quality competition between licensees. Nevertheless, licensing is not always an appropriate strategy for a firm from a profit-maximising perspective, nor is licensing necessarily always feasible.

As noted above, licensing out technology carries with it the risk of creating competitors in the product market, which can erode the market share of the patentee firm. To avoid this risk, firms may decline to license out their technology. Transaction and negotiating costs may also prevent the signing of licensing agreements, if prohibitively large (Arora and Fosfuri 2003).

Furthermore, patent holders may be reluctant to license their innovations if it requires disclosure of commercially sensitive information to third parties, or if they have concerns about the ability of potential licensees to successfully exploit the innovation in question (DeBoos and Wilson nd).

Some empirical information on why organisations engage in licensing agreements has been published by researchers at the OECD, following a survey conducted in 2007 (Zuniga and Guellec 2009). This survey obtained information on licensing out activity from a total of 612 European companies and a total of 1640 Japanese companies. A range of companies of different sizes were surveyed.

For both European and Japanese companies, it was found that the primary motivation to license was to earn revenue (cited by 60 per cent and 52 per cent of companies surveyed respectively), followed by a desire to enter into cross-licensing deals (cited by 18 per cent of companies in each region). In a similar vein, for Australia, Scott Bouvier observed:

> In my experience, patent holders will generally license their inventions to third parties that offer sufficient commercial incentive to do so. The potential to generate revenue or maximise adoptions tend to drive the Australian patent licensing system and ensures that licenses are made available to market. (sub. 2, p. 2)

Zuniga and Guellec (2009) also found that in Europe preventing others from infringing patents was a significant reason for licensing out, cited by 14 per cent of those surveyed. In Japan, however, the next most significant reason for licensing out was to establish patented technology as a de facto standard, and to outsource manufacturing, each of these motivations being cited by 11 per cent of surveyed firms.

Content of licences

There is little information on the content of licences. This reflects the commercial nature of the contracts made between organisations, which often include commercially sensitive information. As researchers at the OECD observed:

> Little is known on licensing transactions from a quantitative perspective: their volume, the profile of companies involved, the sectors where they are more prevalent, the motives for the firms involved, their economic effects … Anecdotal evidence is available for all these questions, but no statistics. (Zuniga and Guellec 2009, p. 6)

Inquiry participants generally held the view that there is a wide degree of variability in licence arrangements. For example, the Centre for Law and Genetics noted that:

> Our survey and interview evidence indicates that there are many different types of agreements, tailored to meet the requirements of the parties transacting and the technology involved. Thus a patent licence agreement (in this industry at least) may contain a myriad of terms … While there have been attempts to draft standard licensing agreements for the licensing of genetic inventions, their success has been limited … (sub. 3, p. 7)

Similarly, DeBoos and Wilson (nd, p. 1) observed that:

> There are very few standard licensing transactions. A lot will depend on the commercial context and the agreement used to transfer the rights should be tailored to accomplish the commercial objectives.

They listed a number of areas where licensing agreements can vary, including:

- the bundle of IP rights being licensed
- the type of activities permitted under the agreement
- whether sub-licensing is permitted
- possible field of use or territorial limits
- the approach to be taken to improvements and infringement issues
- the nature of any obligations to be placed on the licensee
- rewards for the licensor
- the obligations of confidentiality
- dispute resolution mechanisms
- duration of the licence, and termination rights
- obligations post-termination of the licence.

The Advisory Council on Intellectual Property (sub. 35) also noted the potential for licensing contracts to differ widely. The Walter and Eliza Hall Institute of Medical

Research (sub. 13) listed the matters that are often included in biomedical licensing agreements, and the scope for them to differ between agreements (box 4.1).

Box 4.1 **Biomedical licensing agreements**

The Walter and Eliza Hall Institute of Medical Research submitted information on the various types of provisions often included in licensing agreements in the biomedical sector. While certain matters must be enunciated in licensing contracts, their specific form and the emphases on different elements of the contract will inevitably differ from agreement to agreement.

In any licensing agreement, key concepts will be defined, such as the intellectual property (IP) included, the term of the agreement, geographical territory covered, related parties to the agreement, and the type of licensing arrangement entered into (that is, exclusive, non-exclusive, or sole). Common considerations regarding payments include (but are not limited to):

- upfront payments for access to background IP
- royalties, which, for example, may be fixed, increasing, decreasing, or milestone or threshold based
- provisions for royalty stacking in the event that access to other IP is required for commercialisation
- definition of returns in the event there is a combination product requiring IP from other parties.

A licensee will typically be required to ensure that the sale of products occurs on proper commercial terms, and that quantities are available as free samples, or for the purposes of donation.

Confidentiality provisions are standard. Academic licensors often require retained rights to the IP they license out to other parties, subject to confidentiality clauses. Commercial endeavour and performance obligations may also be part of a licence. These obligations seek to ensure that the IP covered by the agreement is commercially exploited, rather than remaining dormant.

Safeguards and procedures also exist to deal with issues that may arise, such as non-performance, conflict resolution, and termination of licences. For instance, if a licensee fails to honour its performance obligations and rectify alleged underperformance, a licensor may elect to limit the territory, or field of an agreement. The licensor may also convert an exclusive licence to a non-exclusive licence, or exclude foundation IP or improved IP from the agreement in light of alleged underperformance.

(continued next page)

Box 4.1 (continued)

Parties typically agree in advance on the procedures for addressing conflict, and failing internal resolution, a third party (or parties) may be appointed. A common example of an external party performing this role is the Licensing Executives Society. Criteria for termination of a licensing agreement are often related to financial solvency of the parties involved, and their adherence to the terms of the agreement.

Source: WEHI (sub. 13).).

Prevalence of licensing

As mentioned, information on the prevalence of voluntary licensing is limited. The PatVal-EU and RIETI-Georgia Tech surveys noted earlier suggest that the extent of licensing is relatively low, at least among surveyed European, Japanese and US patent holders. For example, the PatVal-EU survey found that, across all organisations, less than 15 per cent of patents were licensed in some form (table 4.5). In comparison, about half of all patents were used solely by their owner and nearly 40 per cent were unused. Possible reasons for the low rate of licensing, and the implications it might have for public policy, are discussed later in this chapter.

Table 4.5 **Patent use in PatVal-EU survey, by organisation type[a]**
Per cent

	Internal use only	*Licensing only*	*Cross licensing*	*Licensing and use*	*Blocking competitors*	*Sleeping patents*	*Total*
Large companies[b]	50	3	3	3	22	19	100
Medium sized companies[b]	66	5	1	4	14	10	100
Small companies[b]	56	15	4	7	10	9	100
Private research institutions	17	35	0	6	19	23	100
Public research institutions	22	23	4	6	11	34	100
Universities	26	23	5	5	14	28	100
Other government institutions	42	17	0	8	8	25	100
Other	34	17	4	9	13	23	100
All organisations	51	6	3	4	19	18	100

a Data are based on a sample of 7556 patents granted by the European Patent Office with priority dates between 1993 and 1997. Countries included in the survey were: Germany, France, the UK, Italy, the Netherlands and Spain. The survey was carried out in 2003 and 2004. **b** Small companies defined as those with less than 100 employees. Medium companies defined as those with 100–250 employees. Large companies are defined as having more than 250 employees.

Source: Giuri et al. (2007).

Patent licensing records in Australia

IP Australia possesses a patent register, and a number of voluntary patent licensing agreements have been registered on it over time. Some aggregated information on patent licences is available from this source.[1]

It is important to keep in mind, however, that there was no obligation on parties to register a licence with IP Australia. Hence, its database does not represent a complete record of all voluntary patent licences in Australia (as discussed earlier), and so the actual aggregate characteristics and distribution of licences across industries may differ significantly from the data reported here.

From 1989 to 2012, the number of voluntary licences recorded on IP Australia's register totalled 1091 (table 4.6), although the number was quite variable from year to year. For example, 145 licences were registered in 2011, preceded by 62 in 2010. For the purposes of comparison, a total of almost 18 000 patents were granted in 2011 alone, far exceeding the number of licences recorded with IP Australia over a much longer time horizon. It is difficult to determine whether this is because the extent of licensing in Australia is limited, or a low proportion of licensing agreements were registered with IP Australia.

The data suggest that licensing is not concentrated in a few industries. The technology group with the largest number of licences between 1989 and 2011 was civil engineering, building, and mining, followed by organic fine chemicals.

[1] From 30 January 2012, IP Australia's patent register is no longer a legal securities register, and the details of security interests may be recorded with the Personal Properties Securities Register (PPSR). The PPSR is operated by the Insolvency and Trustee Service Australia, which was unable to provide the Commission with data similar to that provided by IP Australia.

Table 4.6 **Voluntary patent licences recorded by IP Australia**[a]

Technology group	*Total number of licences, 1989–2012*	*Percentage share of registered licences*
Agricultural and food machinery	31	3
Agriculture, food	13	1
Analysis, measurement, control	77	7
Audiovisual	6	1
Basic chemical processing, petrol	21	2
Biotechnology	23	2
Civil engineering, building, mining	163	15
Consumer goods and equipment	72	7
Electrical devices and engineering	33	3
Engines, pumps, turbines	17	2
Environment, pollution	13	1
General processes	42	4
Handling, printing	80	7
Information technology	23	2
Macromolecular chemistry, polymers	7	1
Material processing	23	2
Materials, metallurgy	15	1
Mechanical elements	23	2
Mechanical tools	7	1
Medical engineering	60	5
Not yet classified	1	0
Optics	13	1
Organic fine chemicals	133	12
Pharmaceuticals, cosmetics	87	8
Semiconductors	2	0
Space technology, weapons	12	1
Surfaces, coatings	9	1
Telecommunications	18	2
Thermal techniques	46	4
Transport	21	2
Total	1 091	100

a Data do not include all voluntary licence agreements in Australia. The extent of underreporting is unknown.

Source: IP Australia (unpublished).

Licensing of medical biotechnology in Australia

A study by researchers at the Centre for Law and Genetics at the University of Tasmania sheds some light on licensing behaviour in the Australian medical biotechnology industry (Nicol and Nielsen 2003).

Of the organisations surveyed, only 52 per cent of research institutions, and just under 40 per cent of companies reported that they licensed out their IP. Of those

organisations that did license out, many had only a small number of licences (table 4.7).

Table 4.7 **Licensing out by the Australian medical biotechnology industry, 2003**[a]

	Research institutions		*Companies*	
Number of out-licences	*No.*	*Per cent of research institutions*	*No.*	*Per cent of companies*
0	8	35	24	49
1	3	13	3	6
2–4	3	13	9	18
5–9	2	9	1	2
10–19	0	0	0	0
20–49	1	4	1	2
More than 50	1	4	0	0
Number not specified	2	9	5	10
No answer	3	13	6	12

a Based on a survey by Nicole and Nielsen (2003).

Source: Nicol and Nielsen (2003).

Although some respondents seeking to acquire technology preferred to do so by assignment, others preferred to license in technology due to risk and uncertainty, which can make valuation of the technology for the purposes of assignment difficult. Indeed, royalty payments associated with patent licences have often been justified as a means of risk-sharing between patentees and licensees (Bousquet et al. 1998).

A subsequent study of Australian licensing behaviour in this industry was undertaken in 2007 by Nicol (2010). A total of 59 individuals from the industry were surveyed, with survey respondents holding positions within the organisations they worked for such as chief executive officer, director, patent expert, and chief scientific officer. A significant proportion of respondents (34 per cent), reported that they did not license in technology at all. Nicol (2010) concluded that assignment, rather than licensing, may be the preferred mechanism for accessing technology. The most common justification given by survey respondents for limited licensing was an ability to invent around patents.

Nicol (2010) also reported survey data on the degree of licensing out. Respondents indicated that licensing out was generally not a widespread activity. This could possibly indicate that many of the innovations protected by patents were at too early a stage of development to license out.

Why is there a low rate of licensing?

Several studies have considered whether the number of voluntary licensing agreements entered into by organisations holding patents, and those seeking to utilise them, could be increased. This is often seen as a desirable objective on the grounds that it would lead to a more widespread utilisation of technology, and hence, result in a greater diffusion of innovations.

As noted above, the PatVal-EU survey found a low rate of licensing of patents. The RIETI-Georgia Tech survey identified a similar situation for Japanese and US companies. A low rate of licensing however, does not necessarily indicate that patent owners regularly deny access to patented technologies on reasonable terms. Patent owners have an incentive to maximise the benefit they receive from their inventions. That goal is unlikely to be best served by refusing to license a patent.

The available evidence indicates that refusal to license patents on reasonable terms is not a major barrier to accessing patented innovations. Scott Bouvier submitted:

> … I see the issue of patent holders refusing to license their inventions as an uncommon and exceptional issue in the Australian context.
>
> The more familiar patent licensing issues my clients require assistance with tend to involve contentious negotiations of license terms or disputes that arise after a license has been granted. (sub. 2, p. 1)

Similarly, the Centre for Law and Genetics submitted with respect to the medical biotechnology industry:

> Both survey data and interview data indicated that refusals to license patents are not a pervasive issue for participants in this industry (in both contexts of out-licensing and in-licensing). (sub. 3, p. 6)

It appears that a more significant concern is that patent owners are not able to license as often as they would like to. In this regard, the Institute of Patent and Trade Mark Attorneys and the Australian Federation of Intellectual Property Attorneys noted:

> … there would be far more patentees who are unsuccessful in seeking a licensee in Australia than there would be patentees entering into licensing arrangements. One of the major obstacles for patentees is to find a licensee who is both willing and capable of bringing an invention to market. This is not a problem with the patent system but rather due to the fact that not every patentable idea will be commercially valuable. (sub. 18, p. 5)

The RIETI-Georgia Tech survey measured the gap between a patent owner's willingness to license and actual licensing activity. It was found that, in 2007, 40 per cent of Japanese organisations were willing to license their technology, but

only 21 per cent actually did so. Around 30 per cent of US organisations reported a willingness to license, but only 14 per cent did so (Sadao and Walsh 2009).

Similarly, survey data analysed by Zuniga and Guellec (2009) showed that in 2007, 24 per cent of European firms holding patents were willing to license them, but could not, while the corresponding share for Japanese firms was 53 per cent. A quarter of European firms cited difficulty in finding partners as their main reason for not licensing out, and 18 per cent of Japanese companies regarded this as an important barrier. Other reasons cited included the complexity and cost of drafting and negotiating contracts, lack of readiness of the innovation covered by the patent, and disagreements over pricing.

Further research is required on the impediments that patent owners face in licensing their inventions. This is beyond the scope of the inquiry. Potential barriers discussed in the literature include difficulties in identifying licensing partners; the cost and complexity of drafting and negotiating licence contracts; an invention not being a viable commercial proposition, 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.

4.5 Patent thickets, pools and clearinghouses

While patents provide a means to foster innovation by conferring exclusive rights for an innovation on a patent owner, they may also create difficulties accessing those innovations. Where the users of patented innovations have to negotiate multiple licences in order to gain access to technology, they may face a multitude of overlapping patent rights, referred to as a 'patent thicket'. Patent pools and clearinghouses have emerged internationally as potential mechanisms to obviate thickets. However, competition laws are necessary to ensure that pools are not used to stifle competition. A number of other mechanisms that are used to access patented innovations, such as voluntary licences of right, are discussed in chapter 9.

Patent 'thickets'

It is not unusual for complex products like mobile phones to use multiple patented inventions, many of which have to be used under licence (chapter 5). The more licences a firm has to negotiate with patent holders, the more costly developing their own product may become. Firms also need to be more aware of patents and ensure they do not inadvertently infringe them, leading to higher search costs (Aoki and Schiff 2008).

This can lead to the potential problem of 'patent thickets'. Shapiro (2001) defined a patent thicket as an overlapping set of patent rights requiring those seeking to commercialise new technology to first obtain numerous licences from multiple patentees. The patents required to produce a good can be numerous and the cost of negotiating with all patentees raises the eventual price for both producers and consumers.

The market power inherent in each patent owner's right can lead to those holders extracting a high licence fee in exchange for use of the patent. If each of the multiple patent owners chooses to extract a high price, the required licence fees could limit the profit potential for the product or, in the extreme, make the product commercially unviable. In economics, Cournot labelled this as the 'complements problem' (Shapiro 2001). In the field of licensing, this phenomenon is often referred to as the 'royalty stacking' problem (Browning and Mulhern 2009). Related to this is the 'tragedy of the anti-commons', which refers to a situation whereby a resource is underutilised because of a failure of the owners of IP to coordinate access to required technology (box 4.2).

Box 4.2 **The tragedy of the anti-commons**

To demonstrate the concept of the tragedy of the anti-commons, suppose that there are two complementary technologies, A and B, required to produce another technology, C, and that the producers of C must pay royalties to the owners of the patents for access to their technologies. If the required royalty for use of technology A were to be increased, the costs of producing technology C would rise, leading to a decrease in the quantity of technology C produced. One effect of this would be to reduce the royalties received by the owner of the patent for technology B. Hence, the decision to raise the royalty rate on technology A imposes a cost on the owner of technology B and fails to maximise joint royalty revenues for the owners of technologies A and B. As a result, the production, and hence, utilisation, of technology C is less than optimal.

If, instead, royalties were set by patent holders A and B in conjunction, the imposition of bilateral costs through reduced use of technology could be avoided. The royalty per unit of C produced would be lower than if either patent holder A or B independently determined royalty rates, but joint royalty revenues would be greater. Accordingly, the price of technology C would be lowered, thus benefitting its consumers.

(continued next page)

Box 4.2 (continued)

The greater the number of technologies required as inputs for production, the more severe the problem of obtaining required access may become, thus exacerbating the tragedy of the anti-commons. Although cooperation between patent holders to avoid the tragedy of the anti-commons might be desirable in the case of complementary technologies, cooperative determination of royalties for substitutable technologies is likely to undermine competition and reduce access to technology.

Sources: Aoki and Schiff (2008); Buchanan and Yoon (2000).

Some indication of the potential importance of patent thickets is given by the RIETI-Georgia Tech survey. For both the Japanese and US organisations surveyed, only around 20 per cent of patents could be used on a standalone basis. Most commonly, a bundle of two to five patents was found to be required for commercialisation of an innovation protected by a patent in both Japan (where about 44 per cent of patents required such a bundle) and the United States (where approximately 47 per cent of patents required such a bundle for commercialisation). Furthermore, in both countries, about 30 per cent of patented innovations required access to between 6 and 50 further patents for commercialisation (Sadao and Walsh 2009).

Another potential problem with multiple patents is that of patent 'hold-up'. Hold-up can occur when one firm has invested considerably to develop a specific product and bring it to market, only to find out at a late stage of development, or once the product has launched, that another firm owns intellectual property rights over aspects of the product. In such a situation, the resultant negotiations can cause lengthy delays and higher costs for the firm seeking the licence (Browning and Mulhern 2009). This can undermine competition, with consumers facing fewer choices and higher prices.

Patent pools

A number of private licensing access mechanisms have arisen to obviate potential problems that may result from multiple patents. Cross licensing is one such mechanism. A cross-licensing agreement between two firms gives the firms the right to access each other's patents.

Patent pools are another cooperative mechanism used by firms to enable greater access to patented technologies and other products. A patent pool essentially constitutes a package licence for a number of patents. Patent pools are agreements between two or more patent owners to license one or more of their patents to one

another, or to bundle patents and license them as a package to third parties who are willing to pay the royalties. Licensees may also include the patent holders themselves. The pool may be administered by one or more of the members of the pool, acting on behalf of all of the other members, or alternatively, it might be administered by a management organisation (Aoki and Schiff 2008).

Potential benefits associated with patent pools include:

- lowering the search and transaction costs of licensing by providing a one-stop shop for businesses to obtain the necessary licences required to develop a particular technology, therefore overcoming problems caused by 'blocking' and 'stacking' licences
- reducing or eliminating the need for litigation over patent rights
- facilitating risk sharing among members associated with research and development
- allowing for free sharing of information related to patented technology among members and licensees, where members have incentives to avoid overlapping efforts in areas of innovative effort, especially in the field of biotechnology (Clarke et al. 2000).

Aoki and Schiff (2008) argued that patent pools could enhance efficiency, provided that the patents within the pool cover complementary technologies and products, and hence, facilitate greater access to innovations. However, if the patents in the pool provide intellectual property rights for technology and products that are substitutes, there is potential for members of the patent pool to use it as an instrument for collusion, to the detriment of those seeking access to patented innovations.

Enforcement of competition law and selectivity in admitting patentees to the patent pool can help to allay such concerns. It would generally be undesirable, however, for competition law to hinder attempts by patentees possessing complementary and potentially blocking patents to coordinate practices, such as by engaging in cross licensing, package licensing, or to form patent pools (Shapiro 2001). Patent pools may also be susceptible to problems with maintaining membership stability. Not all members of the pool may necessarily have the same objectives, which can make ongoing management of the pool difficult. For instance, some members of the pool might be research-only organisations, whereas other members are likely to be profit-maximising companies. The disparate motivations for the patenting activity may lead to the possibility of 'free riding' and membership instability (Aoki and Schiff 2008).

An additional concern raised in relation to patent pools is that they could potentially shield invalid patents. Those expecting their patents to be invalidated in court may have an incentive to settle by creating a patent pool. In turn, this may result in patent users and the public being forced to pay royalties on technology that would have become part of the public domain if the patents were actually litigated in court (Clarke et al. 2000).

Furthermore, Telstra Corporation Limited observed:

> Whilst patent pools sometimes address the patent thicket situation, patent pools do not always provide a solution. Participation in patent pools is voluntary and therefore dependent on industry co-operation. (sub. 8, p. 4)

Patent pools are best suited to situations where complementary patents must be combined to produce a new product or innovation, and where there are common technological standards or the essential patents are easy to identify, as in information technology industries. Some overseas examples of established patent pools include the Medicines Patent Pool (box 4.3) and MPEG-2 (box 4.4). No patent pools are recorded on the ACCC authorisation and notifications registers.

Box 4.3 **The Medicines Patent Pool**

In 2006, Knowledge Ecology International and Doctors Without Borders put forward a proposal for a patent pool to UNITAID, which would focus on promoting access to HIV/AIDS medicines. Subsequently, the Medicines Patent Pool was established in December 2009, and works by negotiating voluntary licences with patentees, then non-exclusively licensing these to third parties so that they may create generic versions of drugs for use in developing countries. Royalties from the sale of generics are then paid to patent holders.

In 2010, the Medicines Patent Pool obtained its first licence when the US National Institute of Health provided royalty-free licensing on patents of darunavir (a drug used to treat HIV infection) to the Pool. The scope of the licence encompassed all low- and middle-income countries defined by the World Bank.

The Medicines Patent Pool's first licensing agreement with a pharmaceutical company occurred in 2011, when it entered into an agreement with Gilead Sciences for HIV and Hepatitis B medicines. The terms of the licensing agreement preserve the ability of companies to supply generic versions of the drugs covered under the agreement in the event of the issuance of compulsory licences by national governments.

Sources: Cox (2012); Doctors Without Borders (2010); Medicines Patent Pool (2011).

Box 4.4 **The MPEG-2 patent pool**

MPEG-2 is a digital video compression standard utilised in products such as DVDs. In 1990, a process to set a standard was initiated, and a working group was established in 1993 to develop a framework for licensing. Alternatives to a patent pool, including a clearinghouse were initially considered by the working group, before it finally settled on the former. The MPEG LA corporation was founded to deal with the licensing of MPEG-2 patents. It stated that:

> In the 1990s, the MPEG-2 standard … faced a patent thicket. The single biggest challenge to MPEG-2 adoption was access to essential patents. Many MPEG-2 patents owned by many parties made it virtually impossible for most users to negotiate the number of licenses necessary to use the standard (MPEG LA 2009).

Forming the patent pool for MPEG-2 however, was not without difficulty. Encouraging companies to join the pool was complicated by the different incentives among members of the pool. For instance, Sony is a licensor and a licensee of MPEG-2 patents, and uses patents primarily as a means to protect its IP. By contrast, Columbia University was mainly focused on maximising its royalties. The heterogeneous incentives of those involved led to debate about the appropriate licensing rate to be charged to licensees.

The licensing rate set by the pool also led to some problems among both licensees and licensors. For instance, some licensees already had licensing agreements with MPEG LA member firms, and sought reductions in the royalties payments required for the pool. Instead of altering the MPEG standard licensing terms, MPEG LA advised licensees to seek concessions with the firms with whom their initial licensing agreements had been concluded. The MPEG LA licence itself makes a commitment to not raise royalty rates, except in extreme conditions. Lerner and Tirole (2007) argued that this affects the ability of the pool to attract new licensors. This is because the formula used to distribute royalties gives each licensor a pro rata share of licensing revenues, based on the number of essential patents it owns, while the rate charged to licensees remains constant.

Patent pools have also been suggested by various organisations as useful mechanisms to deal with the specific problem of access and use of patented genes, diagnostic methods, technologies and tools that are used in genetics and biotechnology. Sung (2002) argued that genetic information represents an industry standard analogous to those in the electronics and telecommunications sector and that increasing patent protection in the sector should make cooperative market-based technology transfer strategies through patent pools attractive to members of biotechnology industry, if not inevitable.

Patent commons

A patent commons is a vehicle through which patent holders allow their patents to be used without charge, possibly only for a limited range of purposes (Taubman 2010). This often includes the transfer of ownership rights to the commons.

There are several patent commons in operation internationally. A prominent example is the Eco-Patent Commons, established in January 2008 by IBM, Nokia, Pitney Bowes and Sony in conjunction with the World Business Council for Sustainable Development. It allows companies and individuals to pledge patents that either directly or indirectly confer environmental benefits. In this case, ownership rights over the patented technologies remain with the pledging parties, instead of being transferred to the commons. Potential technology users have no need to specifically request a licence, since any patent pledged to the Commons is automatically licensed royalty-free as long as the patent is used in a product or process that yields an environmental benefit (Hall and Helmers 2011). Since it was launched, about one hundred patents have been pledged by thirteen companies (WBCSD nd).

Hall and Helmers (2011) investigated the motives of firms contributing patents to this particular commons. They found that while patents pledged to the commons were generally climate change related, many were directed towards mitigating environmental damage from manufacturing processes rather than being specifically directed towards mitigating climate change. They also concluded that the technologies pledged to the commons tended to be derivative of earlier technologies, and hence, involved innovations that were not drastic in nature, and perhaps not very valuable to the firms donating them. Rimmer (2011, p. 326) has commented of the Eco-Patent Commons:

> It is questionable whether the Eco-Patent Commons is truly a 'commons' as it is traditionally understood. It could be argued that the information technology companies are co-opting the concept of the 'commons' for the purposes of public relations.

A number of other critiques of the Eco-Patent Commons are noted by Rimmer (2011), which suggest that the veracity of such a commons is at least open to question.

IP clearinghouses

As an alternative to patent pools, IP clearinghouses may be another means by which firms can facilitate the use of patented innovations (although clearinghouses can apply to other forms of intellectual property more generally). Clearinghouses can

have broad objectives, such as providing databases and other informational repository tools, and can facilitate licensing and assignment of patents. Clearinghouses can assist those seeking access to patented technology by helping to reduce search costs and saving time. Besides providing informational services, clearinghouses can also handle administrative matters, such as the collection of royalties on behalf of patentees, and the monitoring of patent use by licensees (Aoki and Schiff 2008). These functions might help to reduce transaction and monitoring costs, and in doing so, facilitate licensing.

An example relevant to patents is the Espacenet online *information* clearinghouse administered by the European Patent Office (Van Overwalle et al. 2007). This service provides a range of information on patents from a repository which includes over 70 million patent documents from around the world, accessible via a searchable database. Espacenet can provide information, for example, on the legal status of patents, allowing a user to determine whether a patent is in force, and in which countries it is in force, as well as enabling a user to view documents cited by or citing the document they are viewing (EPO 2011). These types of services could help curb inadvertent patent infringement and prompt greater trade in technology. IP Australia maintains a searchable patent database (AusPat) which, among other functions, can help reduce the extent of duplication of activity, and save time and money for prospective patent applicants.

5 Specific concerns about patent access

Key points

- The Commission has been asked to examine four areas — gene patents, standard essential patents, climate change and food security — where compulsory licensing has been suggested as a way to address concerns that patents could be used to unduly restrict access to, and reduce the affordability of, important technologies.
- Patent-related controversy and litigation in the field of biotechnology is not new. The current controversy over the patenting of genes has largely arisen due to high profile court cases concerning patents over the tumour suppressor genes, BRCA1 and BRCA2. These genes have been linked to the development of breast, prostate and ovarian cancer.
- Previous reviews have not supported adding an exemption for genetic material to the *Patents Act 1990* (Cwlth). However, like past reviews, the Commission can see a prima facie case for efficient and effective safeguards to address concerns about the patent system's impact on access to healthcare.
- Standard essential patents can exacerbate problems associated with market power and patent thickets in telecommunications and other hi-tech industries.
- As existing legislation protects against market power abuse, it is unlikely that specific compulsory licensing provisions are needed to address problems associated with standard essential patents. In any case, many of the industries associated with standard essential patents are primarily located outside of Australia.
- There are more effective ways for Australia to assist developing countries to address climate change and food insecurity than changing the compulsory licensing provisions. Moreover, developing nations could use their own compulsory licensing provisions if necessary.

The terms of reference for this inquiry 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. A common theme in these cases is a concern about access to, and/or price for, a given technology. This chapter examines these issues, and discusses the potential role of compulsory licensing, in each case. Whether patents should be granted in these areas at all has been considered and rejected in several past reviews and is beyond the terms of reference for this inquiry.

5.1 Gene patents and healthcare

The granting of patents on human genes and associated testing methods has sparked a debate in Australia, and internationally, about the legality and morality of such patents. The argument is both an argument over what the law is and what the law should be. The first aspect is being tested in the courts, and will determine whether genetic material is patentable under current law. There is concurrently a separate and more normative debate being had over whether genetic material should be patentable. A number of past reviews, parliamentary and other, have examined the debate and found little reason to exclude genetic materials from patentability.

Can a gene be patented?

In Australia, the criteria for patentability set out in the *Patents Act 1990* (Cwlth) establish the threshold for granting patents (appendix B discusses these criteria in more detail). IP Australia determines whether an invention meets these criteria. However, the patentability of inventions can be contested in court, and may result in changes to the interpretation of the patentability criteria. A prominent example of such jurisprudence is the 1959 High Court case, *National Research Development Corporation v The Commissioner of Patents* (the NRDC case), which resulted in a significant broadening of the patentability criteria (ACIP 2010c). The invention being contested was a method of using known chemicals as a herbicide to treat soil. The Commissioner of Patent's decision not to grant a patent was overturned by the High Court, which determined the application valid because the invention had economic significance and resulted in 'an artificially created state of affairs' (ACIP 2010c).

The NRDC case led to a broadening of Australia's patentability criteria and to a number of newly emerging technologies being patentable subject matters. These included, methods of medical treatment, living organisms, mathematical algorithms and genetic material (ACIP 2010c). In the case of patents over genetic material, the Australian Industrial Property Organisation (IP Australia's predecessor) declared in 1995 that DNA sequences isolated and purified from the human body (box 5.1) were patentable subject matter, since they satisfied the NRDC case concept of 'an artificially created state of affairs' (ACIP 2010c). It has subsequently granted patents over a wide variety of human genes and genetic material, including those that cover an isolated and purified gene sequence per se (IP Australia 2009c).

This position is consistent with other OECD nations. In 2002, the OECD stated:

> … the position of the official patent authorities in OECD countries has been more or less stable for some time. Assuming that a DNA sequence is novel (not previously

publicly known or used in a public manner) and that the other criteria of patentability are also met (utility, inventiveness/non-obviousness), the substance of the DNA itself can be patented. (OECD 2002, p. 28)

That said, the legality of gene patents in Australia has not been tested in court. Sections 20 and 21 of the Patents Act state that the granting of a patent does not guarantee, or necessarily imply, that a patent is legally valid. The patent system is premised on the idea that patents may or will be tested through legal proceedings (SCARC 2010).

Box 5.1 **Isolated and purified genes**

Deoxyribonucleic acid (DNA) is a nucleic acid containing the genetic instructions used in the development and functioning of all known living organisms. The DNA segments carrying this genetic information are called genes. Natural DNA exists in the human body as one of 46 DNA molecules. Each of these DNA molecules is condensed and intertwined with various proteins, to form a structure known as chromatin that makes up a larger structural complex, a chromosome. Chromosomes are further encapsulated within a series of membranes and suspended in a complex intracellular environment.

Isolated DNA is a free-standing portion of the larger, natural DNA molecule. Isolated DNA has been cleaved (that is, had covalent bonds in its backbone chemically severed) or synthesized to consist of just a fraction of a naturally occurring DNA molecule. In contrast, purification makes pure what was the same material, but was combined, or contaminated, with other materials. Accordingly, isolated DNA is not just purified DNA. Although isolated DNA is removed from its native cellular and chromosomal environment, it has also been manipulated chemically so as to produce a molecule that is different from that which exists in the body. However, there is a key similarity between isolated DNA and the naturally occurring form. That is, the information content contained on the DNAs' nucleotide sequences are identical.

A patent claim on an isolated gene sequence can exclude others from performing genetic tests, because typical methods of testing the gene in question require production of the patented isolated sequence. A similar situation occurs where there is a patent on the process or method involving testing for a particular genetic sequence and then associating that sequence with a disease or condition.

Sources: SCARC (2010); US Court of Appeals for the Federal Circuit (2012).

In the United States and Australia, recent judgements have been issued in prominent court cases concerning patents over the BRCA genes (box 5.2). At the heart of the legal case in Australia is the assertion that an isolated and purified gene from the human body is a discovery and not an invention, and is therefore not patentable (Maurice Blackburn 2012). Traditionally, discoveries have not been regarded as patentable subject matter 'because no knowledge or ingenuity has been applied to produce a new and useful thing' (ALRC 2004, p. 123).

Box 5.2 **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 2002–2003 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.

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 (Maurice Blackburn Lawyers 2012). 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.

Sources: Cancer Voices Australia (2010); Conley and Vorhaus (2011); SCARC (2010); US Court of Appeals for the Federal Circuit (2012).

In examining the differences between the genes that occur naturally in the body and those that are isolated and purified, the Australian Federal Court ruled that that the BRCA1 patent met the requirements of the Patents Act. That is, that an isolated gene is patentable as it is an artificially created state of affairs that has economic significance, and is therefore considered an invention, rather than a discovery. 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.

While the cases will ultimately decide the patentability of genetic material, it may have little practical impact on patenting activity in the future. The controversy related to gene patents could well diminish for several reasons. First, the patents on the BRCA1 and BRCA2 genes expire in August 2015 and December 2016 respectively (IP Australia, pers. comm., 12 October 2012). Similarly, the bulk of existing gene patents, particularly those that cover a gene sequence per se, are due to expire in the near future (SCARC 2010).

Second, the proportion of the human genome that remains under patent may be minimal. While figures as high as 20 per cent (Jensen and Murray 2005) have been suggested, other work shows that this is likely an overestimate and that the figure may be as low as 2 per cent (Commission estimates based on Holman 2012). This number may be even lower in Australia. IP Australia estimated that there were only 202 patents claiming an isolated DNA which remain current, most of which have a commencement date before the completion of the Human Genome Project in 2003 (SCARC 2010).[1] Since then, IP Australia estimates that an additional 34 gene patents have been granted (IP Australia, pers. comm., 12 October 2012).

Third, the number of gene patents is likely to decline in future as it is becoming more difficult to satisfy requirements that an invention is 'novel' and involves an inventive step. This is due to the growth of prior art and skill in the area, making broad patents on isolated genes more difficult to obtain (SCARC 2010). As stated by Pfizer Australia:

> As patent offices world-wide have gained experience with genetic technologies, the patents now granted are much more specific to the biotechnologies than the early broader patents. Since the patent term is 20 years from the date when the priority application is filed, the majority of the early, broad patents are nearing the end of their patent life. (sub. 24, p. 2)

Preliminary results from a recent survey of managers of Australian genetic testing laboratories suggest that it is already rare for there to be a problem with patents

[1] This figure includes patents over human and animal genes.

limiting access to genetic tests (Nicol and Liddicoat, 2013). In particular, few respondents indicated that they paid licence fees or royalties (other than those included in the price of a commercial kit), or had since 2010 received a cease and desist letter or a letter of notification from a patent holder about its patent rights. This is consistent with the view that concerns are essentially based on past attempts to enforce the BRCA patents, and that this has not been an issue since the Australian licensee decided not to enforce its rights (box 5.2). That said, a sizeable minority of survey respondents did indicate that they were concerned that patents could hinder future provision of genetic tests.

Should human genes be patentable?

The current controversy over gene patenting is the latest in what is a fast-moving field, where new products and services are developed from an increasingly complex and cumulative set of underlying technologies. However, controversy in the field of biotechnology, and specifically genetics, is not new. Arguments about genetically modified food, or the cloning of organisms, have been prominent and the ownership of intellectual property (IP) in this field has a history of testing the boundaries of the IP rights system. In 1972, Ananda Chakrabarty filed for a US patent on a single strain of a Pseudomonas bacterium that was particularly efficient at breaking down oil slicks. The US Patent and Trademark Office rejected Chakrabarty's application, on the grounds that it was a product of nature, and that live organisms cannot be patented (Stix 2006). However, by the time the Supreme Court heard the appeal of the case in 1980, research of this nature had become more common place, and the court decided that inventions involving biological materials and some life forms were patentable in the United States (OECD 2002). Other nations followed suit.

Similarly, early patents over genetic material have been controversial and the subject of litigation. The controversy has arisen primarily due to the patenting of BRCA genes, the conduct of the patent holder and licensee, and the resultant court cases. These cases have led various groups to express concerns about the patents and there have been calls to exclude genetic material from the patent system by adding an exception to the Patents Act.

The Patents Act currently contains few specific limitations on patentable subject matter (appendix B). In November 2010, Senators Coonan, Heffernan, Siewert and Xenophon introduced a private members Bill to prevent patenting in certain areas, particularly human genes. However, the Bill failed to pass the Senate following a review by the Senate Legal and Constitutional Affairs Legislation Committee (SLCALC). The majority of committee members recommended against passing the Bill because the:

> … proposed amendments in the Bill, which are focused on addressing a specific issue, could have a large number of unintended consequences across the entire patent system with indeterminate impacts on a range of industries and sectors. (SLCALC 2011, p. 64)

One of the key motivations for the proposed exclusion was to ensure affordable and equitable access to healthcare, a goal shared by the Australian Government. The Australian Government subsidises medical treatment through the Medicare system and pharmaceuticals through the Pharmaceutical Benefits Scheme. It reiterated this goal when announcing this inquiry:

> Of concern to government is a perception that patents over genetic technologies, or a perceived lack of licences to use these patents in Australia, unreasonably restricts or delays patient access to medical advice based on the latest diagnostic tests. (Bradbury and Dreyfus 2012, p. 2)

Past reviews

The debate over gene patenting was also the catalyst for a number of reviews on the issue. These reviews concluded that concerns would be better addressed by means other than changing the scope of patents. These means include compulsory licensing and Crown use.

The first review of gene patents was conducted by the Australian Law Reform Commission (ALRC) in 2004. The review found that a new approach to the patentability of genetic material was not warranted:

> It would represent a significant and undesirable departure from accepted international practice with respect to genetic inventions, and may adversely affect investment in the Australian biotechnology industry. (ALRC 2004, p. 130)

The ALRC (2004, p. 17) went on to recommend that the Patents Act 'should not be amended to exclude genetic materials or technologies from patentability'. Similarly, the Senate Community Affairs References Committee inquiry into gene patents determined that it:

> … would not recommend at this stage that the *Patents Act 1990* be amended to include an express prohibition on human genes and genetic products. … there would need to be a very clear case and significant social and political consensus on the need for such a change. (SCARC 2010, p. 99–100)

A review of patentable subject matter by the Advisory Council on Intellectual Property (ACIP) also did not support an exemption, noting:

> Improving access to beneficial patented technology is better dealt with through mechanisms other than the test for patentable subject matter. These other mechanisms include providing efficient compulsory licensing and Crown use provisions, allowing

> experimental use of patented inventions, non-legislative mechanisms such as patent pools, and other targeted government programs. (ACIP 2010c, p. 7)

The Australian Government responded that, while it agreed 'in principle' not to add an exclusion for genetic material to the Patents Act, it was committed to legislating a broader exclusion aimed at ensuring the patent system reflects community expectations. This exclusion, as recommended by ACIP (2010c, p. 17), would cover any patents that would be 'wholly offensive to the ordinary reasonable and fully informed member of the Australian public'.

Arguments against a gene patent exclusion

The main argument against an exemption in the Patents Act is that it would be contrary to the rationale for patents (discussed in greater detail in chapter 2). According to this argument, without patents, the high costs of bringing a diagnostic (such as the BRCA test) to market would be prohibitive (Institute of Patent and Trade Mark Attorneys and FICPI, sub. 18). The system of patents is seen by its proponents as vital to facilitate investment in the costly, lengthy, and risky developmental processes required to transform the underlying biological discoveries and inventions into marketable products (Schilling 2011).

Opponents of an exemption also note that the debate is based on a misunderstanding of what is being patented. The argument is made that those who want the exclusion mistakenly fear that genes as they exist in the human body are patentable. However, in fact they are not, since s. 18(2) of the Patents Act currently precludes the patenting of human beings and biological processes for their generation (IPTA 2010).

Advocates of the status quo express a preference for the patents system to remain 'technology neutral', since the biotechnology field is moving rapidly and that introducing exemptions could have unforeseen consequences, making some lines of future research unattractive. Technology-specific exceptions affect the flexibility of the current statutory framework and Australian courts have expressed a general reluctance to 'read in' further exclusions to patentable subject matter on the basis of ethical or policy considerations (SCARC 2010). At the time the Patents Act was drafted and presented to Parliament, it was agreed that the Act would not list specific exclusions on patentable subject matter (Moir, cited in SCARC 2010). Some submissions supported this approach. For example, the Walter and Eliza Hall Institute of Medical Research (WEHI) submitted:

> The patent and licensing systems have been faced with new technologies for more than two hundred years and will address many more new technologies without the need for specific technology exemptions. (sub. 13, p. 7)

Medicines Australia (sub. 10) expressed a similar view. Other participants (Janssen Cilag Pty Ltd, sub. 28; Pfizer Australia, sub. 24; WEHI, sub. 13) also reasoned that there was little need to change based on what they saw as an anomaly (the BRCA case). As stated by Pfizer Australia:

> A business decision by a single patent holder, since reversed, is not evidence that Australia's entire patent system is fundamentally flawed … the vast majority of patents on genetic material and technology at work in Australia have not limited research or access to healthcare. (sub. 24, p. 3)

Arguments for a gene patent exclusion

Beyond legal questions concerning the distinction between an invention and a discovery, those that argue for an exclusion for gene patents usually have ethical concerns about the patenting of genes. These concerns tend to be on the basis that they are natural substances and/or parts of the human body (for example, CCA 2010; Palombi 2010). The notion of profiting from the private ownership of such things strikes some as an affront to human dignity (Gargano 2005). Others have questioned the morality of allowing the researchers who identify genetic mutations related to a disease to own that mutation. They argue that patients suffering from such conditions should have control over the property associated with their disease (Greenfield 2006).

Some concerns are also related to problems that may occur in the future. As noted earlier, new and emerging fields in biotechnology often test the boundaries of the IP system. It may well be that the patents system is not compatible with future advances in genetics. For example, submissions to the Senate Community Affairs References Committee's inquiry into gene patents raised concerns related to tests involving multiple genes (SCARC 2010). The inquiry noted 'a general consensus that the trend in genetic testing and treatment would move toward testing multiple genes or whole patient genomes as testing techniques improve and the cost of testing decreases' (SCARC 2010, p. 46). The concern related to this trend is that testing facilities may have to negotiate multiple patents to provide tests. This could be a barrier to more personalised and targeted treatment.

In addition, there are more utilitarian objections to gene patenting. First, there is a large literature that argues that gene patents block further research (for example, Andrews et al. 2006; Heller and Eisenberg 1998). However, recent legislation in Australia should address many of these concerns for domestic researchers. The passing of the 'Raising the Bar' Act amended the Patents Act to allow use of a patented invention for experimental purposes without the authorisation of the patent owner (chapter 8).

Second, there are the previously mentioned concerns about access to healthcare. In addition to the BRCA case, there is wider concern about the effect that patents have on the affordability of medical treatment. In the US, a report by the Secretary's Advisory Committee on Genetics, Health, and Society on gene patents and their effect on patient access to genetic tests concluded that '[w]here patents and licensing practices have created a sole provider of a genetic test, patient access to those tests has suffered'(SACGHS 2010, p. 3). The Royal College of Pathologists of Australasia (sub. 16, attachment 5) cited a number of Australian examples in which patent holders charge a higher price for genetic tests than those tests would cost to conduct in-house. For example, tests of the IgH and TCR gene rearrangements for lymphoproliferative disorders or acute myeloid leukaemia, cost $292 using Invivoscribe Technologies' patented test, but could be tested in-house for $28 per patient (sub. 16, attachment 5). The higher price of patented tests may provide the incentive to invest in research and development, that may otherwise not eventuate. Nevertheless it does not alter the fact that the cost of treatment is increased.

Is there a case for safeguards to ensure healthcare access?

The terms of reference for this inquiry ask the Commission to consider concerns that gene patents may hinder access to affordable healthcare. The Commission recognises that several thorough reviews have looked at this issue and all have come to the conclusion that specifically excluding genes from the patent system is unwarranted. Instead they advocated the use of other mechanisms in addressing this problem. This includes compulsory licensing, the subject of this inquiry.

Like these past reviews, the Commission does not see a case for adding an exemption for genetic material to the Patents Act but recognises that there is a prima facie case for the Government to ensure equitable healthcare access. While the controversy over the BRCA gene patents may be subsiding, the fast moving nature of medical science and biotechnology could present future challenges for the patents system. This could, for example, be the case if healthcare is increasingly dependent on emerging (newly patented) genetic technologies, and personalised medicine that requires the testing of multiple genes. As such, the Commission accepts that there is a case for efficient and effective safeguards to address concerns about the patent systems impact on access to healthcare. Such safeguards are examined in later chapters and include compulsory licensing (chapter 6), Crown use (chapter 7) and a range of other alternative mechanisms (chapter 9) including:

- special compulsory licensing arrangements for public health

- a specific exemption for diagnostic, therapeutic and surgical methods, which some countries have adopted and is allowed by the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS agreement)
- use of government purchasing power in health to push down the cost of patented diagnostic and therapeutic technologies.

5.2 Standard essential patents

A standard essential patent is a patent on an invention that is required to practise an industry standard. Standards can be useful in defining safety and/or quality parameters, or ensuring a level of inter-operability between products (Lindsay 2012). Inter-operability is particularly important in areas such as telecommunications, information technology, and consumer electronics (Bekkers et al. 2011). Some standard essential patents, for example those related to 3G wireless technology in telecommunications, can be crucial for entire industries.

Although some standards emerge organically and remain unofficial, many standards are made official and set collectively by firms, through a standards development organisation (SDO) (box 5.3). SDOs are useful as they can overcome coordination problems between different patent owners and can lessen the costs associated with patent thickets (chapter 4). They achieve this by setting a number of conditions for the disclosure and licencing of relevant patents, in advance. For example, when an SDO approves a technology, it will generally secure a commitment from the owner of an essential patent, or patents, to license its IP to competitors under fair, reasonable and non-discriminatory (FRAND) terms (Herr 2009). The core function of FRAND terms is to prevent 'hold-up' and the setting of excessive licensing fees, once the industry has locked in the standard (Radcliffe and Sproul 2012).

Box 5.3 **Standards development organisations**

Standards development organisations (SDOs) are a diverse group of institutions that can include government departments, industry groups and private bodies. SDOs operate at the national, regional and international level. In Australia, the Accreditation Board for Standards Development Organisations (ABSDO) regulates SDOs and accredits them to produce Australian Standards. Accredited SDOs include the Pharmacy Guild of Australia, the Rail Industry Safety and Standards Board, Seafood Services Australia, the Communications Alliance and Australian Forestry Standards Ltd.

(Continued next page)

Box 5.3 (continued)

Australia's recognised national standards body is Standards Australia. It is the most active SDO in Australia, and plays a key role in the processes through which many international standards are adapted as Australian Standards:

> The policy of Standards Australia is to base Australian Standards on International Standards to the maximum extent feasible … This policy of the use of International Standards as a first option is also included in the ABSDO Requirements for Accreditation of Standards Development Organisations. Australian Standards should be adoptions of International Standards, unless there are valid reasons to the contrary. (Standards Australia 2011, p. 3)

Internationally, a number of large and influential SDOs operate at a global or regional level. At the global level, these SDOs are often organised along industry lines, for example the International Telecommunications Union and the International Electrotechnical Commission (David and Shurmer 1996). Regional examples of SDOs include the European Telecommunications Standards Institute and the Pacific Area Standards Congress.

While companies holding standard essential patents have generally agreed to license them to competitors, at times they have sought to limit the ability of others to access the patent (box 5.4). In other instances, parties have disagreed after the standard has been set about what licensing fee is 'reasonable'. The recent 'smart phone wars' involving patent licences and litigation by major smartphone suppliers and other technology patenting disputes have caused some to express doubts about the framework for standard essential patents (Seidman 2012). Concerns in this case are generally related to abuse of market power by patent holders that have contributed their patents to a standard. Standards effectively rule out substitute technologies and so give the essential patent holders greater scope to exercise market power. This can exacerbate the problems of patent hold-up and royalty stacking (chapter 4).

The Patents Act does not contain any explicit measures related to standard essential patents or FRAND terms. FRAND obligations could be made a defence against patent infringement, as in Germany (box 5.5). Alternatively, Koelman (2006) has suggested that a compulsory licensing scheme compelling FRAND obligations on all standard essential patent holders could in large part resolve concerns about market power. Using compulsory licences in this manner was suggested by the CSIRO (sub. 26) and Telstra Corporation Limited (sub. 8).

However, the Commission considers that despite a lack of explicit measures relating directly to standards or FRAND terms in Australian law, it is doubtful that legislation of this nature is required. Section 46 of the *Competition and Consumer Act 2010* (Cwlth) provides broad protection for competitors or potential competitors against the misuse of market power. Furthermore, where the patentee is in

contravention of Part IV of the Competition and Consumer Act, a licence can be sought under the current compulsory licensing provisions in the Patents Act and under the Commission's proposed reforms (chapter 6).

Box 5.4 **Apple vs. Samsung**

A worldwide intellectual property dispute between Apple and Samsung has raised several issues related to standard essential patents and FRAND terms. Although cases are ongoing in most jurisdictions, an early finding in the Netherlands shows that the issue of which patents are essential to a standard, and what constitutes FRAND compensation, are key aspects of the current litigation.

In October 2011, the Hague District Court in the Netherlands denied Samsung's request for an injunction blocking Apple from utilising four patents essential to the 3G/UMTS standard in its iPhones and iPads (Carrier 2012). This was the first example of a court denying an injunction on a standard essential patent, with the court finding that a FRAND declaration obliged Samsung to offer a licence to Apple prior to seeking an injunction. In addition, the court found that Samsung had requested an excessively high licensing fee, 'very out of line' with FRAND commitments (Kuipers, Groenevelt and Lamme 2011). The court also found that Samsung had exhausted its rights by previously licensing its technology to Qualcomm, which then licensed the rights to Apple (Kuipers, Groenevelt and Lamme 2012).

In addition to suggesting that compulsory licencing should be used to compel licensing on FRAND terms for all standards essential patents, Telstra Corporation Limited also contended that:

> Communication networks and emergency services are of critical social importance. Patents relating to these fields should be considered 'standard essential patents' and therefore potentially subject to compulsory licences. (sub. 8, p. 3)

The Commission does not agree that specific measures aimed at these industries are necessary. The rationale for considering compulsory licensing of standard essential patents is to address the enhanced market power the standard can confer. The competition ground and the new public interest ground for compulsory licensing proposed by the Commission in chapter 6, would perform that function. In addition, the Patents Act is drafted to be technology neutral and altering the legal status of patents in specific industries may have unintended consequences (SCARC 2010).

Box 5.5 **German compulsory licences to address FRAND breaches**

Under German law, in patent infringement lawsuits, it is possible for the user of a standard essential patent to plead that antitrust regulations force the patentee to grant a compulsory licence for the subject matter of the patent in dispute (known as the compulsory licence defence). The user may consider pleading the compulsory licence defence where:

- the patentee refuses to grant third parties a licence regardless of the terms and conditions
- the patentee is prepared to grant a licence and has granted licences in the past, but its practices could be discriminatory (it gives unequal treatment to potential licensees) without a justified reason, or demands unreasonable licensing terms.

To assert the defence of the compulsory licence, the user is required to have submitted to the patentee a written licence that specifies the licensing fee and all terms and conditions that are normally stipulated in a licence contract. This requires the user to seriously consider what is FRAND in the particular case. Only if the user has requested FRAND terms from the patentee and the patentee has unjustifiably refused the offer, can the defence of the compulsory licence be asserted.

If the compulsory licence defence is successful, the patentee may not enforce a cease-and-desist claim directed to future breaches. However, the patentee may claim the FRAND licensing fee for the use of the patent during the period covered by the litigation.

An example of a case of this type involves the GSM standard for digital mobile communication networks. GSM is the most widely used mobile communication standard worldwide and is covered by around 4 700 essential patents. In *Siemens vs. Amoi (4a) (2007)* O 124/05, Amoi successfully relied on the compulsory licence defence in Germany's Dusseldorf District Court. The court regarded the conditions of the licence agreement offered by Siemens as inappropriate. In particular, it objected to Siemens' demand of full cross-licensing of all Amoi's patents for all electronic devices and systems produced, sold, and used by Siemens without payment of a licence fee. The court also ruled that Siemens' licence offer was not fair, since it did not contain an upper limit on the overall costs of licences (including Siemens) in the GSM standard.

Source: Herr (2009).

It may also be that the controversy over standard essential patents is overstated. In October 2012, the International Telecommunications Union held a roundtable to assess the effectiveness of FRAND-based patent policies used by SDOs. The vast majority of industry participants at the roundtable indicated in submissions that recent litigation was not representative of widespread problems with FRAND. For example:

> … the [F]RAND regime has successfully been the basis for hundreds of licensing agreements agreed bilaterally in an amicable way and, accordingly, has clearly enabled

> market entry by facilitating broad distribution of technology. … Litigation is an integral part of the IP system, and the use of courts to resolve disputes between competitors is simply a sign of a vibrant and functioning market. (Nokia 2012, pp. 1–2).
>
> … existing [F]RAND-based licensing practices function precisely as intended and have permitted spectacular innovation and growth in the mobile communications industry. … Calls for change rooted in exaggeration — chiefly, the claim that the commercial disputes between a few market participants amount to a widespread 'patent war' afflicting the mobile communications industry — should be approached with scepticism. (Qualcomm Incorporated 2012, pp. 1–2)
>
> In fact, in the past decades, a large number of such new vendors have emerged around the world and become highly successful, demonstrating that the principles of open access to standards and sharing of [intellectual property rights] through FRAND licensing do serve as true market enablers. Indeed, the European telecoms industry has enjoyed remarkable growth in the last two decades, providing affordable communication to billions of people world-wide. Prices of devices and network services have fallen. In addition, devices and network equipment are empowered by continuously improved and standardised technologies, generating enhanced performance and superior features for consumers … (Ericsson 2012, p. 3)

In any event, existing provisions are unlikely to be called upon often in Australia to address disputes related to standard essential patents. Many of the industries associated with standard essential patents are primarily located outside of Australia. A survey of eleven prominent SDOs conducted for the European Union found that 91 per cent of standard essential patents were owned by companies from the United States, Europe or Japan (Blind et al. 2009). This accords with the view of Standards Australia, which sees its role as ensuring that Australia adopts standards already set by the large international and regional SDOs (box 5.3).

5.3 Access concerns for developing nations

Compulsory licensing has been put forward as a solution to a number of problems faced by developing nations. It has been suggested as a way to stimulate technology transfer to alleviate climate change and ensure food security. In theory, this would occur where a domestic firm in the developing nation is able to produce a patented invention at lower cost. The firm would be given a licence to produce the product thereby lowering the cost for end consumers in that nation. Alternatively, the compulsory licence forces the patent holder to sell its technology to the developing country at lower prices.

There appears to be little scope for the Australian compulsory licensing provisions in this context, given current legislation. At present, with the exception of foreshadowed changes for pharmaceuticals (chapter 8), the Patents Act does not

allow compulsory licences to be sought for exports. This accords with Australia's international obligations. In particular, Article 31(f) of the TRIPS agreement requires that where the law allows for the unauthorised use of patented material, it is predominantly for the supply of the domestic market (appendix D).

That said, the Commission acknowledges that developing nations may lack the production or manufacturing capacity that would make compulsory licencing effective. A similar concern related to the problem of access to pharmaceuticals — in particular HIV/AIDS drugs — led WTO members to negotiate a waiver of Article 31(f) for the domestic supply of pharmaceutical exports to developing countries (detailed in chapter 8 and appendix D).

Some commentators have called for the extension of compulsory licencing to allow for exporting other technologies to developing nations. For example, Dr Matthew Rimmer (sub. 11, 15) argued that Australia should alter its compulsory licensing provisions to facilitate the export of products with 'humanitarian applications', including technologies that could help mitigate climate change or food insecurity. However, the Commission considers that a sustainable solution to the problem would involve a multilateral approach such as that taken with essential medicines, and as noted in chapter 8, analysis of the merits of this approach is beyond the terms of reference for this inquiry.

In any case, putting aside the issue of the legality, the Commission does not have any compelling evidence that Australian IP legislation is a significant barrier for developing nations in responding to climate change or food insecurity. The following pages examine climate change and food security, and the role compulsory licensing could play. The conclusion drawn is that policies that address the issues directly, rather than through IP law, are likely to be more effective.

Climate change and alternative energy

At the 15th session of the Conference of the Parties to the United Nations Framework Convention on Climate Change (UNFCCC) in 2009 — commonly known as the Copenhagen Summit — the G77 (an intergovernmental organisation of 77 developing nations) and China proposed a range of measures aimed at encouraging the spread of alternative energy and other mitigation technologies to developing countries (TERI 2009).[2] Among other things, this included making the

[2] Article 4 of the United Nations Framework Convention on Climate Change (UNFCCC) contains specific commitments for parties to facilitate the transfer of mitigation technologies. This commitment is reaffirmed in article 10 of the Kyoto Protocol.

technologies subject to compulsory licensing. They also called for UNFCCC agreements to include criteria on compulsory licensing for patented mitigation technologies (G77 and the Government of the People's Republic of China nd).

Advocates of compulsory licensing for alternative energy and other mitigation technologies have argued that the negotiation of compulsory licensing of pharmaceuticals under the TRIPS agreement is a precedent (appendix D).

A new paragraph highlighting compulsory licensing was drafted as part of the pre-Copenhagen negotiations (specifically the report of the Ad hoc Working Group on Long-term Co-operative Action):

> Developing countries have the right to make use of the full flexibilities contained in the [TRIPS] agreement, including compulsory licensing. (UN 2010, p. 28)

However, the Copenhagen Accord itself makes no mention of compulsory licensing or any IP right issues (TERI 2009).

The argument for the inclusion of compulsory licensing in the UNFCCC process is that patents awarded to mitigation technologies increase the price of technologies beyond the means of developing countries. Hence, it is asserted that developing countries do not have the financial means to access technologies that would reduce their emissions. However, the literature related to the developing world's ability to access climate change technologies does not point to a major problem with patents (box 5.6).

In addition, simply allowing the licensing of a technology may not be sufficient to induce the transfer of green technologies to developing nations. As pointed out by the Alliance for Clean Technology Innovation:

> Most of today's technologies are complex, multifaceted, and rely on numerous patents and other forms of technical knowhow and ability. Often, just to install a technology, or to operate it, will require complex technical ability and knowledge … A compulsory licence in general, even if it gives access to a particular patent, may not provide access to the technology as a whole, let alone the ability to install it, operate it, derive its full benefits, and do so in a reliable and sustainable way. (sub. 9, pp. 4-5)

Box 5.6 **Patents and technology transfer**

There is little doubt that polices that allow developing countries to access patented products at cheaper prices will increase their uptake of those products at the margin. However, where countries do not protect the rights of patent holders, it can dampen the incentives of patent holders to license or invest in those countries (UN 2007). In the case of climate change technologies, the net result of these competing effects is unclear as no comprehensive study has been conducted on the potential impact of IP rights on climate-related technologies (ICTSD 2009).

However, research by Barton (2007) on solar, wind and biofuel technologies found that the impact of patents on developing countries' access to these technologies is unlikely to be significant. This is because licensing costs are small compared with other deployment costs involved in technological adoption and transfer. Relaxing access to patents would not do much to change total costs in most cases. Furthermore, the prevalence of substitution energy sources means that patents do not necessarily allow the patent holder to charge prices higher than that which would be apparent under competitive conditions. Instead Barton (2007, p. 20) nominated barriers to trade as 'almost certainly the most important' barrier to technology transfer. Other scholars have supported this conclusion (Graleigh 2011; Levi et al. 2010).

Similarly, the Intergovernmental Panel on Climate Change (2000) listed various barriers to technology transfer including: a lack of information; insufficient human capabilities; political and economic barriers such as lack of capital, high transaction costs, lack of full-cost pricing, and trade and policy barriers; lack of understanding of local needs; business limitations, such as risk aversion in financial institutions; and institutional limitations, such as insufficient legal protection, and inadequate environmental codes and standards. Most of these have nothing to do with intellectual property.

Given the limited impact that compulsory licensing is likely to have on the transfer of green technologies to developing countries, it appears that other policy mechanisms will be more effective in reducing global emissions and helping developing nations to adapt to climate change. In the case of Australia, the Australian Government has committed to domestic climate change mitigation policies, and has several initiatives related to global action on climate change. These include:

- participation in negotiations under the UNFCCC and the Kyoto Protocol
- the Bilateral Climate Change Program, which aims to leverage key bilateral and regional relationships to promote climate change action
- the International Climate Change Adaptation Initiative, which assists Pacific Island nations to enhance understanding of climate change and develop adaptation responses.

Food security

The main thrust of arguments made in relation to food security also relate to the concerns that developing countries do not have the financial means to access new and potentially beneficial technologies, such as new plant varieties. The development of new high yielding plant varieties was a major driver of the 'green revolution', which helped alleviate malnutrition, hunger and related health problems in millions of people in developing countries (IFPRI 2002). The World Health Organisation and World Trade Organisation Secretariat (2002) noted concerns about access to patented food biotechnology products. In addition to improving food security, it noted that some products of this nature have additional health benefits. It cited the example of 'Golden Rice', a genetically modified rice that may help to alleviate Vitamin A deficiency, a major cause of blindness in developing countries.

In addition, some non-government organisations (NGOs), such as the Action Group on Erosion, Technology and Concentration (ETC Group) and the Food Ethics Council, have expressed concerns about the holding of gene patents by large agro-biotechnology businesses (ETC Group 2010; FEC 2002). These NGOs are opposed to the ownership of genetic material, and are concerned that a single large corporation will be able to block future use of the material and hinder innovation. Compulsory licensing has been suggested as a way to allow access to this type of patented material at a cost that is affordable for developing countries (Correa 2012). In addition, the United Nation's report of the Special Rapporteur on the Right to Food has also recommended compulsory licensing for this purpose:

> States may wish to resort to compulsory licensing or the use of eminent domain doctrines where patents create obstacles to the development of varieties that can contribute to food security. (UN 2009, p. 21)

The goal of ensuring global food security is an important one, and one that the Australian Government has stated its commitment to:

> As world citizens, we are committed to providing Australians and our overseas trading partners with a safe, healthy, plentiful and affordable food supply. Global food security is at the heart of social and political stability—and it is in our interests as a nation. (Australian Government 2012, p. iii)

However, compulsory licensing is unlikely to be an effective means to address concerns about global food security. First, it is unclear that using the compulsory licensing provisions to address global food insecurity would improve food output in the long run. The very purpose of the patent system is to stimulate innovation that will result in higher output in the long run (chapter 2). Second, even in cases where compulsory licensing could provide some short-term benefit by allowing access to

patented material, it is unlikely the most effective way to increase food output in aggregate. There are a number of root causes of food insecurity including poverty, conflict, poor infrastructure and poor yields due to water, soil and climate conditions. In many developing nations, deficient or non-existent supply chains may impede farmers' ability to reliably sell their produce. Where this problem exists, the incentive to increase output is severely weakened (PC 2011). Policies that address these issues are likely to be more effective in increasing total food production.

Insofar as Australia has an obligation to help feed people in other countries, IP policy is not a critical concern. Rather, and as is currently the case, it should form part of the international aid program administered by the Australian Agency for International Development (AusAID). In addition, working to reduce agricultural subsidies and trade barriers would increase opportunities for developing countries to increase their food production, and thereby improve their incomes and ability to buy food. These measures are likely a more appropriate — and probably more effective — approach to addressing food insecurity in developing countries.

Domestic food security

Domestically, the goal of food security is a less pressing concern. Most Australians can access a diverse, safe and plentiful supply of food. Over 90 per cent of fresh fruit and vegetables, meat, milk and eggs sold in Australia is domestically produced and Australia exports over half of its agricultural produce (Australian Government 2012). Moreover, Australia's income level (and hence buying power) and the somewhat lower costs of selling produce domestically, suggest that Australia will continue to be in a very strong position to satisfy its food requirements (PC 2011). Hence, the compulsory licensing provisions of the Patents Act do not appear to have an important role in addressing food security concerns within Australia. Moreover, where concerns arise about accessing patented plant varieties, there is a separate compulsory licensing regime under the *Plant Breeder's Rights Act 1994* (Cwlth) (box 5.7).

Box 5.7 **Compulsory Licensing in the Plant Breeder's Rights Act**

The *Plant Breeder's Rights Act 1994* (Cwlth) was initially developed to provide intellectual property protection for plant varieties (chapter 2). Similar to the *Patents Act 1990* (Cwlth), compulsory licensing provisions are included as a safeguard measure to ensure access to protected material. Section 19 of the Plant Breeder's Rights Act guarantees reasonable public access to reasonable quantities of plant varieties at reasonable prices:

> (1) … the grantee of PBR [plant breeder's rights] in a plant variety must take all reasonable steps to ensure reasonable public access to that plant variety.
>
> (2) Reasonable public access to a plant variety covered by PBR is taken to be satisfied if propagating material of reasonable quality is available to the public at reasonable prices, or as gifts to the public, in sufficient quantities to meet demand.
>
> (3) For the purpose of ensuring reasonable public access to a plant variety covered by PBR, the Secretary [of the Department of Innovation, Industry, Science and Research] may, on behalf of the grantee, in accordance with subsections (4) to (10), license a person whom the Secretary considers appropriate:
>
> (a) to sell propagating material of plants of that variety; or
>
> (b) to produce propagating material of plants of that variety for sale;
>
> during such period as the Secretary considers appropriate and on such terms and conditions (including the provision of reasonable remuneration to the grantee) as the Secretary considers would be granted by the grantee in the normal course of business.

6 Compulsory licensing provisions

Key points

- There are legitimate reasons for the limited use of compulsory licensing. The costly and time-consuming application process could be a barrier, but there are no clear options for improving the process, without also lowering the quality of the outcomes.
- There is a clear case for reforming both criteria for ordering a compulsory licence — the competition test, which addresses unlawful anti-competitive conduct, and the 'reasonable requirements of the public' test, which acts as an access regime for all other cases, where greater availability of the patent is in the public interest.
- The competition test operates via cross referencing Part IV of the *Competition and Consumer Act 2010* (Cwlth) (CCA) in the *Patents Act 1990* (Cwlth). This creates overlap because a compulsory licence remedy can also be constructed under the broad remedy provisions of the CCA itself. There is also uncertainly and inconsistency due to differences between the two Acts in the rights afforded to prospective applicants and the potential litigation avenues and process.
- Section 133(2)(b) should be removed from the Patents Act, so that a compulsory licence order based on restrictive trade practices of the patent holder is only available under the CCA. The compulsory licence remedy should be added to the list of orders available to the court under the broad remedy provisions of the CCA.
- Section 51(3) of the CCA exempts some licence conditions from some provisions of Part IV of the CCA. While its effect on compulsory licensing is limited, the case for retaining this section is weak.
- The reasonable requirements of the public ground for ordering a compulsory licence is unlikely to promote efficient outcomes.
  - It stands alone in Australian jurisprudence, rather than leveraging off comparable provisions in other laws. This increases uncertainty and costs of the parties.
  - It has protectionist objectives that are inconsistent with community-wide welfare.
- The reasonable requirements of the public ground should be replaced with a new public interest ground that focuses on providing access to patented inventions in a way that promotes the wellbeing of the community as a whole.
- The Australian Government should seek to remove s. 136 from the Patents Act. In the future, relevant international agreements should be incorporated directly into the Patents Act. This would reduce uncertainty for the parties and ensure a more appropriate degree of scrutiny for any changes to the law.

6.1 Efficiency of the compulsory licensing process

As discussed in chapter 1, there have been few applications for a compulsory licence in Australia, and none have been successful. There are several possible reasons for the limited number of applications:

- A compulsory licensing mechanism may act as an effective deterrent against refusals to license.
- Compulsory licensing is a safeguard that is only needed in exceptional circumstances.
- The process for granting a compulsory licence is so costly and time consuming that a potential licensee rarely finds it a viable option.

Compulsory licensing may be a deterrent in negotiations

The limited number of compulsory licensing applications is not the only indicator of the effectiveness of the mechanism. A common argument is that compulsory licence provisions are used as a negotiating tool by the potential licensee, without the need to resort to a formal application. Due to the confidential nature of negotiations, evidence of the effectiveness of compulsory licence provisions as a deterrent is hard to obtain and is generally anecdotal. Submissions on the issue have been mixed. Some participants (for example, Centre for Law and Genetics, sub. 3) indicated there was little evidence of the effectiveness of compulsory licensing as a deterrent. Others (for example, FB Rice, sub. 7; Association of Australian Medical Research Institutes, sub. 17) indicated that compulsory licences played a role in negotiations. The Law Council of Australia (sub. 32) provided some examples (box 6.1).

Box 6.1 **The use of compulsory licensing as a deterrent in negotiations**

The Law Council of Australia provided some examples of when the threat of a compulsory licence application helped a licensee achieve a negotiated outcome:

1. A licence of bauxite processing technology was negotiated after proceedings were commenced seeking orders for a compulsory licence. A negotiated outcome was achieved before the proceedings progressed beyond pleadings.
2. After discussions stalled in relation to a licence to a patent covering a hepatitis E assay kit, an application and statement of claim pursuant to section 133 (1) of the *Patents Act* were prepared. The pleadings were given to the patentee and a licence was subsequently granted without the need for the proceeding to be issued.
3. In a claim in relation to another assay kit, proceedings were commenced in which the cross-claimant alleged invalidity, or in the alternative, sought a compulsory licence. A negotiated licence was ultimately agreed prior to trial. (sub. 32, p. 3)

Compulsory licensing is rarely needed

The evidence reviewed by the Commission indicates that the most likely reason for the limited number of compulsory licensing applications is because they are a rarely needed safeguard. It is generally in the parties' interest to negotiate a voluntary agreement. As discussed in chapter 4, often patent owners would prefer to license more than they do. In addition, prospective licensees have other options to counteract or circumvent a patentee's refusal to license.

It is generally in a patent holder's interest to license

Voluntary agreements about access to a patented invention can generate benefits for both parties to the transaction. As discussed in chapter 4, there are many reasons why organisations might license their patented technology, including:

- to earn revenue from royalties and other payments
- to take advantage of collaboration — for example, from utilising the licensee's additional manufacturing or research capacity, or from spreading the risk associated with commercialisation.

Many inquiry participants commented that compulsory licensing was rarely used, because it was usually in the interests of both parties to negotiate a voluntary agreement. For example, Scott Bouvier observed:

> Based on the patent licensing activity of my clients, it is my view that the compulsory licensing provisions are infrequently invoked because they are not generally necessary in an Australian context where most patent holders have sufficient economic or other commercial incentive to license their inventions on reasonable terms. (sub. 2, p. 1)

Similarly, FB Rice (sub. 7, p. 2) stated that limited use of compulsory licensing was 'more likely indicative that the provisions are rarely required'.

The Law Council of Australia (sub. 32, p. 3) argued that a voluntary outcome was superior for a licensee, because the agreement could incorporate other know-how of the patentee and thus be better adapted to the licensee's needs than a narrow compulsory licence 'to work the patented invention'.

Several other participants (for example, CSIRO, sub. 26) observed that compulsory licensing was a last resort mechanism and that typically, the issue was resolved earlier through other mechanisms, including voluntary negotiation.

While a voluntary licence will not always be achievable, for the most part there are legitimate commercial reasons for the failure to achieve a negotiated agreement

(outlined in chapter 4). Hence, in most cases there is no policy reason for allowing non-voluntary access to a patent.

There are essentially only two circumstances where parties in the private sector would not voluntarily negotiate a socially beneficial licence.

- The patent owner benefits from blocking an actual or potential competitor. As discussed in chapter 4, a survey of patents granted in Europe in the 1990s found that, on average, around 20 per cent were used to block competitors (Giuri et al. 2007). However, this may simply be evidence of patentees protecting the value of their intellectual property rights, rather than refusing access to their invention by prospective licensees. As noted above and in earlier chapters, the qualitative and quantitative evidence that participants provided to this inquiry indicates that refusals to license are rare in Australia.
- A potential licensee would not be able to earn a sufficient return on the licence, compared to the benefits that the licence will create for the broader community. This may be because a large proportion of the benefits to the community is from spillovers or broader public gains that cannot be captured by a private sector licensee.

A potential licensee working in the private sector would only seek a compulsory licence in the first scenario. In the second scenario, Crown use provisions are likely to be a more effective and appropriate mechanism (chapter 7).

In sum, compulsory licensing is a safeguard that only needs to be invoked in exceptional cases.

Other options for potential licensees

There are several mechanisms within the *Patents Act 1990* (Cwlth) that provide alternatives to compulsory licensing (chapter 1). For example, the Crown use provisions make compulsory licence applications unnecessary for Crown entities — Commonwealth and State Governments and their authorities (chapter 7). A compulsory licence is also not needed if a patented invention is used for experimental purposes, or for the purpose of obtaining regulatory approval, because these are now exempted from patent infringement (chapter 8).

There are also other options a prospective licensee can take, such as those mentioned by the Centre for Law and Genetics:

> Where a refusal to license is encountered, various methods of counteracting the refusal are employed by industry participants, including challenging patents, inventing around, or ignoring the patents and continuing to conduct research. The reality is that there are

few circumstances in which a patent holder would deny a licence, and in most cases the refusal will be entirely justifiable. (sub. 3, p. 16)

In sum, the limited use of compulsory licensing is not necessarily indicative of a problem with the provisions. It can, as discussed above, be due to the rarity of cases where it is needed (chapters 4 and 5) or the effectiveness of the provisions as a deterrent against refusals to license. Nevertheless, it is widely recognised that obtaining a compulsory licence would be costly and time consuming. The nature of this concern, and potential measures to address it, are considered below.

Cost and timeliness of the process

Various participants argued that the limited use of compulsory licensing is, at least in part, caused by the cost of the process. For example, the Centre for Law and Genetics observed:

> … our empirical evidence indicates those who would consider applying for a compulsory licence perceive that the financial cost is prohibitively high ... We submit the fact that there have been so few applications for compulsory licences indicates that there is very likely some issue associated with the time and cost involved in making applications. (sub. 3, pp. 10-11)

Under s. 133(1) of the Patents Act, applications for an order to grant a compulsory licence must be made directly to the Federal Court. This could potentially be a source of high financial cost and delay for the parties. In this regard, Alphapharm claimed:

> … the Australian court system is not an optimal vehicle for the administration of compulsory licensing. This is because Australian courts are very expensive, very slow and lack the necessary powers to mediate quickly and effectively to resolve a patent dispute … (sub. DR48, p. 5)

Due to the absence of Australian jurisprudence on compulsory licence applications, there is no direct evidence on the associated costs of litigation. Furthermore, the broader evidence on the costs of pursuing a civil action in the Federal Court is scarce, and its relevance would be limited by the bespoke nature of individual cases. Nevertheless, the legal costs are likely to be substantial. For example, a survey commissioned by the Australian Law Reform Commission (ALRC) found that professional fees for intellectual property cases that were filed in the Federal Court ranged between $8000–$400 000 for applicants and $2000-$280 000 for respondents (Matruglio 1999). While no comparable surveys appear to have been undertaken since, the Attorney-General's Department observed that 'these costs have obviously increased over the last ten years' (Australian Government 2009, p. 121).

The administrative fees of the Federal Court are a further cost on the parties, and for corporations can include the following fees, among others (Federal Court of Australia 2012b):

- a fee of $2248 for filing a document to commence proceedings
- a fee of $3746 to set a proceeding down for hearing
- daily hearing fees ranging between $1499–$5320, depending on the length of the hearing — the Advisory Council for Intellectual Property previously reported that the average trial time for patent matters finalised between 1996 and 2001 was 7.25 days (ACIP 2003).[1]

Participants provided a range of estimates for the likely cost of a compulsory licence application, but they generally indicated a substantial cost:

> I would generally expect an application to the Federal Court for a compulsory licence order, if contested, to involve fees in the range of $200 000 to $500 000. Very few patents are likely to be seen to be sufficiently profitable at the early stage to justify such costs. (Scott Bouvier, sub. 2, p. 2)

> … a reasonable estimate for a relatively straightforward application would be in the order of $105,000 (junior counsel only) to $150,000 (senior and junior counsel). However, the costs for an application for a compulsory licence under a pharmaceutical patent which is vigorously contested by the patent owner could easily reach $1m and probably higher. (IPTA and FICPI, sub. 18, p. 10)

The time taken to finalise a matter in the Federal Court could be the most significant contributor to broader costs of the parties (ACIP 2003). Federal Court statistics indicate that it is not uncommon for matters to take longer than 12 months to finalise (figure 6.1).

The above costs are likely to be compounded by the uncertainty associated with the outcome of a compulsory licence application. As noted earlier, there is virtually no Australian jurisprudence on compulsory licensing, and the extrinsic guidance on the meaning of the relevant provisions of the Patents Act is very limited. Furthermore, as the decision in *Fastening Supplies Pty Ltd v Olin Mathieson Chemical Corp.*[2] illustrates, even where the test in s. 133 is satisfied, the Federal Court has some discretion on whether to order the compulsory licence. This could be a source of additional uncertainty, and a further cost to the parties.

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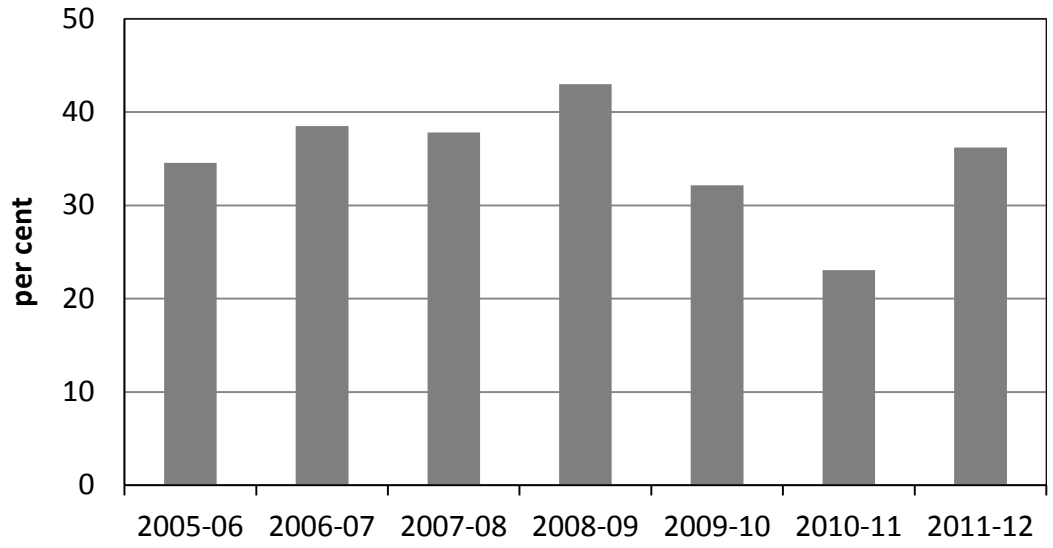
1 The above fees, however, represent only a fraction of the actual costs of the court. The Commission has estimated that in 2010-11, the Federal Court recovered around 11 per cent of its civil recurrent expenditure through court fees (SCRGSP 2012).

2 [1969] HCA 61.

Figure 6.1 **Timeliness of Federal Court judgments**

Per cent of matters aged over 12 months outstanding at 30 June[a]



[a] Excludes appeals and related matters.

Source: Federal Court of Australia (2012a and previous issues).

The Walter and Eliza Hall Institute of Medical Research observed:

> The current provisions and lack of precedent mean that there is uncertainty due to high cost and uncertain delays, with no known way of estimating the prospect of success or financial return. (sub. 13, p. 5)

Notwithstanding the above, the Federal Court (sub. 29) outlined a range of approaches that it utilises to improve the efficiency of its processes, including:

- case management — several techniques are employed, such as:
  - an individual docket system — a case is managed by the same judge until finalisation
  - national panels in specialist areas of jurisdiction, including patents — panel cases are heard by judges with expert knowledge in the area
  - special listing arrangements — an expedited process applies to cases meeting certain criteria
- ancillary processes — the Court can refer cases to internal or external alternative dispute resolution and can also engage expert referees to assist it on particular issues
- guidance to parties and practitioners on general process, as well as on particular types of proceedings, including those under the Patents Act.

Benefits of lower cost dispute resolution may not be great

Even if the current process entailed high costs for some potential applicants, the gains from moving to an alternative process for compulsory licensing may not be great.

First, as noted previously, the available evidence suggests that compulsory licensing is rarely needed. Such licences have also been rarely granted in other countries, including those which allow a lower-level court or an administrative body to grant compulsory licences (at lower cost), (appendix C).

Second, with the exception of the administrative fees of the Federal Court, it is unclear whether the cost of the process could be avoided by simplifying it or by moving the hearing to a different forum. The resources dedicated by the parties to winning a compulsory licence dispute depend on what is at stake for them. If the gains from winning (or costs from losing) are high, a party is likely to commit more funds to the case. This could manifest both in spending more to prosecute its initial case and in appealing an unfavourable outcome. Consequently, introducing a new lower rung in the dispute resolution hierarchy would typically only be beneficial in marginal cases that are currently not proceeding because the costs of the existing process outweigh the benefits. Where the value of a compulsory licence to the parties is high, lower-cost dispute resolution is unlikely to generate a great benefit to them, and may even increase the cost, if it adds a step to the current process.

The Institute of Patent and Trade Mark Attorneys (IPTA) and the Australian Federation of Intellectual Property Attorneys (FICPI) commented:

> The likely legal and ancillary costs … will depend largely on the extent to which the patentee is prepared to contest the application. Factors which will impact on the overall cost include: whether the … dispute involves simple or complex technology; whether the market is small, well defined, large, complex, new and emerging or mature; the availability of local witnesses; the resources available to one or both of the parties to apply to preparation or defence of the application … (sub. 18, p. 10)

The CSIRO observed:

> If an administrative determination on compulsory licensing were to be introduced, such decisions would presumably be subject to review, either as an appeal on the merits or by way of judicial review, which, if invoked, could well increase the overall time and cost of a compulsory licence application. Moreover, the main costs incurred in either judicial or administrative environments are those incurred by the parties in preparing for the hearing; these are often the same for either type of venue. (sub. 26, p. 4)

Third, in considering lower-cost dispute resolution options, it is important to be mindful of any adverse effects on the quality of the outcome, as well as the

behaviour of the parties. To the extent that compulsory licensing disputes are highly technical and complex, the current process and legal forum may be an appropriate reflection of that. In those cases, moving the responsibility to a lower court or removing some of the procedural steps may reduce the quality of the outcome. Furthermore, to the extent that it is desirable to build a body of precedent in an area that currently has virtually no jurisprudence, it may be appropriate that early decisions on the principles of the law are vested with a superior court that records its proceedings.

Making the process less costly may also encourage misuse of the provisions by the parties. Scott Bouvier observed:

> … a competitor or frustrated potential licensee might take advantage of the compulsory licensing regime if it was more easily accessible and/or if the financial disincentives of making an application to the Federal Court were removed. For instance, the regime could be used to find out more information about a licensor (as a 'fishing expedition') or as a tactical measure, such as by a large organisations against a competitor to slow down the competitor's commercialisation process. (sub. 2, p. 3)

With the caveat about the limited benefit from introducing a lower-cost dispute resolution mechanism in mind, the Commission has concentrated on changes to existing institutions and processes. Some participants disagreed with this approach. For example, Alphapharm proposed that:

> … an intellectual property regulator be established and that the regulator be given extensive powers to intervene and mediate in regard to intellectual property in Australia. The regulator should also be given the power to grant compulsory licences ... (sub. DR48, p. 5)

Assessing the general case for an intellectual property regulator is beyond the terms of reference for this inquiry. However, the Commission does not consider that establishing a new agency solely for compulsory licence matters is justified.

Alternative dispute resolution

Alternative dispute resolution (ADR) refers to a process other than judicial determination in which an impartial person assists the parties in resolving the dispute. Three ADR mechanisms are commonly identified — mediation, conciliation and arbitration. There is currently no comprehensive legislative framework governing the operation of ADR in Australia, with different arrangements applying depending on the law and jurisdiction (NADRAC nd).

ADR can be initiated voluntarily by consenting parties at any stage of the dispute, or can be ordered by a court as part of its case management process, once litigation

has commenced. Mandatory ADR is sometimes advocated as a pre-requisite to, or an early step of, patent litigation (ACIP 2003).

Of the three types of ADR, conciliation and mediation focus on facilitating a negotiated outcome between the parties.[3] These types of ADR would generally generate the greatest benefit where the parties resort to litigation before exploring voluntary dispute resolution options. It is unclear what gains would be achieved by introducing a formal requirement for mediation or conciliation for compulsory licensing matters. The existing 'reasonable requirements of the public' ground for compulsory licences already appears to have a similar effect by requiring the applicant to try for a reasonable period to obtain an authorisation to work the invention on reasonable terms and conditions. More generally, an application for a compulsory licence, in and of itself, could be interpreted as evidence of failed negotiations between the parties. In that context, imposing an additional requirement to negotiate would simply add to the costs of the parties.

On the other hand, arbitration, which involves a specialist arbitrator hearing the dispute and making a binding determination, could, in theory, be the next step following the failure of negotiations. Some researchers have advocated compulsory arbitration for patent disputes. For example, in the context of the European Union, Kingston (1995) argued that using an expert arbitrator in favour of an ordinary court would lead to a quicker and lower-cost resolution of patent disputes and address the problem of intimidation of the smaller party by the bigger one. He further claimed that most of the decisions by the arbitrator would not be appealed, because courts would be reluctant to overturn the technical findings of a specialist.

However, the National Alternative Dispute Resolution Advisory Council (NADRAC 2009) acknowledged evidence that, in Australia, commercial arbitration has become a costly and slow process that often approximates that of the courts. It also reported concerns that, because arbitral awards are usually not published and generally not based on a system of precedent, there could be uncertainty and confusion among parties, practitioners and arbitrators.

The Commission can see potential benefits for the parties in utilising arbitration over a standard court process. However, it has strong reservations about making the process compulsory or capable of being initiated by one of the parties without the other's consent. This would amount to a significant change to existing legal practice. Currently, s. 53A of the *Federal Court of Australia Act 1976* (Cwlth)

[3] While they both pursue the same objective, conciliation differs slightly from mediation in that the intermediary between the parties plays a more active role in advising the parties about the issues and possible outcomes (NADRAC nd).

requires the parties' consent for arbitration orders made by the Federal Court.[4] NADRAC (2009) has previously looked at the option of giving judges the power to order binding arbitration in federal jurisdiction matters, and found that there are constitutional constraints on the Australian Government's ability to legislate it. It ultimately recommended that the parties' consent remain a requirement for this process.

In sum, the case for changing the existing ADR arrangements is weak. Voluntary ADR is already available to the parties. The Federal Court also uses ADR as part of its case management process. Whether that case management itself is efficient, is a broader matter outside of the scope of this inquiry. However, there is no clear policy reason for unique treatment of compulsory licence applications within that process.

Mandating the use of mediation or conciliation would likely add to the costs with little net effect, while compulsory arbitration has not been applied in any other federal law, and may be unavailable for constitutional reasons.

Administrative dispute resolution

Some participants argued in favour of moving the responsibility for determining compulsory licensing matters to an existing administrative body.

Scott Bouvier (sub. 2) suggested the function could be vested with IP Australia with subsequent right of appeal to the Federal Court. A comparable arrangement applies to trade mark disputes. For example, the Registrar of Trade Marks can hear and determine applications to remove the trade mark from the register for non-use. However, the key difference between that arrangement and the proposal in relation to compulsory licensing is that the powers of the Registrar of Trade Marks are generally limited to the issuing and revoking of registrations and do not extend to licensing or any other commercial interactions between the owner of the trade mark and third parties.

The approach of vesting compulsory licensing powers with the relevant patent office has been adopted in some countries,[5] but the Commission does not support it. The current structure, functions and resources of IP Australia do not appear well adapted to a compulsory licensing role. For example, IP Australia, in its current dealings does not appear to have significant exposure to the *Competition and*

4 Similar provisions exist in the *Family Law Act 1975* (Cwlth) and the *Federal Magistrates Court Act 1999* (Cwlth). The *Administrative Appeals Tribunal Act 1975* (Cwlth) also does not give the President of the Tribunal powers to direct a proceeding to arbitration (NADRAC 2009).

5 For example, in the United Kingdom, Canada, Japan and India.

Consumer Act 2010 (Cwlth) — a potential key factor in compulsory licence matters. There is also no apparent expertise on determining appropriate compensation for the licence. The Law Council of Australia observed:

> [IP Australia], as it stands, would not be so well equipped to make such assessments. The assessments are predominantly accounting and commercial assessments and are likely to require determination of the credibility of witnesses, better handled by judges with experience of determining commercial disputes. (sub. 32, p. 2)

Under the current provisions, IP Australia is recognised as a potential participant in compulsory licence hearings (s. 139 of the Patents Act). The Commission considers that this is a more appropriate recognition of IP Australia's role in such matters.

The Centre for Law and Genetics (sub. 3) proposed vesting compulsory licensing powers in an expanded Copyright Tribunal of Australia, noting its experience in setting licence royalties. The Tribunal is an independent body administered by the Federal Court of Australia. It currently has jurisdiction on statutory and voluntary copyright licence matters, and has a general focus on determining remuneration (Copyright Tribunal of Australia 2009).

The Commission considers that this proposal is unlikely to generate significant efficiency gains. First, any synergies between the current functions and expertise of the Tribunal and a proposed role in patent compulsory licensing are likely to be limited. There are significant differences between copyright and patent licences. The former are likely to have a standard form, not involve highly technical issues and be issued to a large number of relatively homogenous users. In contrast, patent licences are likely to involve technical matters and be of a bespoke nature in the rights they confer. Thus any remuneration principles applied by the Tribunal may be of limited relevance to patent licences. Moreover, the Tribunal does not have a significant body of decisions to draw on. Over the past 30 years, there have only been 43 reported decisions, with only 8 decisions in the past 5 years.[6]

Second, from the limited evidence of the Tribunal's past operations, it is unclear whether there would be a material reduction in the costs of the parties. The Tribunal is presided over by a Justice of the Federal Court, and it draws registrar and administrative support from the Federal Court (Federal Court of Australia, sub. 29). The timeliness of its determinations appears comparable to Federal Court judgments on intellectual property matters. The Copyright Law Review Committee (2000) previously reported that the average time for the Tribunal to finalise matters was

6 This overstates the number of matters considered by the Tribunal, as some matters involved more than one decision.

22 months. An examination of the determinations issued since that report indicates similar timelines.

The Commission also examined the possibility of transferring the responsibility for compulsory licensing to the Australian Competition Tribunal or the Administrative Appeals Tribunal. It has concluded that those bodies are ill suited for the function, because their jurisdiction is limited to review of administrative decisions and does not cover civil law disputes between private parties.

Federal Magistrates Court

The Federal Magistrates Court (FMC)[7] is a lower-level federal court, which was established in 1999 'to provide a simple and accessible alternative to litigation in the Federal Court' (FMC nd). Its legislation requires the Court to 'operate informally and use streamlined procedures'. The FMC has broad jurisdiction, which includes (among other areas) administrative law, competition and copyright matters.

While a direct comparison of the efficiency of the FMC and Federal Court processes is difficult due to the differences in the complexity of the matters heard by the courts, FMC statistics indicate that it generally finalises its matters faster than the Federal Court. For example, in 2011-12, the FMC completed 78 per cent of the applications under general federal law within 6 months, and 94 per cent within 12 months (FMC 2012). In comparison, 36 per cent of the matters outstanding in the Federal Court on 30 June 2012 were aged over 12 months.

The Advisory Council on Intellectual Property (ACIP) has previously examined the case for extending the jurisdiction of the FMC to patent, design and trade mark matters. It observed that the FMC:

> … has the advantage of lower court fees and currently quicker times for resolution (though this may change as cases accumulate). It also uses innovative procedures such as fixing the trial date at the first hearing date which expedites the matter. (ACIP 2003, p. 30)

ACIP also noted that vesting such powers in a lower court may compromise the quality of the outcomes, due to the technical nature of the disputes. However, it also cited submissions that the quality of the outcome was less a function of the level of the court in the hierarchy than of the expertise of the adjudicator. Ultimately, it recommended for the jurisdiction of the FMC to be extended to patent matters.

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7 In November 2012, the Australian Parliament passed the Federal Circuit Court of Australia Legislation Amendment Bill 2012, which renamed the Federal Magistrates Court as the Federal Circuit Court of Australia.

The FMC in its past annual reports has expressed support for the recommendation:

> The Court considers the conferral of enhanced intellectual property jurisdiction would provide an alternative forum for those who may not otherwise pursue such actions. (FMC 2011, p. 37)

Notably, the FMC may already have jurisdiction to be involved in some compulsory licence matters, through its power to deal with cases involving the contravention of s. 46 of the *Competition and Consumer Act 2010* (Cwlth) (discussed in section 6.2).

ACIP's recommendation to extend the jurisdiction of the FMC to patent matters was not implemented by the Australian Government.[8] In its response, the Australian Government noted that the FMC was intended to deal with simpler and shorter cases, and that patent cases are generally longer than trade mark and design cases, and concluded:

> … the Government recommends that further consideration be given to conferring the Federal Magistrates Court specific jurisdiction in patent related disputes in the light of experience gained in the implementation of the recommendations for trade marks and designs, and the operation of the transfer mechanism in the *Jurisdiction of the Federal Magistrates Court Legislation Amendment Act 2006*, over a period of two years from implementation of the recommendations. (IP Australia ndb)

The Commission considers that extending the jurisdiction of the FMC to cover compulsory licensing matters is not justified at this time. The Court's function as a forum for speedy resolution of simpler cases is not well suited to a complex and untested area of the law, such as compulsory licensing. The absence of expertise within the FMC on patent matters would undermine any cost savings during and after the hearing, as well as increase the likelihood of appeal of the initial decision.

In light of the above, the Commission has concluded that, at this stage, the Federal Court is the most appropriate forum for developing the relevant jurisprudence.

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.

8 The *Intellectual Property Laws Amendment (Raising the Bar) Act 2012* (Cwlth) extended the jurisdiction of the FMC to some trade mark and design matters.

Timeliness of the process for pharmaceuticals — data protection provisions

Some inquiry participants were concerned that data protection provisions in the *Therapeutic Goods Act 1989* (Cwlth) could effectively delay a compulsory licensee's access to the market by up to five years (Dr Hazel Moir, sub. 31; Public Health Association of Australia, sub. 4 and DR52). This is because s. 25A of the Act prevents the data used to register a medicine as a therapeutic good from being used by another party to register their own product for five years after the original registration.

The Commission considers that, because the data protection provisions operate independently of the Patents Act, their assessment is outside of the scope of this inquiry. However, it notes that s. 25A of the Therapeutic Goods Act reflects Australia's obligations under Article 17.10.1 of the Australia–United States Free Trade Agreement (AUSFTA), which does not provide for any waiver of data protection for compulsory licences. The Commission also notes that the issue of data protection is currently being considered by a review of the system of patents for pharmaceuticals (IP Australia 2012k).

Reducing the uncertainty of the parties — is there a case for an objects clause?

The key sources of uncertainty relate to the operation of the specific grounds for a compulsory licence order and the Commission has made some suggestions that should clarify and better focus those grounds in sections 6.2 and 6.3.

Nevertheless, one overarching concern that applies to the operation of the compulsory licensing provisions in general, relates to the absence of a broader objects clause in the Patents Act.

Two past inquiries recommended that a statement of objectives is introduced into the Patents Act (SCARC 2010; ACIP 2010c). ACIP (2010c, p. 5) proposed that the purpose of the Patents Act should be:

> … to provide an environment that promotes Australia's national interest and enhances the well-being of Australians by balancing the competing interests of patent rights holders, the users of technological knowledge, and Australian society as a whole.

The Australian Government (2011a) agreed to those recommendations but has not implemented them to date.

Several participants to this inquiry (for example, Civil Liberties Australia, sub. 12; Business SA, sub. 20) also argued in favour of introducing a statement of objectives

into the Patents Act. Some participants while supporting this option, argued that any statement needed to be specific to give operational guidance to the courts.

For example, Dr Hazel Moir observed:

> Certainly an objectives statement is desperately needed in the Patent Act but it needs careful consideration. It should be clear and specific about the goal of inducing technological innovation. It should also make it clear that patentable inventions must also deliver a benefit to the public. (sub. DR46, p. 10)

The Commission considers that introducing a general objects clause into the Patents Act could help clarify the role of compulsory licensing and the considerations that should guide the court in making the order. However, there is a tradeoff between improving certainty of the parties and the need to retain flexibility to allow courts to adapt to the individual circumstances of each case. In that context, the statement proposed by ACIP has the Commission's in-principle support.

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.

6.2 Competition provisions

Under s. 133(2)(b) of the Patents Act, one of the grounds for a compulsory licence order involves a competition test, namely:

> (b) the patentee has contravened, or is contravening, Part IV of the Competition and Consumer Act 2010 or an application law (as defined in section 150A of that Act) in connection with the patent.

This section examines the current arrangements applying to the competition ground for compulsory licensing and considers potential reform options.

The other ground for granting a compulsory licence order — the 'reasonable requirements of the public' test — is discussed in section 6.3.

Origins of the competition test

The competition test was introduced into the Patents Act in 2006 as a consequence of the Australian Government's response to the recommendations of the review of intellectual property legislation by the Intellectual Property and Competition

Review Committee (IPCRC 2000). The IPCRC review examined the potential rationale for compulsory licensing provisions in the context of the reasonable requirements of the public test in the Patents Act and recommended that a competition-based test replace the existing test as the sole trigger for compulsory licensing (box 6.2).

However, in its response to the review, the Australian Government (Attorney General's Department nd) considered that limiting the operation of compulsory licensing to competition concerns would:

> … not cover some situations where the non-working of the invention, or other effective denial of reasonable access to it, has some negative effect on the public interest which is not dependent on competition in the market.

The Commission agrees with this view.

Box 6.2 The competition test recommended by the IPCRC

The IPCRC recommended that the 'reasonable requirements of the public' test be replaced with a competition test similar to the third-party access rules under Part IIIA of the *Trade Practices Act 1974* (Cwlth):

> The Committee recommends that s. 135 of the Patents Act be repealed and that s. 133(2) be amended to include an order requiring a compulsory license to be made if and only if all of the following conditions are met:
>
> a) access to the patented invention is required for competition in the (relevant) market;
>
> b) there is a public interest in enhanced competition in that market;
>
> c) reasonable requirements for such access have not been met;
>
> d) the order will have the effect of allowing these reasonable requirements to be better met; and
>
> e) the order will not compromise the legitimate interests of the patent owner, including that owner's right to share in the return society obtains from the owner's invention, and to benefit from any successive invention, made within the patent term, that relies on the patent.
>
> Such orders should be obtainable on application first to the Australian Competition Tribunal, with rights of appeal to the full Federal Court. (p. 17)

In elaborating on the effect of its recommendation, the IPCRC observed:

> … the Committee would expect that the expression 'required for competition in the (relevant) market' would amount to there being no other option for competition in that market; and that the enhancement of competition that would be secured by the grant would have to be material and substantial. As a result, the test would, in these respects, be somewhat more stringent than those that have applied in the United States and in Canada. (p. 163)

Source: IPCRC (2000).

The Australian Government decided to introduce a competition-based test as an additional ground for a compulsory licence order, rather than replace the reasonable requirements of the public test. Following the endorsement of this decision by the ALRC (2004), the new ground was added to s. 133 of the Patents Act in 2006. However, rather than adopting the test proposed by the IPCRC, which focused on *enhancing competition*, the amendment presented the compulsory licence as an enforcement mechanism directed at *remedying anticompetitive behaviour*. This was achieved by defining the competition ground as a contravention of Part IV of the *Competition and Consumer Act 2010* (Cwlth) (CCA).

Summary of the current legislative arrangements

The competition ground for invoking compulsory licensing derives from the interplay of the provisions in two pieces of legislation. Section 133 of the Patents Act introduces the ground with cross-reference to contravention of Part IV of the CCA. Consequently, it is the latter that provides the content on the conduct that could give rise to a compulsory licensing order.

Part IV of the CCA

Part IV of the CCA concerns restrictive trade practices. It contains several broad provisions prohibiting conduct deemed likely to lessen competition. These include:

- agreements that restrict dealings or affect competition (s. 45)
- misuse of market power (ss. 46, 46A)
- acquisitions that would result in a substantial lessening of competition (s. 50).

In addition, the CCA prohibits some specific conduct outright, including:

- agreements containing 'cartel provisions' (Division 1)
- price fixing between competitors (s. 45C)
- boycotts (ss. 45D, 45DA, 45DB)
- exclusive dealing (s. 47)
- resale price maintenance (s. 48).

Part IV overrides any conduct specifically authorised by the Patents Act when applying the competition provisions of the CCA. It also exempts the imposition of conditions on licences and assignments of patents, to the extent that they 'relate to the subject matter' of the patent, from all of the provisions of Part IV, with the exception of ss. 46 and 48 (box 6.3).

In practice, applications for compulsory licences under the competition ground would most likely fall under s. 46, because it is a section that most directly applies to refusals to license. There is some jurisprudence indicating that s. 46 can be used to create an access regime, which is effectively what a compulsory licence involves.[9] Several expert commentators — including Professor Corones (quoted in SELC 2006), Nielsen and Nicol (2008) and Lawson (2008a) — have argued that an applicant can seek a compulsory licence for breaches of Part IV under the remedy provisions of the CCA. For example, under s. 80 of the CCA, the court can grant an injunction on the terms it considers appropriate, including 'requiring a person to do an act or thing'.[10] Section 87 gives the court broad powers to make any order it thinks appropriate.

Box 6.3 **CCA provisions specific to intellectual property**

Part IV of the *Competition and Consumer Act 2010* (Cwlth) has two provisions that apply specifically to intellectual property. Section 51(1) states (in part):

> (1) In deciding whether a person has contravened this Part, the following must be disregarded:
>
> (a) anything specified in, and specifically authorised by:
>
> (i) an Act (not including an Act relating to patents, trade marks, designs or copyrights); or
>
> (ii) regulations made under such an Act.

Section 51(3) qualifies this by exempting some types of conduct from some sections of Part IV:

> (3) A contravention of a provision of this Part other than section 46, 46A or 48 shall not be taken to have been committed by reason of:
>
> (a) the imposing of, or giving effect to, a condition of:
>
> (i) a licence granted by the proprietor, licensee or owner of a patent, of a registered design, of a copyright or of EL rights [exclusive rights] within the meaning of the *Circuit Layouts Act 1989* , or by a person who has applied for a patent or for the registration of a design; or
>
> (ii) an assignment of a patent, of a registered design, of a copyright or of such EL rights, or of the right to apply for a patent or for the registration of a design;
>
> to the extent that the condition relates to:
>
> (iii) the invention to which the patent or application for a patent relates or articles made by the use of that invention …

It appears that Part IV of the CCA has not been widely used so far to gain access to intellectual property, although it is difficult to ascertain instances where it may have

9 *NT Power Generation Pty Ltd v Power and Water Authority* (2004) 219 CLR 90.

10 However, this remedy is not available to anyone other than the ACCC for breaches of s. 50.

been used as a threat in negotiations. The Commission has not seen any evidence of compulsory patent licences being issued under this ground. However, s. 46 has been used several times to extract access to copyrighted information (box 6.4).

Box 6.4 **Uses of section 46 to provide third-party access to copyright information**

In the case of ASX Operations Pty Ltd v Pont Data Australia Pty Ltd (1990) 27 FCR 260, ASX Operations attempted to increase the price and restrict the supply of wholesale electronic information to Pont Data — its competitor in the provision of information services. The Court ruled that ASX Operations contravened s. 46 of the *Trade Practices Act 1974* (Cwlth) and ordered it to supply the information on the terms that prevailed before the contravention.

The ACCC has also previously used s. 46 to induce owners of copyrighted information to provide access to third parties. It reported that it had extracted an undertaking from Telstra to ensure access for third parties to telephone directories data after threatening litigation under s. 46 (ACCC 1997a). The ACCC negotiated a supply charge for the provision of the data and claimed that access was achieved on 'fair and reasonable terms'. While negotiations were conducted under s. 46, the ACCC Chairman noted that 'this outcome should be viewed in the context of the new access regime embodied in Part IIIA of the TPA' and that the outcome established 'a framework for access to competitors, on fair terms, in downstream markets to an information database which has many of the properties associated with an essential facility' (ACCC 1997a).

The ACCC (1997b) also reported that it settled a case against the Commonwealth Bureau of Meteorology (BOM), where it alleged that BOM breached s. 46 because of its refusal to supply direct access to some of its specialised data services. The settlement had several elements, including:

(a) the publication of an agreed access policy document which details the basis and rights of access to information held by the Bureau and the considerations that apply; and

(b) the use of a model licence agreement which

  (i) sets out conditions applicable to the access and use of information held by BOM;

  (ii) provides dispute resolution procedures (including the option of mediation by an independent third party);

  (iii) specifies termination grounds and rights of parties; and

  (iv) provides for additional forecasting elements to be offered to the media in addition to the basic service offered by BOM whilst maintaining consistency with the comprehensive forecasting to the public through the free to air and print media.

Intellectual property is not covered by Part IIIA provisions

The CCA treats third-party access to intellectual property differently from services provided by nationally significant infrastructure facilities, such as certain railways, where providing access to other parties would promote competition objectives.

Part IIIA of the CCA governs the provision of access to services to promote 'effective competition in upstream and downstream markets' (s. 44AA). The use of intellectual property, except where it is an integral but subsidiary part of the service, is explicitly excluded from the scope of Part IIIA (s. 44B).

Consequently, intellectual property receives somewhat unusual legal treatment in that the grounds for access are derived from particular conduct deemed to be a restrictive trade practice under the CCA.

Assessment and reform of competition provisions

There are two potential problems with the current arrangements. The first arises from possible inconsistencies between the application of s. 133(2)(b) of the Patents Act and Part IV of the CCA. The second relates to the operation of s. 51(3) of the CCA.

Inconsistencies between the Acts

The current arrangement, where the trigger for a remedy under one piece of legislation is derived from a cross-reference to another legislation is a potential source of duplication.

It appears that Part IV of the CCA could operate independently of the Patents Act. The then Australian Government clarified the scope of s. 133(2)(b) in an explanatory memorandum to the Intellectual Property Laws Amendment Bill 2006:

> This provision to be inserted into the Patents Act is intended to complement the remedies available under the Trade Practices Act [now the CCA], and is not intended to limit the court's powers under the Trade Practices Act. It is intended to clarify that a compulsory licence for a patent is available as a remedy under the Patents Act for *any* breach of Part IV of the Trade Practices Act. This is in addition to any other remedies that may be available under the Trade Practices Act. (Baldwin 2006, para. 167)

The provisions of the Patents Act and CCA have some differences with respect to the rights afforded to prospective applicants, as well as the potential litigation avenues and process. In the absence of clear guidance on which legislation prevails

when the respective provisions are in conflict, the current arrangement can give rise to inconsistencies and uncertainties in application.

Range of remedies

While the Patents Act provides recourse to the specific order of a *non-exclusive* compulsory licence, the range of orders available under the CCA is much broader, and potentially includes damages in addition to any form of compulsory licence. Whether or not a compulsory licence is ordered under those broad provisions is at the discretion of the court, and applying under the Patents Act may provide the applicant greater certainty of obtaining this particular remedy. Nevertheless, some commentators (for example, Lawson 2008a) have concluded that the broader range of remedies under the CCA would make an application under the Patents Act unlikely.

Prescribed period

Under s. 133 of the Patents Act, an application for a compulsory licence can only be made at the end of a 'prescribed period', currently defined by the Patents Regulations 1991 (Cwlth) as three years after the filing of the patent. Conversely, the CCA does not constrain the timing of actions for contravention of Part IV of the Act, potentially allowing prospective licensees to apply for an order before an equivalent application can be lodged under the Patents Act.

Who can seek a compulsory licence

The Patents Act does not specify who can apply for a compulsory licence following a contravention of Part IV of the CCA. In theory, this opens the course of action to any third party. In contrast, under the CCA, a compulsory licence could only be sought as a *remedy* for contravention of the Act, which means that it is only available to those who have suffered a loss from the contravention.

Pricing

Section 133(5)(b) of the Patents Act requires that any court-imposed payment to the patentee for a compulsory licence is 'just and reasonable having regard to the economic value of the licence and the desirability of discouraging contraventions of Part IV of the Competition and Consumer Act 2010'. There is no equivalent provision in the CCA. Professor Corones (quoted in SELC 2006) argued that this

could lead to potentially conflicting determinations depending on whether the action was brought under the CCA or the Patents Act.

Jurisdiction of courts

Under the Patents Act, the Federal Court is the lowest court that has jurisdiction with respect to compulsory licensing matters. On the other hand, s. 86(1A) of the CCA confers jurisdiction on the FMC for 'any matter arising under section 46 … in respect of which a civil proceeding is instituted by a person other than the Minister'.

As noted earlier, s. 46 of the CCA is likely to be of greatest relevance in the context of compulsory licence applications for contravention of Part IV of the CCA. Thus, there may be cost savings in applying for an order directly under the CCA (although, as discussed earlier, these may not be great).

Addressing the overlap between the CCA and the Patents Act

The cross-referencing of the CCA in the compulsory licensing provisions of the Patents Act undermines the effectiveness of the latter as a standalone ground for compulsory licensing. The CCA appears to provide broader and lower-cost access to potential applicants, as well as a superior range of remedies, although there is some uncertainty for the applicant on whether the court would choose to apply its broad discretionary powers to issue a compulsory licence. Consequently, it is unclear that an application for a compulsory licence would be made under s. 133(2)(b) of the Patents Act. At the same time, the existence of two somewhat inconsistent regimes that may allow the grant of compulsory licences could be a source of uncertainty for the parties and the courts.

The Commission has considered three options to address the duplication and potential inconsistency between the CCA and the Patents Act:

1. Amend s. 133 of the Patents Act to state that it operates as a standalone code, which overrides any powers under the CCA to grant compulsory licences.
2. Return to the arrangements that existed prior to the amendment of the Patents Act. This would involve removal of the competition ground from the Patents Act, leaving the CCA as the only legislation that provides remedies for anticompetitive conduct.
3. Remove the competition ground from the Patents Act (as with option 2) and add a specific compulsory licence remedy provision to the CCA.

The Commission does not support the first option. This approach may resolve the inconsistencies relating to compulsory licence applications under the two Acts. However, it would not address the duplication between the Patents Act and the CCA for patent-related matters involving restrictive trade practices, where, for example, a compulsory licence is sought in addition to a remedy under the CCA. In addition, under this arrangement, compulsory licence applications for restrictive trade practices would still be subject to the 'prescribed period' requirement. Thus, there would be an inconsistency in the availability of different remedies depending on the timing of the application. There is no clear policy reason why restrictive trade practices matters should be governed by separate regimes depending on the remedy. Similarly, there is no clear rationale for imposing prescriptive rules on when particular remedies for contravention of Part IV of the CCA become available.[11]

Making s. 133 of the Patents Act a standalone code would also not address the apparent anomaly under s. 133(2)(b) that allows a person who was not affected by the contravention of Part IV of the CCA to apply for a compulsory licence. In this context, the remedy provisions of the CCA are a more appropriate mechanism.

The second option would leave the responsibility for remedying anticompetitive behaviour relating to patent access with the regime that is specifically designed for the task. It would also result in a more streamlined regime, while limiting the scope for parties not affected by the contravention of Part IV of the CCA to obtain compulsory licences under that ground. However, this approach may leave some uncertainty for the parties over whether the court would use its discretion to order compulsory licences under the broad remedy provisions of the CCA, a point also noted by the ACCC (sub. DR50).

Consequently, the Commission supports the third option. An explicit recognition of compulsory licences in the remedy provisions of the CCA would allow plaintiffs to rely on a specific provision and reduce uncertainty for both parties. Notably, this option was also recommended by the Industrial Property Advisory Committee (1984, p. 30) in its report on *Patents, Innovation and Competition in Australia*:

> In the United States, the courts do have power to order compulsory licences to redress antitrust breaches, and that power on occasions has been exercised to great effect. Its existence and the possibility that it will be exercised also operate as important influences upon patentees to grant licences for the purposes of avoiding or settling

[11] The prescribed period requirement in the Patents Act originated from the Paris Convention. However, under the Convention, the requirement only applies to cases involving a failure to work the patent (Article 5(A)(4)). Thus, there is no international treaty obligation on Australia to apply the prescribed period to compulsory licences issued under the competition ground.

> antitrust litigation. In our opinion, the vesting of a similar power in the relevant Australian court would be likely to assist in curbing unjustifiable, anticompetitive, patent-related conduct. Accordingly, we recommend the introduction of a power of this kind as an additional discretionary remedy in cases of contravention of Part IV of the Trade Practices Act. It would be more logical for the relevant provisions to appear in the Trade Practices Act rather than the Patents Act, but either would accomplish the desired result.

A possible way of operationalising this proposal would be to add compulsory licences to the list of remedies available to the court under s. 87(2) (box 6.5).

Box 6.5 **Section 87 of the Competition and Consumer Act 2010 (Cwlth)**

Section 87(1) of the *Competition and Consumer Act 2010* (Cwlth) states:

> … where … the Court finds that a person who is a party to the proceeding has suffered, or is likely to suffer, loss or damage by conduct of another person that was engaged in … contravention of a provision of Part IV … the Court may … make such order or orders as it thinks appropriate … (including all or any of the orders mentioned in subsection (2) of this section) if the Court considers that the order or orders concerned will compensate the first-mentioned person in whole or in part for the loss or damage or will prevent or reduce the loss or damage.

Sections 87(1A) and 87(1B) state that an application for a remedy under s. 87 can be made by the ACCC on behalf of anyone who has suffered, or is likely to suffer damage, provided the ACCC has obtained their consent for the application.

Section 87(2) lists some of the remedies available to the court, including orders to:

- declare the whole or any part of a contract void
- vary a contract or arrangement
- refund money or return property
- compensate for damage or loss
- supply specified services
- vary or terminate an instrument creating or transferring an interest in land.

To ensure that compulsory licence orders under the CCA contribute to the general body of precedent on compulsory licensing, it is desirable that the new remedy provision in the CCA imposes the same requirements on compulsory licence orders as apply in the Patents Act. Specifically, the new provision should contain the requirement of non-exclusivity (s. 133(3)(a) of the Patents Act), impose limits on subsequent assignments of the licence (s. 133(3)(b)) and provide for compensation determined in the same manner as under the Patents Act.

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.

Problems with section 51(3)

Section 51(3) has existed since the inception of the *Trade Practices Act 1974* (Cwlth). There have been two significant reviews of its operation — a review under the auspices of the Competition Principles Agreement by the National Competition Council (NCC 1999), and a review by the IPCRC (2000). While the reviews differed slightly on their recommendations for reform, they identified similar problems in the section's operation.

Uncertainty of application

There is general uncertainty about the scope of s. 51(3). The section exempts conditions in a patent licence from several provisions of part IV, to the extent that the condition 'relates to' the invention to which the patent relates or articles made using that invention. The only reported case dealing with s. 51(3) contained comments from a single High Court judge on the meaning of the words 'relates to':

> In bridging the different policies of the Patents Act and the Trade Practices Act, s.51(3) recognises that a patentee is justly entitled to impose conditions on the granting of a licence or assignment of a patent in order to protect the patentee's legal monopoly … Section 51(3) determines the scope of restrictions the patentee may properly impose on

> the use of the patent. Conditions which seek to gain advantages collateral to the patent are not covered by s. 51(3).[12]

However, the meaning of the words 'relates to' is still unclear. The Hilmer review concluded:

> The true scope and hence significance of the provision remains uncertain because the important 'relates to' requirement has not been subject to any definitive judicial interpretation. (Hilmer, Rayner and Taperell 1993, p. 150)

The NCC (1999, p. 186), after considering several submissions to this effect, concluded that the 'uncertainty reduces the effectiveness of section 51(3) in achieving its objectives'. The IPCRC (2000, p. 207) cited advice from the Australian Government Solicitor, which 'highlighted the lack of clarity as to exactly which conduct is exempted'.

Consequently, both the NCC and the IPCRC recommended that the ACCC issue guidelines clarifying the operation of the section.

The Australian Government accepted the recommendation of the IPCRC. Subsequently, the ACCC reported that it was preparing the guidelines that would define:

- when intellectual property licensing and assignment conditions might be exempted under s. 51(3);
- when intellectual property licences and assignments might breach Part IV; and
- when conduct that is likely to breach the Act might be authorised. (Fels 2002, p. 9)

In its 2003-04 annual report, the ACCC noted:

> The ACCC has prepared draft intellectual property guidelines that will be released for public consultation when proposed legislation to amend section 51(3) of the Trade Practice Act is introduced to parliament. (ACCC 2004, p. 103)

To date, the amendments to s. 51(3) referred to by the ACCC have not been implemented, and the guidelines have not been released.

Debate on the appropriateness of section 51(3)

Some commentators have argued that s. 51(3) currently has narrow application. For example, Hanks (2007) claimed that much of the relevant conduct would still be caught by ss. 46 and 48 of the CCA, to which the exemption does not apply. He also

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12 *Transfield Pty Ltd. v Arlo International Limited* (1980) 144 CLR 83, per Mason J at pp. 102-03.

observed that s. 51(3) only covered *conditions* in licences and did not apply to *refusals* to licence.[13]

Nevertheless, the NCC (1999, p. 149) argued that intellectual property rights should be treated similarly to other types of property rights:

> … section 51(3) was most likely enacted to prevent a perceived clash between the interests of intellectual property owners and competition law … The original objective is no longer relevant. It is now accepted that intellectual property laws do not create legal or economic monopolies. Intellectual property laws create property rights and the goods and services produced using intellectual property rights compete in the marketplace with other goods and services.

Consequently, the NCC recommended an amendment of s. 51(3) to ensure that arrangements such as price-fixing, cross-licensing, and patent pooling, as well as price and quantity restrictions, were caught by the Act. This recommendation effectively amounted to a repeal of s. 51(3).

Similarly, the ACCC argued in its submission to the IPCRC (2000) and in a submission to the current ALRC review into *Copyright and the Digital Economy (*ACCC 2012) that IP rights should be treated in the same manner as other property rights and that s. 51(3) should be repealed.

However, the IPCRC (2000) concluded that the licensing of intellectual property warranted different treatment to other forms of property, because:

- Initial owners of intellectual property rights are not always best placed to exploit them.
- Intellectual property rights often do not map simply onto products and complex webs of cross-licensing are required to put those rights to productive use.
- Forcing the parties to invent around existing knowledge, because they cannot obtain a licence due to competition concerns could waste more resources than would be gained from increased competition.

The IPCRC recommended replacing s. 51(3) with a new outcomes-based section stating:

> … a contravention of Part IV of the TPA, or of section 4D of that Act, shall not be taken to have been committed by reason of the imposing of conditions in a licence, or the inclusion of conditions in a contract, arrangement or understanding, that relate to

[13] Refusals to license could also include situations where the refusal is a result of the licensee not agreeing to conditions demanded by the licensor. Hanks (2007) discussed High Court authority on situations where the price demanded by the owner of the property amounted to a 'constructive refusal to deal'.

> the subject matter of that intellectual property statute, so long as those conditions do not result, or are not likely to result in a substantial lessening of competition. The term 'substantial lessening of competition' is to be interpreted in a manner consistent with the case law under the TPA more generally. (IPCRC 2000, p. 215)

The Australian Government accepted this recommendation in part:

> Sections 46, 46A or 48 would be treated as per the old subsection 51(3). IP licensing would be subject to the provisions of Part IV, but a contravention of the per se prohibitions of sections 45, 45A and 47, or of s. 4D, would instead be subject to a substantial lessening of competition test. (Attorney General's Department nd)

To date, this amendment has not been implemented.

Reform options for section 51(3)

The Commission has examined several options for reform of s. 51(3):

1. Repeal s. 51(3) or amend it in accordance with the recommendation of the NCC (1999).
2. Amend s. 51(3) in accordance with the recommendations of the IPCRC (2000).
3. Amend s. 51(3) in accordance with the Australian Government's response to the IPCRC (2000). This would entail removing the exemption from the per se prohibitions under ss. 45, 45A and 47 of the CCA, where the licence conditions substantially lessen competition.
4. Retain the status quo.

The Commission has not received any evidence that s. 51(3) played a material role in decisions that could potentially lead to a compulsory licence application. However, the provision's scope is broader than those matters. The section also covers what would otherwise be offences under the CCA relating to voluntary licensing of patents, trade marks and designs — issues which are outside the terms of reference of this inquiry.

Several participants contended that s. 51(3) played an important role in facilitating voluntary licensing agreements. IPTA and FICPI (sub. DR41, p. 3) argued that:

> … the section performs a valuable task in providing a safe harbour for patent licences and assignments. If these provisions were fully exposed to the CCA, transaction costs would increase and uncertainty would be introduced into an environment where generally there is a high degree of risk attached to the commercialisation process. The justification for section 51(3) is that it applies to give certainty of non-application of certain provisions of the CCA where, in the vast majority of situations, those provisions would not, in any event, apply. This is for the reason that a patented invention is

unlikely to exhibit such market power that a condition relating to that invention would have the effect … of substantially lessening competition in a relevant market.

Croplife (sub. DR42, p. 5) cited comments from two of its (unidentified) member companies, arguing that a repeal of s. 51 (3) could discourage licensing activity:

> 'A general observation is that in our business Australia could be simply carved out of such agreements if exclusivity were not available in what is already deemed a small market. Regulatory costs would only enhance that view.'
>
> 'Where [CropLife member] permits other parties to license its intellectual property … [it] often places strict contractual conditions around the way in which the intellectual property may be used, including the territory in which it may be used by the licensee. In addition, [CropLife member] may also from time to time require a licensee to promote its products to the exclusion of others. Should these conditions no longer be allowable, this may well factor in a disinclination to license its intellectual property.'

Similar views were expressed by the CSIRO (sub. DR47) and Richard Hoad (sub. DR49).

While the Commission accepts that the provision may generate some benefit to prospective licensees, it is unclear whether this benefit is significant. As discussed above, s. 51(3) has rarely been raised in litigation. Several reviews have concluded that the uncertainty surrounding its purpose and application was undermining its effectiveness. Moreover, as observed by the ACCC (2012), the section in its current form refers to trade marks legislation that was superseded in 1995. To the Commission's knowledge, despite the likely non-application of the provision to trade marks from 1995, the issue was only formally raised with the Australian Government by the Law Council of Australia in 2010 (Law Council of Australia 2011).

More importantly, s. 51(3) creates a unique competition law arrangement for intellectual property. Generally, to the extent that there are competition issues warranting government intervention, it is desirable to treat them similarly across the different sources of market power. The alternative approach of customising competition law for different sources of market power could generate economic distortions, by inefficiently encouraging some types of behaviour over others. In its submission to this inquiry, the ACCC observed:

> While recognising the importance of granting and protecting exclusive intellectual property rights, the ACCC considers that the exception provided by section 51(3) for certain licence conditions from the competition provisions of the CCA potentially excludes significant anticompetitive conduct from the application of this Act. The ACCC considers that the licensing or assignment of such intellectual property rights should be subject to the same treatment under the CCA as any other property rights … (sub. DR50, pp. 1-2)

Section 51(3) has no exact analogues in EU or US legislation, although EU legislation provides some generic exemptions in the application of competition law, which could apply to intellectual property.[14] The US *Antitrust Guidelines for the Licensing of Intellectual Property* (US Department of Justice and the Federal Trade Commission 1995) state:

> The Agencies [U.S. Department of Justice and the Federal Trade Commission] apply the same general antitrust principles to conduct involving intellectual property that they apply to conduct involving any other form of tangible or intangible property … As with other forms of private property, certain types of conduct with respect to intellectual property may have anticompetitive effects against which the antitrust laws can and do protect. Intellectual property is thus neither particularly free from scrutiny under the antitrust laws, nor particularly suspect under them.

In its submission to the ALRC's review of *Copyright in the Digital Economy*, the ACCC (2012, p. 5) observed:

> … in other jurisdictions, such as the United States, IP rights are subject to the same competition laws as all other property rights … in these jurisdictions, there has been neither an erosion of IP rights for creators nor any apparent impact on the incentives for the production of copyright material.

The Commission notes the IPCRC's reasons for its recommendation not to repeal the section and its conclusion that the per se prohibitions in the CCA could discourage some arrangements that were efficient (even if they reduced competition). However, Part VII of the CCA, which allows the ACCC to authorise most conduct prohibited under Part IV, when there is a net public benefit, is a mechanism designed to address such circumstances.

Several inquiry participants (for example, CSIRO, sub. DR47; IPTA and FICPI, sub. DR41) argued that repeal of s. 51(3) would expose licensees to additional transaction costs under the notification and authorisation provisions of the CCA. However, if those provisions do not operate effectively, this would be an argument for their reform, rather than for creating a unique regime for intellectual property.

Ultimately, s. 51(3) appears to play a relatively minor role in compulsory licensing, and the issue is broader than the terms of reference for this inquiry. Nevertheless, as a matter of broad principle, the Commission agrees with the conclusions of the NCC and the ACCC that intellectual property should be subject to the same

[14] EU legislation provides 'block exemptions' from competition law for some types of technology transfer agreements and an 'exceptional circumstance' defence for refusals to licence. However, some commentators (for example, Anderman and Shmidt 2007) have argued that, in practice, general doctrines of competition law usually apply to intellectual property.

treatment under the CCA as other property rights. It has not seen convincing evidence to rebut that principle in the context of access to patents.

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.

Should the application of the competition law to the licensing of intellectual property be clarified?

Irrespective of whether s. 51(3) is retained, repealed, or amended, there is a strong case for clarifying the application of Part IV of the CCA to the licensing of intellectual property.

As discussed above, the uncertainty associated with the scope and operation of s. 51(3) has been noted in several reviews. On the other hand, any change to the existing arrangements would itself generate some uncertainty for the parties. In a recent submission to the ALRC's review into *Copyright and the Digital Economy*, the ACCC (2012, p. 35) observed:

> … repeal of section 51(3) may give rise to some initial uncertainty for some owners of IP rights as to whether their licensing and assignment arrangements may fall within the ambit of Part IV of the CCA. The ACCC considers that providing guidelines which clarify the types of behaviour likely to result in a breach of the CCA's provisions will assist in resolving this transitional issue.

The Commission agrees with the ACCC and supports the development of guidelines clarifying the operation of Part IV of the CCA in relation to the licensing of intellectual property. The key considerations are the focus and scope of the guidelines, as well as their status in law. Hanks (2007) criticised the IPCRC proposal for:

- unclear focus — the guidelines were to clarify the ACCC's enforcement policy, but also to provide sufficient direction to IP owners on what types of behaviour would substantially lessen competition; the wide consultation process risked generating 'disembodied guidelines' that would not fulfil their purpose of clarifying the ACCC enforcement policy

- absence of clear authority underpinning the guidelines — the guidelines issued by the ACCC would only have a 'ring of authority' if they concern ACCC policy, rather than being a general treatise on competition law.

Several other jurisdictions have issued guidelines clarifying the application of competition law to intellectual property, including the European Union, United States and Canada (European Commission 2004; US Department of Justice and the Federal Trade Commission 1995; Competition Bureau Canada 2000). Notably, the US guidelines are generally well regarded in the literature and could be used as a starting point.

6.3 Reasonable requirements of the public

Even if it operates effectively, the current competition test would not cover all circumstances in which a compulsory licence could promote public welfare. Part IV of the CCA focuses on remedying anticompetitive conduct. Specifically, s. 46 of the CCA requires an anticompetitive purpose in addition to the exercise of market power by the patent holder. Consequently, the current test would not apply to situations where the patentee exercises their market power without a goal of damaging their competitor or preventing or deterring competition, even if the outcomes of such behaviour are not in the public interest — price gouging is an example of such behaviour.

In discussing the effectiveness of s. 46 in operating as an access regime, the Hilmer report (Hilmer, Rayner and Taperell 1993, pp. 243, 245) noted the 'uncertainties and delays associated with reliance on the general competitive conduct rules' and specifically, 'the difficulties in demonstrating a proscribed purpose'. The Commission has previously found:

> … as a stand-alone mechanism for providing efficient access to essential infrastructure services, there remain considerable doubts about the efficacy of Section 46 specifically and Part IV more generally. This is particularly the case as Australian trade practices law does not normally provide remedies against firms which are able to earn monopoly rents … Further, it is significant that no major developed country relies solely on general competitive conduct rules in this area … (PC 2001, p. 112)

The current 'reasonable requirements of the public' test

Under s. 133(2)(a) of the Patents Act, a court may issue a compulsory licence where it is satisfied that the 'reasonable requirements of the public' with respect to the patented invention have not been satisfied (box 6.6). This is conditional on the applicant trying for a 'reasonable period' to obtain from the patentee an

authorisation to work the invention on 'reasonable terms and conditions'. Additionally, the patentee must be unable to provide a reasonable explanation for any failure to exploit the patent. Section 135(1) of the Patents Act provides guidelines for the interpretation of the 'reasonable requirements' of the public.

Box 6.6 **'Reasonable requirements of the public' test**

The Federal Court may order a patentee to grant an applicant a licence to work a patented invention on the grounds that the 'reasonable requirements of the public' are not being satisfied. The criteria for making this order are specified in s. 133(2)(a) of the *Patents Act 1990* (Cwlth):

(a) all the following conditions exist:

(i) the applicant has tried for a reasonable period, but without success, to obtain from the patentee an authorisation to work the invention on reasonable terms and conditions;

(ii) the reasonable requirements of the public with respect to the patented invention have not been satisfied;

(iii) the patentee has given no satisfactory reason for failing to exploit the patent.

Guidance on the reasonable requirements of the public is given in s. 135(1):

(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.

Problems with the test

Unclear purpose

As noted earlier, IPCRC (2000, p. 162) concluded that instances where compulsory access is warranted include 'situations in which bargaining between parties is not able to achieve an outcome or, more importantly, situations in which the access right acts as a pro-competitive remedy that tempers the exclusivity that the patent right primarily provides'. To some degree, ss. 133(2)(a) and 135 could be construed as promoting a competition objective. However, this objective is not explicit and any interpretation of the purpose of the section is further clouded by references to the protection of domestic industries and by the lack of jurisprudence to give meaning to the words of the sections (discussed below).

This lack of clarity of purpose is likely to undermine the effectiveness of this ground for compulsory licensing.

Uncertainty of language

The concept of 'reasonable requirements of the public', as it is defined in the Patents Act, does not appear to have direct analogues in other Australian jurisprudence. Given the limited case history of compulsory licensing in Australia, there is limited guidance on how the court might interpret the 'reasonable requirements' of the public. This is in contrast to the concept of 'public interest' which is commonly applied across a range of areas. While there are some differences depending on the context, the courts are able to draw on some precedents from other applications of the test.

Lawson (2008b) suggested that the construction of the provision implies that one or more of paragraphs (a), (b) and (c) of s. 135 must be established before the reasonable requirements of the public can be considered to have not been satisfied. In addition, there are a number of terms in the test that may be open to varying interpretations, potentially creating uncertainty for prospective compulsory licence applicants. This uncertainty has been noted by a number of commentators:

> The *Patents Act* does not provide any guidance regarding what would be considered a 'satisfactory reason for failing to exploit the patent'. This would be a matter for the court to determine. (ALRC 2004, p. 618)

> The phrases 'reasonable period' and 'reasonable terms and conditions' are not defined in the *Patents Act* or considered in any Australian cases ... the necessary threshold of reasonableness is unclear, and predicting how a court might assess the threshold is uncertain. (Lawson 2008b, p. 132)

The uncertainty may reduce the incentive for firms to apply for a compulsory licence, even where they are experiencing considerable difficulty accessing a patent. As has been noted by the ALRC (2004, p. 624):

> … the existing lack of clarity in the 'reasonable requirements of the public' test may be one reason why few compulsory licences have been sought, or granted, under the *Patents Act*.

Protectionist language

The language contained in s. 135(1) of the Patents Act (box 6.6) appears to conflate the interests of individual trades or industries with those of the broader public. For instance, s. 135(1)(a) suggests that the reasonable requirements of the public are not satisfied if 'an existing trade or industry in Australia, or the establishment of a new trade or industry in Australia, is unfairly prejudiced' by non-access to a patented invention. Section 135(1)(b) covers instances where the patentee is willing to license, but the conditions of licence are considered to be 'unfairly prejudiced' to Australian trade or industry.

The IPCRC (2000, p. 162) observed that, while there is a case for compulsory licensing provisions, the wording of the reasonable requirements of the public test is outdated:

> … there may be instances where a compulsory access right is warranted. These include situations in which bargaining between parties is not able to achieve an outcome or, more importantly, situations in which the access right acts as a pro-competitive remedy that tempers the exclusivity that the patent right primarily provides ... Indeed, the threat of compulsory licensing may lead to innovations being worked sooner and more widely than they would otherwise have been. The current terms of the section seem poorly aligned to securing these goals. Rather, they hark back to a period where the primary concern was the promotion of domestic industry, rather than securing the best use of resources and achieving high levels of productivity. Moreover, they lack an explicit competition test, and do not seem to allow for the legitimate interests of the rights owner to be adequately protected.

The Commission considers that the conflation of the reasonable requirements of the public with the interests of Australian industry is problematic. The purpose of the reasonable requirements of the public test should not be to protect the interest of a particular trade or industry, if this comes at a net cost to the broader community. For example, there may be instances where providing a compulsory licence has a benefit to a trade or industry today, but compromises community-wide welfare over time by reducing the incentive of foreign firms to market their products in Australia.

To the extent that protecting the interests of a particular Australian industry is desirable for economic efficiency, it is more appropriate to consider this as part of a broader public interest test, than treating the interests of the industry as an end goal.

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.

The Commission's conclusions on the reasonable requirements of the public test

Determining whether the reasonable requirements of the public test is likely to be efficient and effective is difficult. With a limited case history, any assessment is largely reduced to speculation about how the court may interpret the provisions of the Patents Act.

Nevertheless, the Commission has identified above some problems, which are likely to compromise the provision's effectiveness and efficiency. First, the test appears to stand alone in Australian legislation or Common Law, rather than being consistent with and leveraging off comparable provisions in other laws. This increases the uncertainty for the parties on how the provisions would be interpreted and hence, the costs of a compulsory licensing dispute. Second, s. 135 appears to pursue protectionist objectives, which may be inconsistent with community-wide welfare.

As also noted above, the competition test recommended in section 6.2 would not address all circumstances where a compulsory licence may promote the public interest. Thus, rather than simply repealing the reasonable requirements of the public provisions, they should be replaced with a new test based on the public interest.

A new public interest ground

As noted earlier, the Australian Government elected not to adopt the competition ground proposed by the IPCRC (2000). As a result, third-party access to patents is governed by CCA provisions that do not have access as their primary function.

There is merit in replacing the current reasonable requirements ground with a new ground for compulsory licensing of patents, which is based on public interest considerations. In addition to addressing the shortcomings identified earlier, this would better complement the current competition ground.

Should the new ground draw on existing access provisions of the CCA?

In arriving at its recommendation on the new ground for compulsory licensing, the IPCRC considered housing the test within Part IIIA of the *Trade Practices Act 1974* (Cwlth) (by removing the exemption for intellectual property in s. 44B). It concluded that Part IIIA was poorly suited to handle intellectual property rights, because those rights did not fit into the 'facility' and 'service' concepts underpinning the relevant sections — a view the Commission agrees with. Nevertheless, it sought to make its test generally consistent with Part IIIA.

The Commission also agrees with the principle that the new ground should, where possible, utilise the precedents from existing jurisprudence. At the same time, the contextual differences between intellectual property and infrastructure that is subject to access regulation also need to be recognised. Thus, while the test proposed below utilises some of the elements of existing access regimes, it does not map them directly.

What circumstances should the access regime target?

As discussed in section 6.2, s. 46 of the CCA does not cover circumstances where there is no anticompetitive purpose in the patentee's actions, but granting access to another party would, nevertheless, promote the public interest. For example, this may include situations where a patent confers on the patentee monopoly power in a downstream or upstream market and the patentee exercises that power to restrict the supply of the good or service and/or raise prices. It may also include a situation where the patentee is not working the invention in Australia and there are no substitute products available — that is the existence of a patent is blocking the emergence of a new market.

Such circumstances should be recognised in a new threshold requirement: '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 ACCC (sub. DR50) proposed that competition issues should be specifically referred to in the context of the public interest test. However, the Commission considers that its proposed threshold requirement is better aligned with the objectives of the regime, which are not to enhance competition per se, but to deliver a net benefit to the community through greater availability of a patented invention. Furthermore, while a successful compulsory licence application may often result in enhanced competition , it would not always be the case. For example, focusing solely on promoting competition will not address circumstances where the patentee is not using the patent and there are no competing products available in the market.

The public interest requirement

Intellectual property access regimes have in the past been criticised by some commentators as being generally incompatible with the objectives of IP law. For example, Hoad (2003, p. 33) argued that the compulsory licensing provisions proposed by the IPCRC:

> … have the potential to seriously undermine the incentive to innovate provided by patent laws. This is due to the danger posed by a broadly defined access regime. The patent laws currently correlate the reward for innovation with the value of the creation — the more valuable the advance over the prior art, the greater the financial rewards flowing to the patentee … A broad access regime has the reverse effect — the greater the advance, the more likely that the invention will be required to compete in the market, and therefore the greater the risk that a compulsory licence will be granted.

However, this need not be the case if the tradeoff between the rights of the patent holder and the interests of the broader public are adequately recognised in an explicit public interest test and, where a licence is ordered, in the terms of the order.

In this context, it is important to clarify the tradeoff involved in determining the public interest. Specifically, it should involve consideration of:

- benefits to the community from meeting the relevant unmet demand — these should include the direct benefits to the consumers of the relevant good or service, and any spillover effects, such as, for example, improved public health or environmental outcomes
- commercial costs and benefits to the patent holder and the licensee from granting access to the patented invention
- other impacts on the wellbeing of the community — these should include the benefits from greater competition and the likely impacts on innovation. The latter would involve considering both the negative influences, such as any resulting disincentives to invest in innovation and to disclose it through a patent, and positive effects, such as an increase in follow-on innovations relying on the original patent.

IPTA and FICPI (sub. DR41) proposed that the public interest test should require a substantial section of the Australian public to be suffering detriment from the behaviour of a patentee. This would exclude cases where the cost of current behaviour is concentrated among a minority, but is sufficiently large in aggregate for there to be a net benefit to the community from granting a compulsory licence. The Commission, therefore, favours a public interest test based simply on a net benefit to the community, without any prescription on how this is distributed. Nevertheless, the Commission agrees that it is desirable for the new ground to contain a safeguard against trivial or vexatious applications. To achieve this, the test

should contain a threshold requirement that the public interest in ordering a compulsory licence must be substantial, for the application to succeed.

IPTA and FICPI also argued that the public interest test should explicitly require an applicant to demonstrate capability of

> … producing the relevant product or providing the relevant service within the timeframe, in such quantities and on such terms and conditions as are likely to alleviate the detriment [to a substantial section of the Australian public]. (sub. DR41, p. 2)

The Commission does not support this proposal. It is questionable that court consideration of this issue is needed, given the clear commercial incentive for prospective applicants to only apply for compulsory licences where they are able to exploit them — a non-exclusive non-transferable licence has no value other than in use. Furthermore, a compulsory licence holder would not necessarily have to be able to serve the 'substantial section of the Australian public' that IPTA and FICPI define as their benchmark for there to be a net benefit to the community.

Ultimately, if an individual applicant is unable to meet the entire shortfall in demand, the preferable solution is not to deny that applicant access, but to allow access to other applicants until the shortfall is eliminated. The Commission expects its proposed provision to operate in this manner. This is because compulsory licences would remain non-exclusive, allowing new applicants to seek access, as long as Australian demand has not been reasonably met and, in the process, to rely on the findings of the judge in the original application.

Pricing and the public interest

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

Several participants argued that it was desirable to introduce pricing guidelines to assist the court in determining compulsory licence terms. Telstra Corporation argued that additional guidance would provide certainty for both patentees and prospective licensees, and proposed:

> The Patents Act should include more detailed guidance regarding the criteria for courts to consider in determining the terms of compulsory licences. These should include consideration of the revenue of the product and the number of patents that apply. The benefit of such additional guidance is to provide certainty for both patentees and prospective licensees. (sub. 8, p. 5)

Other participants (for example, CSIRO, sub. 26; Law Council of Australia, sub. 32) argued that courts routinely make decisions on compensation for intellectual property rights and can draw on Australian jurisprudence on patent infringements, international decisions on compulsory licences, as well as market data on voluntary licensing. However, such data may not be applicable to compulsory licence disputes. For example, the criteria for determining relief for patent infringement in s. 122(1A) of the Patents Act include (among others):

> (a) the flagrancy of the infringement; and
>
> (b) the need to deter similar infringements of patents; and
>
> (c) the conduct of the party that infringed the patent …

Such considerations would be irrelevant in the case of a compulsory licence issued under the proposed public interest test.

Nielsen and Nicol (2008) reported considerable variance in the manner in which courts awarded compensation for compulsory licences in the United States and United Kingdom. They also observed that in Australia:

> … in the few successful cases brought under s. 46 of the TPA, there has been a marked reluctance on the part of the courts to impose a price upon the parties where there has been no previous dealing. Even where there has been some dealing between the parties the matter is not clear cut. In Pont Data Australia Pty Ltd v ASX Operations Pty Ltd, there was marked divergence between the trial judge and the Full Court of the Federal Court on the issue of the price at which copyrighted information should be supplied by the unsuccessful respondent. (Nielsen and Nicol 2008, pp. 353-4)

There is merit in providing some guidance on pricing. As well as reducing uncertainty and costs of the parties, it could improve the efficiency of the outcomes, by ensuring that the relevant considerations are taken into account by the court. However, the potential scenarios in which a compulsory licence may be ordered are too diverse to have a useable set of specific one-size-fits-all criteria.

To that end, it is desirable to have a broad set of principles that allow any order to be adapted to the individual circumstances of the case. The key consideration that should be recognised in the principles is the need to balance the right of the patentee to obtain an appropriate economic return on their investment, and the rights of the public to the invention being exploited efficiently.

To improve certainty for the parties, the pricing principles should be consistent, where possible, with those adopted in Part IIIA of the CCA (box 6.7).

Box 6.7 **Pricing principles for Part IIIA access disputes**

Section 44ZZCA of the Competition and Consumer Act 2010 (Cwlth) outlines the pricing principles for access disputes:

> The pricing principles relating to the price of access to a service are:
>
> (a) that regulated access prices should:
>
> (i) be set so as to generate expected revenue for a regulated service or services that is at least sufficient to meet the efficient costs of providing access to the regulated service or services; and
>
> (ii) include a return on investment commensurate with the regulatory and commercial risks involved; and
>
> (b) that the access price structures should:
>
> (i) allow multi-part pricing and price discrimination when it aids efficiency; and
>
> (ii) not allow a vertically integrated access provider to set terms and conditions that discriminate in favour of its downstream operations, except to the extent that the cost of providing access to other operators is higher; and
>
> (c) that access pricing regimes should provide incentives to reduce costs or otherwise improve productivity.

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.***

6.4 Interaction with international agreements

The operation of the compulsory licensing provisions in Australia is further complicated by Australia's international treaty obligations. Section 136 of the Patents Act directs the Federal Court not to make a compulsory licensing order that is inconsistent with Australia's international treaties. Australia is a signatory to a number of international agreements that contain specific commitments regarding compulsory licensing. They include: the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights 1994 (TRIPS); the Paris Convention for the Protection of Industrial Property 1883 (Paris Convention); and AUSFTA.

The key international agreements authorising compulsory licensing — TRIPS and the Paris Convention — essentially place no limits on the grounds for granting a compulsory licence (appendix D).

In contrast, AUSFTA may constrain the circumstances in which the mechanism can be applied.

Effect of AUSFTA on the current compulsory licensing provisions

Some commentators (DeBoos 2012; Lawson 2008b) argued that there is a potential inconsistency between Article 17.9.7 of AUSFTA (box 6.8) and the 'reasonable requirements of the public' test in the Patents Act.

The wording of AUSFTA appears to limit non-voluntary access to patents to the competition test for compulsory licensing (paragraph 17.9.7(a)), and Crown use (paragraph 17.9.7(b)) (Lawson 2008b).

Box 6.8 **Australia-United States Free Trade Agreement**

Article 17.9.7 of AUSFTA limits the use of non-voluntary licensing to the following circumstances:

(a) to remedy a practice determined after judicial or administrative process to be anti-competitive under the Party's laws relating to prevention of anti-competitive practices; or

(b) in cases of public non-commercial use, or other circumstances of extreme urgency, provided that:

  (i) the Party shall limit such use to use by the government or third persons authorised by the government;

  (ii) the Party shall ensure that the patent owner is provided with reasonable compensation for such use; and

  (iii) the Party may not require the patent holder to provide undisclosed information or technical know-how related to the patented invention that has been authorised for use in accordance with this paragraph.

AUSFTA does not appear to contain any provision that directly corresponds to Australia's reasonable requirements of the public test. This has been previously noted by the ALRC (2004, p. 617):

> On its face, AUSFTA appears to exclude the grant of a compulsory licence where the 'reasonable requirements of the public' have not been satisfied in ways that are not related to competition within a market, and do not involve non-commercial use.

Likewise, Nielsen and Nicol (2008, pp. 356-7) observed that:

> ... now that we have a specific anticompetitive conduct ground [for compulsory licensing], the legitimacy of the reasonable requirements [of the public] test becomes more tenuous. While there is some scope for establishing anticompetitive behaviour at common law, compulsory licensing on this basis would seem to be precluded by the requirement in art 17.9.7(a) of AUSFTA ... The mystery deepens as to the true scope of the reasonable requirements test!

In contrast to this view, the Australian Government has advised that AUSFTA is consistent with Australian law:

> Article 17.9 also contains a number of provisions relating to the procedure for ... compulsory licensing which generally reflect current Australian law. (DFAT 2004, p. 100)

IP Australia, in its advice to the Senate Economics Legislation Committee inquiry into the Intellectual Property Laws Amendment Bill, stated:

> In AUSFTA, the term 'anti-competitive practices' is interpreted broadly and covers the present compulsory licence provisions under the Patents Act. These provisions provide

> for the grant of a compulsory licence if, among other conditions, 'the reasonable requirements of the public' have not been met.
>
> As such, there is no conflict with section 136 of the Patents Act nor is there any issue of preferential or different treatment of US persons. (SELC 2006, attachment, p. 14)

On the other hand, the Australian Government has previously argued that it is important to retain the reasonable requirements of the public test, along with a competition test, as its removal:

> ... would limit the grounds on which to obtain a compulsory licence to the situation where access to the patented technology is required to ensure competition in the (relevant) market, rather than the broader grounds based on the 'reasonable requirements of the public.' (Attorney General's Department nd)

In light of the potential inconsistency with AUSFTA, the legality of the reasonable requirements of the public test has been questioned by some commentators:

> The reasonable requirements of the public test was retained during the process of amendment [of the Patents Act], but the subsequent conclusion of AUSFTA throws into doubt the legality of this test. (Nielsen and Nicol 2008, p. 188)

Notwithstanding the above, the compatibility of AUSFTA with the reasonable requirements of the public provisions of the Patents Act remains an issue for the courts to determine. This may reduce the efficiency of the compulsory licensing mechanism.

Section 136 undermines the efficiency of compulsory licensing

More broadly, the Commission considers s. 136 of the Patents Act problematic, because it reduces the transparency and scrutiny of the legislative process and can also be a source of uncertainty for the parties.

Reduced transparency and scrutiny

On a literal reading, s. 136 prevents the court from making an order that is inconsistent with any international treaty, whether or not that treaty has been incorporated into Australian legislation by the Parliament.

This appears to vest a law-making power with the Executive and thus would contradict the general principle enunciated by Justice Gummow in 1992 in *Minister for Foreign Affairs and Trade v Magno*:[15]

> It is for Parliament not the Executive to make or alter domestic law. Legislation is necessary to render international obligations enforceable in the courts.

In addition to eroding the line between the functions of the different branches of government, this arrangement is likely to be less transparent and subject to lower levels of scrutiny than if the changes to the Patents Act were legislated by the Parliament. While there are several requirements in the current treaty-making process aimed at increasing transparency and scrutiny,[16] there is a risk that some lower-level or indirect impacts could be overlooked, particularly if the treaty has a broad scope. Notably, in the case of AUSFTA, the issue of potential inconsistency with s. 133(1) of the Patents Act was not raised in consultations conducted by the Joint Standing Committee on Treaties and was not discussed in the Committee's report. Transparency and Parliamentary scrutiny would be improved if specific provisions of a treaty only became binding after being explicitly incorporated into Australian legislation.

Reduced certainty for the parties

Section 136 is also likely to be a source of uncertainty. First, it widens the scope of legal inquiry that the parties would need to undertake to prosecute their case. In addition to interpreting the requirements within the Patents Act, the parties and the courts would have to consider the applicability of a potentially broad range of international treaties.

Second, s. 136 requires the court to interpret the language in a treaty that may not be compatible or reconcilable with the language in Australian legislation. In a workshop hosted by the Department of Foreign Affairs and Trade, Jennings (2003) observed:

> The preferred method of giving effect to treaties is to translate the relevant provisions of the treaty into traditional legislative language. In so doing, a statute might refer to particular terms in a treaty but use the language of domestic law to give effect to the majority of obligations ... This method introduces an element of certainty into the implementation of treaties which is perhaps lacking in simply giving the treaties the

15 (1992) 112 ALR 529 at 534.

16 These include the requirement to prepare a National Interest Analysis that includes a regulatory impact statement (where applicable) and to table it in the Parliament prior to implementing the treaty. In addition, the Joint Standing Committee on Treaties is required to review and report on tabled treaties (DFAT nd).

force of law or in stating that a statute is subject to Australia's international treaty obligations.

Potential redundancy

Finally, there is also a question of whether s. 136 is redundant, given the availability of the option of incorporating the relevant treaty provisions into the Patents Act. For example, AUSFTA was implemented by enacting the *US Free Trade Agreement Implementation Act 2004* (Cwlth). Schedule 8 of that Act introduced several amendments to the Patents Act.

Participants' comments

In light of the above, the Commission proposed in its draft report that s. 136 of the Patents Act be repealed and that relevant current and future treaty obligations in relation to compulsory licencing be incorporated directly into the Patents Act or its subordinate legislation.

Dr Hazel Moir supported this proposal:

> I support draft recommendation 6.3 to repeal S.136. It is very poor practice in a democracy to import international agreements in this manner. Any new legal practices agreed in international agreements should be considered by parliament and specifically and clearly incorporated into Australian law. (sub. DR46, p. 10)

In contrast, two participants argued against it. CropLife claimed that:

> Repealing s.136 of the Patents Act would mean that Australian courts could effectively compulsory license patents in contravention of international agreements entered into by Australia. Repealing this section would send a worrying signal to Australia's bilateral and multilateral treaty partners and foreign investors … [and the] suggestion that individual obligations be incorporated into legislation … would give rise to incredibly convoluted legislation in which the application of provisions depend on the nationalities of the parties to a dispute and/or transaction. (sub. DR42, p. 4)

However, the Commission's proposal would not change Australia's obligations under international treaties. It would only affect the process by which those obligations are incorporated into domestic law. Furthermore, as noted above, s. 136 appears redundant, given that other parts of the Patents Act have been amended in the past to give effect to international treaties.

The Commission also disagrees that its proposal will lead to convoluted legislation and result in confusion. Incorporating Australia's international treaty obligations into domestic law will not require Australian residents to undertake any additional legal inquiry, because they already have to navigate the web of international treaty

obligations under the current arrangement. As discussed above, expressing those obligations in domestic legislative language and consolidating them within the Patents Act is likely to improve, rather than reduce certainty. It is also unlikely that the Commission's proposal would lead to specific provisions in the Patents Act that depend on the nationalities of the parties, given that Australia is bound by Article 4 of TRIPS — 'Most Favoured Nation Treatment'. Under that provision, Australia is prohibited from discriminating between TRIPS member countries, in the context of the Patents Act.

Medicines Australia was also concerned that the proposal could:

> … require frequent amendments to the Act as Australia becomes party to new international treaties covering intellectual property rights. The clear advantage of the existing legislation is that it reduces the need for frequent legislative changes to account for new treaties ... (sub. DR43, p. 2)

Incorporating international treaties into domestic legislation may involve additional administrative costs. However, it is unlikely that the incremental costs would be substantial relative to the benefits of this approach. As discussed above, the process was already adopted in the case of the AUSFTA, so in that case the Commission's proposal would not have introduced significant additional costs. The approach of incorporating treaties into legislation would also be consistent with how Australia has implemented treaties on other matters, such as the environment, human rights and arms control.[17]

In sum, the Commission remains of the view that adopting its proposal would increase transparency, improve certainty for the parties and generally enhance the operation of compulsory licensing provisions.

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.

6.5 Dependent patent ground — is it still needed?

Section 133(3B) of the Patents Act specifies an additional 'dependent patent' ground for compulsory licensing (box 6.9). In its current form, the provision only

[17] For example, the *Chemical Weapons (Prohibition) Act 1994* (Cwlth); the *Australian National Registry of Emissions Units Act 2011* (Cwlth), and the *Australian Human Rights Commission Act 1986* (Cwlth).

applies to applicants for a compulsory licence under s. 133(2), who would be unable to work that licence without infringing another patent. The provision does not operate as a standalone ground, and appears to grant applicants for a compulsory licence under s. 133(2) more rights than, for example, the patentee against whom that licence is being sought.

Some commentators have argued that this outcome was an anomaly caused by poor drafting of the section. IPTA and FICPI argued:

> … there is an error in the wording of s. 133(3B). This provision is clearly intended to cover the situation where a patentee cannot work the invention because of another patent owned by another party, which is the situation referred to in Article 31 of TRIPS. (sub. 18, p. 16)

They further proposed an amendment to the provision to make dependent patents a standalone ground for compulsory licensing in the Patents Act.

The ALRC (2004) has previously considered this option. It acknowledged the criticism of current arrangements and noted that in the United Kingdom dependent patents were a separate ground for compulsory licensing. However, it stated that participants' responses to the question of whether a similar arrangement should apply in Australia were mixed. The ALRC (2004, pp. 77-78) observed that while some supported this approach, several submissions:

> … argued that such a provision would be unnecessary, because dependent patents are already adequately covered by the 'reasonable requirements of the public' test or that it would be undesirable, because it would undermine the value of the original patent granted, and the patent system.

The ALRC concluded that reform of the provision was not necessary because the reasonable requirements of the public test already covered the circumstances in which a dependent patent situation may arise.

The Commission, similarly, considers that its recommended competition and public interest tests would make a separate dependent patent ground redundant. As discussed earlier, the only circumstances in which a compulsory licence would be an effective mechanism for improving public wellbeing relate to anticompetitive conduct and instances where the patentee can constrain the supply of the product or service to the point that Australian demand is not being met on reasonable terms.

Box 6.9 **Dependent patent provision in the Patents Act**

Section 133(3B) of the Patents Act states:

> If the patented invention cannot be worked by the applicant [for a compulsory licence] without his or her infringing another patent:
>
> (a) the court is to make the order only if the court is further satisfied that the patented invention involves an important technical advance of considerable economic significance on the invention (other invention) to which the other patent relates; and
>
> (b) the court must further order that the patentee of the other invention:
>
> (i) must grant to the applicant a licence to work the other invention insofar as is necessary to work the patented invention; and
>
> (ii) is to be granted, if he or she so requires, a cross-licence on reasonable terms to work the patented invention; and
>
> (c) the court must direct that the licence granted by the patentee of the other invention may be assigned by the applicant:
>
> (i) only if he or she assigns the licence granted in respect of the patented invention; and
>
> (ii) only to the assignee of that licence.

That said, there is merit in retaining the existing arrangement, where a compulsory licence for a dependent patent is available on an expedited basis, once the threshold public interest test is passed in relation to the primary compulsory licence application. This would reduce the cost of navigating a patent thicket, while retaining the integrity of the public interest ground.

7 Crown use and acquisition

Key points

- Crown use and acquisition provisions allow governments to access patents without the owner's authorisation. Crown use has rarely been invoked, and Crown acquisition powers have never been used to the Commission's knowledge.
- Governments will generally find Crown use to be a less costly and time-consuming option than compulsory licensing. For example, governments do not have to apply to the Federal Court to access the patented invention.
- Crown use can be applied to healthcare-related patents, given governments' major responsibility for healthcare provision. However, inquiry participants were uncertain about whether:
  - Crown use can be utilised by non-government healthcare providers, given that it can only be used 'for the services of' a government
  - Crown use can be utilised by State Governments for services outside the state
  - State Governments have to invoke Crown use individually, rather than coordinate their actions.
- To reduce such uncertainty, the *Patents Act 1990* (Cwlth) should be amended so that it is 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 no less than 14 days before it occurs. These requirements should be able to be waived in emergencies. 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 terms of reference for this inquiry ask the Commission to consider recommending alternative mechanisms to compulsory licensing. The Crown use and acquisition provisions — set out in ss. 161–171 of the *Patents Act 1990* (Cwlth) — can be considered to be such alternatives. This chapter examines the functioning of the provisions, and their interaction and potential overlap with compulsory licensing. Reforms are proposed to clarify when Crown use can be utilised, and to strengthen the requirements for transparency and accountability.

7.1 Current arrangements

The Crown use and acquisition provisions provide for the Commonwealth or a State Government, or a person or organisation authorised by the Commonwealth or a State, to use a patent with protection from legal action for patent infringement. The legislation allows for these parties to compulsorily acquire a patent (s. 171), have one assigned to them (s. 172), or to use the patent under what is effectively a compulsory licence (s. 163).

Crown acquisition

Under s. 171 of the Patents Act, the Crown can acquire a patent. As in the case of Crown use, the legislation allows for court determination of remuneration (s. 171(4)) and requires the Crown to inform the patentee of its actions. The Crown must also publish a notice of the acquisition 'in the *Official Journal* and the *Gazette* unless, in the case of the acquisition of an invention that is the subject of an application for a patent, a prohibition order, or an order under s. 152, is in force in respect of the application'(s. 171(3)(b)).[1] While governments may have acquired patents voluntarily, there are no publicly recorded instances of compulsory acquisition through the Crown acquisition provisions (LESANZ 2011).

Crown acquisitions of intellectual property can be considered an application of the broader powers of acquisition held by the Australian Government. For example, ss. 51(vi) and 51(xxxix) of the Constitution provide executive and legislative powers to the Australian Government in situations of national emergency or military operations. Moreover, the Australian Government has the power to enact laws with respect to the acquisition of property on just terms under s. 51(xxxi).

Crown acquisition appears to be an option that would only be invoked when a government wants to exclude others from using an invention. It is not necessary to acquire the property right in its entirety for a government to exploit an invention, given the existence of Crown use. Crown use is also less costly, since the patentee retains ownership of the patent and is able to continue to use the invention in question. As such, the patentee does not have to be compensated for the loss of this use or for the loss of licence fees from third parties. The Commission has hereafter focused its analysis on Crown use.

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[1] A prohibition order under s. 173 or an order under s. 152 of the Patents Act allows the Minister or the Commissioner respectively to prohibit/restrict the publication of information about the subject matter of an application for a patent. Section 173 also allows the Minister to prohibit/restrict access to a microorganism deposited for the purposes of s. 41.

Crown use

Crown use provisions were introduced in Australia with the enactment of the *Patents Act 1903* (Cwlth). The origin of these provisions was English patent law, which provided the template for Australian laws (SLCLAC 2011). England had a history of Crown use of patents, but formal provisions were not adopted there until 1883 (ALRC 2004). Historically, the justifications for Crown use were:

- the Crown should not be impeded by patents (which are, in effect, Crown grants) from acting in the public interest, particularly in relation to matters of national defence
- unlike private traders, the Crown, through its departments and authorities is ordinarily engaged in public services, rather than commercial activities, and therefore should be in a special position in regards to use of patented inventions. (ACIP 2005a, p. 9)

Under ss. 163–170 of the Patents Act — commonly referred to as the Crown use provisions — governments can use patented inventions in a similar fashion to compulsory licensing. However, the Crown use provisions are a less costly and more timely option for governments to access than applying for a compulsory licence. With Crown use, patented inventions can be used without first seeking the owner's permission. However, as soon as practicable after an invention has been exploited, the relevant authority must inform the patentee of the exploitation and provide any information about the exploitation that is reasonably required (unless it would be contrary to the public interest to do so). Crown use can only be invoked for the services of the Commonwealth or of a State (s. 163(1)). Where the provisions are invoked, the patent holder is entitled to remuneration under s. 165 of the Act. In the absence of an agreement between the relevant government authority and the patent holder, either party can apply to a prescribed court to determine the terms.[2]

Instances of Crown use in Australia

Crown use has been rarely used. In a 1997 report to the TRIPS Council, the Australian Government stated that it expected Crown use to have been minimal (ALRC 2004). The primary difficulty in establishing patterns of use is in uncovering cases of uncontested use. However, there are two reported cases in which Crown use has been contested in court (box 7.1).

[2] A prescribed court is either the Federal Court, the Supreme Court of a State, the Supreme Court of the Australian Capital Territory, the Supreme Court of the Northern Territory, or the Supreme Court of Norfolk Island.

Box 7.1 **Contested cases of Crown use**

General Steel Industries Inc v Commissioner for Railways (NSW) (1964) 112 CLR 125

The NSW State Commissioner for Railways' use of an invention for central bearing structures for railway carriage construction was held to be allowed under s. 125 of the *Patents Act 1952 (Cwlth)* (the predecessor to s. 163 of the current Patents Act). It was considered that the use was 'for the services of the State'.

Stack v Brisbane City Council (1994) 131 ALR 333

Brisbane City Council's use of a patented invention for water meter assemblies was held to be within the scope of Crown use. It was considered that Brisbane City Council was an authority of a State for the purpose of s. 163. The focus of the case was on whether the functions of Brisbane City Council have the 'stamp of government' and whether they have been given the power to direct or control the affairs of others on behalf of the State.

Source: LESANZ (2011).

While the provisions appear to be rarely invoked, submissions to a review of Crown use by the Advisory Council on Intellectual Property (ACIP), claimed that the threat of using the provisions in negotiations was far more prevalent (ACIP 2005a). These submissions reportedly claimed that some intellectual property right owners had 'been put under considerable pressure by organisations threatening to invoke the provisions in situations where it was not clear whether these organisations had the requisite authority or the legal requirements to qualify as a Crown entity'(ACIP 2005a, p. 8).

Why are the Crown use provisions seldom used?

Similar to the case of compulsory licences (chapter 6), the limited history of litigation over the Crown use provisions could suggest a variety of things. First, it is likely the provisions are intended to be a safeguard for rare instances in which the patents system is hindering government action to address an urgent issue (for example, providing treatment in an epidemic). It may be that such cases are rare because patent holders are usually willing to license reasonably and widely and/or few instances arise where urgent access is required.

Second, governments may be reluctant to use the provisions, as they involve significant interference with the rights of patent holders. If the provisions were relied upon too readily, confidence in the patents system could be damaged.

Third, it could be the case that there are rarely any problems for governments in securing access to patents. This could be because governments usually offer just terms. Alternatively, it could be that the cost of litigation to challenge Crown use, or the terms offered under Crown use, can force an unwilling licensor to the negotiating table and ensure an acceptable result for the government.

Fourth, it may be that there is a lack of knowledge about the provisions and the appropriate arms of government are unclear on how and when it is appropriate to invoke the provisions.

Finally, it may be that there are a number of problems with the provisions that discourage governments from utilising them.

7.2 Past reviews

The most comprehensive review of the Crown use provisions was conducted by ACIP in 2005. The review encompassed the Crown use provisions in the Patents Act and the *Designs Act 2003* (Cwlth). It called for various changes to place greater discipline on use of the provisions and reduce uncertainty about the compensation received by patent holders (box 7.2). The Australian Government did not issue a response to the recommendations, on the grounds that there was no substantial evidence that the provisions were being misused (ACIP 2010b). Instead, it wrote to Commonwealth Ministers, and to State and Territory innovation and local government Ministers, outlining governments' obligations when exercising their rights to Crown use.

The Australian Law Reform Commission (ALRC 2004) also examined Crown use as part of a review of gene patents. Its recommendations were aimed at making the Crown use provisions more 'fit for purpose' in ensuring access to healthcare. This included amendments that specifically raise healthcare as a rationale for invoking the provisions, and amendments to clarify the remuneration responsibilities of governments in these instances.

The recommendations of the ALRC were endorsed by the Senate Community Affairs References Committee (SCARC) in its review of gene patents (SCARC 2010). The SCARC (2010, p. xviii) also recommended:

> … the Patents Act 1990 be amended to clarify the circumstances in which the Crown use provisions may be employed; and that the Government develop clear policies for the use of the Crown use provisions.

Box 7.2 **Recommendations from the ACIP review of Crown use**

In 2005, the Advisory Council on Intellectual Property made the following recommendations to the Australian Government about Crown use.

The Need for Prior Consent

The Patents Act should be amended to ensure that, prior to any use of a patent by the Crown, there are genuine efforts to obtain authorisation from the rights holder. Furthermore, the Crown should be required to offer reasonable commercial terms and attempt to reach agreement within a reasonable period of time.

These requirements may be temporarily waived in cases of national emergency or other circumstances of extreme urgency, or in cases of public non-commercial use by entities operating solely in the public interest. This would not extend to public/private organisations that predominantly operate for profit.

Definition of the Crown and Ministerial Approval

The Patents Act should require organisations using the Crown use provisions to seek Ministerial approval prior to any such use. At the state level, organisations will require the prior approval of the relevant state Attorney-General, and at the federal level, require the prior approval of the federal Minister with portfolio responsibility for the patents legislation. The requirement to obtain Ministerial approval may be temporarily waived for emergency or public non-commercial use.

Remuneration and Processes

The Patents Act should state that patent owners affected by the Crown use provisions are entitled to compensation that is 'just and reasonable taking into consideration the circumstances of the case'. To facilitate agreement between the parties there should be a prescribed statutory remuneration process in the patents legislation.

Source: ACIP (2005a).

7.3 Assessment and reform of Crown use

The issues raised by past reviews suggest that there may be a case for reforming Crown use. This section assesses that need, drawing on those reviews and the views of participants for this inquiry. Recommendations are made to clarify the scope of Crown use and improve transparency and accountability of governments seeking to use the provisions.

The role of Crown use

Inquiry participants were generally supportive of retaining the provisions, particularly given the role that Crown use can play in healthcare:

> [Crown use provisions] have a legitimate role to play with regard to domestic issues relating to access to healthcare. (Centre for Law and Genetics, sub. 3, p. 10)
>
> The Department recognises the potential value of the Crown Use provisions in protecting national public health interests. (Department of Health and Ageing, sub. 22, p. 5)

That said, utilising the provisions involves significant interference with the rights of patent holders. As a result, some inquiry participants cautioned that routine use of the provisions could undermine confidence in the patents system, and as such, the provisions should only be invoked in exceptional circumstances:

> [The Institute of Patent and Trademark Attorneys and the Australian Federation of Intellectual Property Attorneys] would caution the Crown against use of the Crown use provisions except in cases of extreme urgency in order to preserve the integrity of the patent system so far as patentees and investors are concerned. (IPTA and FICPI, sub. 18, p. 7)
>
> Crown Use provisions provide a safeguard to any adverse impact of patent protection on public interest. These provisions should be used cautiously and for exceptional circumstances only since undertaking research and development in biomedicine is risky and expensive. (WEHI, sub. 13, p. 8)

This would include public health emergencies. A practical example is the US and Canadian Governments' consideration, in 2001, to invoke their powers to access a treatment for anthrax without the patent owner's authorisation (box 7.3).

Emergency use of this nature is relatively less contentious in the context of international trade. For example, the United States has been a critic of the routine use of non-voluntary licensing provisions (SLCALC 2011). In contrast, the US and other WTO members have accepted emergency use as legitimate. The Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS agreement) explicitly provides for the emergency use of a patented invention (by the government or a third party authorised by the government) without the authorisation of the patent holder (appendix D).

Box 7.3 **Emergency use of Bayer's patent for ciprofloxacin**

In September of 2001, a series of bioterrorism attacks occurred in the United States with the spreading of anthrax *(Bacillus anthracis)* spores through the mail. The attacks led to the deaths of five people, the infection of 17 others, and many more tested positive for anthrax exposure.

Public fear about the attack led thousands of Americans and Canadians to take antibiotics as a prophylactic measure. A broad spectrum antibiotic made by Bayer A.G. (Bayer), ciprofloxacin (Cipro), became the drug of choice for many. It was believed that Cipro would be effective at treating infections from anthrax since it was chosen by the U.S. Army for use against a potential biological weapons attack from Iraq, during the Gulf War. In the following days, thousands of people sought to obtain the drug and the fear of Cipro shortages became acute.

In order to increase production of Cipro, the US and Canadian Governments considered overriding Bayer's patent. Canada, in fact, overrode Bayer's patent for a few days until Bayer reached a deal with the Canadian government. In the United States, some politicians urged the enlistment of generic drug companies to manufacture Cipro in order to avoid a shortage. However, such intervention was ultimately not necessary, as by 25 October 2001 the United States Government had also reached a deal with Bayer. Bayer agreed to accelerate its production of Cipro to meet the increased demand, and to drop its price. Before October 2001, the average price of Cipro was $US4.25 per tablet, but Bayer cut its prices by more than 70 per cent as a result of its agreements with the United States and Canada.

Source: Resnick and De Ville (2002).

While the Commission agrees that Crown use provisions should not be routinely used, and that they are particularly useful in emergencies, the provisions have a wider application. Like compulsory licensing among private parties, Crown use should continue to be an option, irrespective of whether there is an emergency, if a patented invention is not available to the Australian community on reasonable terms and conditions. That said, in order to avoid undermining the efficiency goal of the patents system, governments using the Crown use provisions should ensure that the benefits of use outweigh the costs.

Clarifying the scope of Crown use

Inquiry participants raised several concerns about the scope of Crown use, particularly in the context of healthcare. Given that Crown use is less costly and more timely to access for a government applicant than a compulsory licence, it will typically be the most cost-effective option for governments to access patents for healthcare purposes. However, inquiry participants were uncertain about whether this could occur in practice for several reasons.

The Law Council of Australia (sub. 32) noted that the scope of Crown use is constrained by s. 165A of the Patents Act. Under this provision, Crown use can be stopped by a court if it 'is not, or is no longer, necessary for the proper provision of services of the Commonwealth or State'. The Law Council of Australia concluded that it is:

> … unlikely that the Crown use exception could be applied in a situation where price negotiations for a voluntary licence are on foot or where the patented product is in fact available, albeit at a higher price. (sub. 32, p. 11)

As discussed below, such limitations may be desirable to make governments accountable for the circumstances in which they rely on Crown use and what compensation they pay.

Some participants were concerned that the courts could interpret the Crown use provisions narrowly to exclude many applications to healthcare. This uncertainty arises because s. 163(1) of the Patents Act, which limits Crown use to cases where an invention is used 'for the services of' a government, is open to interpretation. It seems unlikely that this would preclude healthcare services provided by governments, given that Crown use has previously been allowed for government-owned railways and domestic water supply (box 7.1).

However, some participants were concerned that the term 'for the services of' a government may not extend to the non-government portion of the healthcare sector. For example, the Australian Government Department of Health and Ageing (DOHA) expressed the view that:

> There is some lack of clarity as to how far 'the services of' the government extend, but it is unlikely it would extend to use of the patent by non-government service providers (such as privately owned medical testing laboratories). (sub. 22, p. 5)

This is important because the Australian health system involves different tiers of government, as well as the non-government sector (box 7.4).

DOHA suggested that its concern could be addressed by:

> … broadening the [Crown use provisions] to allow the Crown to license its access to the patent to a non-government entity, where it would be in the public health interest to extend services beyond those provided directly or indirectly by the Crown. (sub. 22, p. 5)

However, this seems unnecessary, because s. 163(1) of the Patents Act already allows any 'person authorised in writing by the Commonwealth or a State' to exploit the patented invention, at any time, so long as it is 'for the services of the Commonwealth or the State'. There is no limit to the number of people that can be authorised, or any requirement that the person be a government employee.

Box 7.4 **Levels of responsibility in Australian healthcare**

The healthcare system in Australia is complex, involving many funders and healthcare providers. Responsibility for funding and provision is split between different levels of government, and between the public and non-government sectors.

In 2010-11, the Australian Government provided 43 per cent of the total health funding, while state and territory and local governments funded 26 per cent (AIHW 2012). The Australian Government operates the Medicare and the Pharmaceutical Benefits Scheme. It also jointly funds a number of aspects of the healthcare system, such as public hospitals and mental health services with state and territory governments, through the National Health Care Agreement. Under this agreement, state and territory governments are also responsible for the delivery of a number of other services, including community health, ambulance services and disability services.

Non-government sources of funding contributed 31 per cent of total health funding in 2010-11 (AIHW 2012). This funding — from private individuals and private health insurers for example — is used to fund the services of both public and non-government healthcare providers. The non-government sector's provision of healthcare comprises a wide range of services, including private medical practitioners, community and private hospitals, pathology services and pharmacies.

Another concern raised by participants was that the Crown use provisions are not well suited to cases where coordination is needed across state boundaries.

> Under current laws, each state/territory would … need to negotiate recompense to the patent holder individually (or if agreed as joint parties), rather than the Commonwealth negotiating on behalf of all state/territory governments. (DOHA, sub. 22, p. 6)
>
> If a particular State Government invokes Crown use of a gene patent to provide a particular medical genetic test for its citizens, would the provision for Crown use extend to the testing of samples that had been sent from another State for analysis? If not, each State would need to invoke Crown use of that gene patent and develop its own test to meet the needs of the patients in its own jurisdiction. (Royal College of Pathologists of Australasia, sub. 16, p. 2)
>
> … questions exist over *which* Crown must authorise the use. For example, the NSW 'Crown' may have to authorise Sydney University to exploit a patented invention, and the Queensland Government authorise exploitation by [University of Queensland]. (Civil Liberties Australia, sub. 12, p. 6)

Conversely, it could be argued that there are no significant barriers to coordinating Crown use because the provisions do not limit its geographic coverage. In particular, s. 163(1) of the Patents Act places no restriction on where a person must reside if they undertake Crown use on a government's behalf. This should enable a government to authorise Crown use by a healthcare provider in another jurisdiction. Moreover, the Patents Act does not preclude states and territories from coordinating their actions, including possibly with the Australian Government.

While it is debatable whether the abovementioned issues are indeed barriers to applying Crown use to healthcare, it is evident that there is uncertainty among stakeholders. This could itself be an impediment to the effective utilisation of Crown use. For example, DOHA noted that legal advice it had received led it to the conclusion that it was not viable to apply Crown use to healthcare because:

- the scope of the provisions is unclear
- the ability of the Australian Government to authorise use of a patent by third parties was doubtful and untested
- the required amount of compensation to the patent holder is unclear (DOHA, pers. comm., 30 October 2012).

Some inquiry participants proposed that such uncertainty be addressed by explicitly stating in the Patents Act that Crown use is applicable to healthcare (for example, Centre for Law and Genetics, sub. 3; Civil Liberties Australia, sub. 12; Matthew Rimmer, sub. 11). The ALRC (2004, p. 33) called for a similar amendment in its review of gene patents:

> The Commonwealth should amend the Patents Act to clarify that, for the purposes of the Crown use provisions, an invention is exploited 'for the services of the Commonwealth or of a State' if the exploitation of the invention by a Commonwealth or State authority (or by an authorised person) is for the provision of healthcare services or products to members of the public.

This was endorsed by the Senate review of gene patents (SCARC 2010). However, the Australian Government (2011a, p. 11) rejected this proposal on the grounds that:

> The Government does not see a need at present to develop a health-specific policy on the circumstances in which Crown use provisions should be exploited as the provisions are available for all Commonwealth, State and Territory services. The Government agrees that the circumstances in which a patented invention should be exploited pursuant to the Crown use provisions should be considered on a case-by-case basis.

Identifying healthcare as a special case in the Patents Act would also be contrary to the general approach of having a technology-neutral patents system. Technology neutrality is desirable because it reduces complexity, and therefore, the overall costs of the patents system. Furthermore, a neutral system has the flexibility to accommodate patenting of new and emerging areas of technology. In contrast, a patents system that differentiates between specific would constantly need updating. Altering the legal status of patents in specific industries could also have unforeseen consequences, possibly making some lines of future research unattractive (SCARC 2010).

Nevertheless, the Commission recognises that stakeholders are likely to remain uncertain about the scope of Crown use, given the lack of jurisprudence, and that

this can limit the effectiveness of the provisions. It therefore proposes that the phrase 'for the services of' a government be clarified in the Patents Act, while maintaining technology neutrality. In particular, it is proposed that it be made 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.

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.

Dr Hazel Moir (sub. DR. 46) argued for a broader interpretation so that Crown use can be applied to industries such as communications, transport and utilities that, while largely operating in the private sector, are heavily regulated in the public interest. However, the Commission considers that the term 'services of a government' cannot reasonably be interpreted as including industries dominated by private businesses which supply products without significant public funding. In such cases, businesses operating in the sector can seek a compulsory licence on the grounds that it is in the public interest. Alternatively, governments may be able to address their concerns by reforming how the relevant industry is regulated.

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.

Measures to improve transparency and accountability

In addition to clarifying the scope of Crown use, the Commission considers that reforms are needed to strengthen transparency and accountability.

Ministerial oversight

The ACIP review contended that there was a lack of clarity about which entities constituted the Crown. A number of entities could potentially qualify as the Crown, including: employees; commissions; statutory authorities; statutory corporations; government business entities; government owned corporations; and private corporations under contract to the government (ACIP 2005a). Similarly, the ALRC (2004) raised concerns of ambiguity on the issue of whether some research institutes have sufficient government involvement to be considered the Crown. It pointed out that such institutions may be established by state legislation and be affiliated with public sector universities or hospitals, but be self-governing, with their own set of research priorities and sources of funding.

Case law has shown that the definition of the Crown can be broad. *Stack v Brisbane City Council*[3] interpreted the scope of Crown use to include municipal councils and statutory authorities throughout Australia (ACIP 2005a).

The ambiguous definition of the Crown could result in several issues related to the misuse and misunderstanding of the Crown use provisions.

- Some organisations can be mistaken about whether or not they qualify as the Crown for the purposes of the Crown use provisions. These organisations may believe they have immunity from patent infringement actions, when in fact they do not.
- There may be instances where the provisions are misused, compromising the principles of competitive neutrality. This could occur where bodies gain an unfair competitive advantage in the marketplace, by invoking the provisions, despite the fact that they may not have been intended to have access to them.
- Some patent holders may feel obligated to license their inventions when the person seeking a licence does not in fact have Crown status.
- Some patent holders may not seek infringement remedies that they are in fact entitled to.

[3] (1994) 131 ALR 333

One way to address the lack of transparency surrounding who can invoke Crown use is to charge an authority with the responsibility for determining when a use of patented material is valid. ACIP (2005a) proposed that the Ministers charged with this power at the state level should be the relevant Attorneys-General, and that the Minister responsible for the Patents Act should have this power at the federal level.

There are some problems with Ministerial oversight. Critics of the approach cite a danger of politicising access to Crown use, and creating unnecessary bureaucracy (ACIP 2005a). The introduction of Ministerial oversight might also increase uncertainty and inconsistency, as Ministerial decisions may not be based on the system of case law and precedent.

However, ACIP (2005a) reported that a significant majority of the stakeholders it consulted supported the concept of using Ministerial approval for this purpose. These stakeholders indicated that this would help maintain competitive neutrality in the market and provide certainty, accountability and transparency (ACIP 2005a). Additional certainty and transparency would improve the efficiency of the patents system by better defining the property right associated with a patent. The addition of oversight also better aligns the Crown use provisions with the compulsory licensing provisions, which have judicial oversight. For these reasons, the Commission is supportive of the change proposed by ACIP, including that the Minister that approves Crown use is the relevant state's Attorney-General or the Federal Minister responsible for the Patents Act. In approving instances of Crown use, the Minister should have regard to community-wide costs and benefits of such use, including the impact any such use has on the patents system and the rights of the patentee.

In addition, the Commission considers that, where a Minister has approved an instance of Crown use, a statement of reasons should be provided to the patentee 14 days before exploitation of the invention. This is similar to requirements in existing administrative review legislation. Applicants for reviews under the *Administrative Decisions (Judicial Review) Act 1977* (Cwlth) and the *Administrative Appeals Tribunal Act 1975* (Cwlth) can request reasons for decisions that are reviewable. Under this legislation, the statement of reasons must be provided as soon as is practical, but within 28 days of the request.

A statement of reasons would assist the patentee in making a decision on whether to exercise their right to appeal. The notice of 14 days would provide the patentee time to consider the statement before exploitation occurs. Disclosure of reasons would encourage the Minister to reflect more carefully on the decision and be more diligent in authorising instances of Crown use. The reasons could also guide future

decisions, help create principles and standards of operation and, over time, decrease disputes.

Consent of the patentee

The current provisions do not require the Crown to obtain consent from, or inform, the patentee of its intentions *before* it has exploited a patent. The Crown can voluntarily seek consent before, during or after it has exploited the patent. However, under s. 169, if the patentee believes that the Crown is exploiting, or has exploited, its patent, it can apply for a declaration from a prescribed court that this is the case. The same section expressly provides that the Crown can respond with a counter-claim for revocation of the patent.

This contrasts with the compulsory licensing provisions, which require those seeking a compulsory licence to have 'tried for a reasonable period, but without success, to obtain from the patentee an authorisation to work the invention on reasonable terms and conditions' (s. 133(2)(a)(i)). Instituting a requirement to seek consent prior to relying on Crown use would impose on the Crown similar requirements as apply to commercial entities seeking a compulsory licence. As noted in chapter 6, voluntarily negotiated licences will usually generate superior outcomes, and the need to seek prior consent provides an important impetus for achieving this outcome.

It could also be argued that the lack of a requirement to first attempt to reach a negotiated outcome means that the Crown use provisions are inconsistent with the TRIPS agreement (ACIP 2005a). In particular, Article 31(b) of the TRIPS agreement only waives this requirement in cases of 'national emergency or other circumstances of extreme urgency or in cases of public non-commercial use'.

The Australian Government (1997) noted that it considered all Crown use to be 'public non-commercial use'. In contrast, ACIP (2005a) observed that the private provision of previously traditional government services, and the quasi-government status of many bodies, may lead to Crown use that is not strictly 'public non-commercial'. It was specifically concerned that:

- exploiting the provisions for commercial use has the potential to undermine confidence in the patents system
- unauthorised use has the potential to financially damage patent holders
- the lack of obligations on governments increases uncertainty for businesses.

ACIP (2005a) further argued that:

- a patent holder needs information concerning the exploitation as soon as possible in order to minimise any commercial losses arising from the exploitation, and to ensure other related business decisions can be made with certainty
- Crown entities should be forthright, open and transparent
- patent holders should not be burdened with the expense of costly court proceedings simply to obtain information about whether the Crown is or has been exploiting their patents.

The Commission agrees that requiring governments to seek prior consent before invoking Crown use would improve the transparency of the provisions. This, coupled with the requirement for ministerial approval, will have the effect of removing uncertainty about when the provisions have been used, thereby better protecting the patentee's rights.

Pricing

Unlike compulsory licencing, there is no guidance for pricing access to a patented technology in the existing Crown use provisions. They do not contain any reference to a standard of remuneration for the patentee. In other words, the provisions do not contain an express right to 'adequate' or 'reasonable' remuneration considering the 'economic value' of use. However, s. 165(2) states that, when parties fail to come to an agreement, either party can apply to a prescribed court for a determination on any terms of the exploitation, including remuneration. ACIP (2005a) contended that the lack of guidance on pricing can leave patentees disadvantaged, and that the lack of an applied standard or criterion to refer to in any negotiations could weaken their bargaining position in seeking to obtain fair and equitable agreement. ACIP (2005a, p. 4) suggested that the Crown use provisions should stipulate that remuneration is paid promptly and is 'just and reasonable taking into consideration the circumstances of the case'. This is consistent with recommendations made by the ALRC (2004).

The effect of these recommendations is to impose upon the Crown the same compensation requirements as those that face commercial entities in accessing a patent with a compulsory license. The Commission has proposed reform of the pricing of compulsory licences (recommendation 6.2), so that any compulsory licence is required to have regard to the right of the patentee to obtain a return on investment commensurate with the regulatory and commercial risks involved. This principle should also apply to the Crown use provisions, so as to align Crown use with compulsory licensing in the manner suggested by past reviews. It would also

help develop jurisprudence over remuneration conditions and harmonise Crown use with international agreements such as the TRIPS agreement and the Australia–United States Free Trade Agreement (AUSFTA). Article 31(h) of the TRIPS agreement and article 17.9.7(b)(ii) of AUSFTA both use language indicative of a standard of remuneration (appendix D).

In addition to guidance on pricing, ACIP (2005a, p. 30) contended that there was 'no clear reason why there is no formal process of remuneration, at least in non-emergency type situations'. It argued that a structured remuneration process would provide more certainty about respective obligations in negotiations, in addition to addressing the inherent inequality of bargaining power between the patentee and the Crown. This was seen as a particular problem for small to medium enterprises, as they lacked the resources and bargaining power of multinational corporations.

ACIP (2005a) suggested a number of reforms of the remuneration process.

- If parties fail to agree on the terms of exploitation, then there should be recourse to alternative dispute resolution.
- A structured procedure be implemented into the Crown use provisions to guide the parties to reach an amicable outcome.
- If the patent holder believes an authority is using a patent without either seeking a commercial licence or notifying the patent holder of such use, the patent holder can seek the assistance of the State or Commonwealth Ombudsman.

The sum of these recommendations is to introduce alternative dispute mechanisms for Crown use. While reforms such as ACIP's would help redress the inequality of bargaining power between the patentee and the Crown, the Commission considers that the package of reforms suggested in this chapter would be a preferable way to achieve this goal. The changes suggested by the Commission protect patentees' rights by improving transparency and accountability in the process of Crown use, without the potentially costly process of implementing a formal alternative dispute resolution process. Given how rarely Crown use is used, it is doubtful that at present the benefits of such a mechanism would outweigh the costs of establishing it.

A package of reforms

Many of the reforms explored in this chapter follow those recommended by ACIP in its 2005 review (box 7.3). However, as noted, the Australian Government chose not to implement these proposals because there was no evidence that the provisions were being misused (ACIP 2010b). The Commission is sympathetic to the Government's reasoning. The costs of initiating reforms solely for the Crown use

provisions, given the dearth of evidence that there is a problem, argue for retaining the status quo. In addition, the infrequent utilisation of Crown use suggests that the benefits from reform are likely to be small. However, in light of recommendations requiring changes to the Patents Act made in chapter 6, the Commission considers that several beneficial concurrent changes to the Crown use provisions could be made at relatively low cost. Some inquiry participants supported these changes (Health Forum of Australia, sub. DR38; Human Genetics Society of Australasia, sub. DR40). Other participants were concerned that they would place an overly onerous impost on governments (Alphapharm, sub. DR48; Dr Hazel Moir, sub. DR46).

The Commission acknowledges that the abovementioned reforms would reduce the cost and time advantage of Crown use compared to compulsory licensing, but does not consider the effect to be significantly different from the status quo. 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.

The net effect of these measures is to ensure that governments and their authorised entities meet certain obligations when seeking to use patents. The measures aim to make the process for their utilisation transparent and accountable, to protect against the possibility of misuse. In addition, they have the advantage of harmonising aspects of compulsory licensing and Crown use. It is also important to note that the reforms recommended here are intended to work in tandem with recommendation 7.1. That is, they are aimed at striking a balance between protecting patentee rights, and giving governments and the public confidence that Crown use can be invoked if a patent is unduly preventing the community's access to a technology.

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.

8 Other forms of non-voluntary access in Australia

Key points

- There are several mechanisms, other than compulsory licensing and Crown use, for accessing patents without the authorisation of the patent holder.
- Legislative exemptions for experimental use and for the purpose of obtaining regulatory approval have reduced uncertainty about accessing patented inventions without the consent of the patentee.
- A foreshadowed exemption for the purposes of exporting pharmaceuticals to developing countries is expected to have limited implications for existing compulsory licensing and Crown use provisions.

The *Patents Act 1990* (Cwlth) contains provisions allowing several forms of non-voluntary access to patents, in addition to compulsory licensing and Crown use and acquisition (chapter 1). This chapter examines the other provisions that are most relevant to this inquiry — exemptions from infringement for research and experimental use, and for the purpose of obtaining regulatory approval. A foreshadowed change to the Patents Act to provide an additional ground for issuing a compulsory licence — for the purpose of exporting pharmaceuticals to developing countries — is also discussed.

8.1 Experimental exemption

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

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

Box 8.1 **The experimental purposes exemption**

Section 119C of the *Patents Act 1990* (Cwlth) states that:

(1) A person may, without infringing a patent for an invention, do an act that would infringe the patent apart from this subsection, if the act is done for experimental purposes relating to the subject matter of the invention.

(2) For the purposes of this section, experimental purposes relating to the subject matter of the invention include, but are not limited to, the following:

  (a) determining the properties of the invention;

  (b) determining the scope of a claim relating to the invention;

  (c) improving or modifying the invention;

  (d) determining the validity of the patent or of a claim relating to the invention;

  (e) determining whether the patent for the invention would be, or has been, infringed by the doing of an act.

The exemption does not apply to research that uses, but is not related to, the subject of a patent. In other words, patented research tools are not intended to be covered by the exemption.

Rationale and assessment

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

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

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

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

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

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

'Raising the Bar' experimental exemption reform

The experimental exemption, introduced as part of the 'Raising the Bar' reforms, aims to clarify the rights and obligations of researchers, and reduce uncertainty around patent infringement related to the use of patented inventions in research. According to the explanatory memorandum, the exemption only applies to experimental research, and does not cover research undertaken for commercial purposes. Specifically, the 'exemption should apply to tests, trials and procedures that a researcher or follow-on innovator undertakes as part of discovering new information or testing a principle or supposition' (Australian Government 2011b, p. 71).

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

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

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

To illustrate its reservations, Civil Liberties Australia (sub. 12) listed four scenarios involving the use of gene patents that it considered may not be covered by the experimental exemption.

- A researcher uses a patented gene sequence to test a multi-gene screening test, with the goal of commercialisation.
- University-based researchers outsource gene profiling to universities with better facilities, as this may be considered a commercial service.
- A university uses patented gene sequences as part of a teaching program, which is not likely to be considered experimental use.
- A person provides their DNA for a study exploring the link between particular genes and cancers. Under Australian guidelines for ethical research, they must be given the option of being told their test results, which could reveal a patented genetic mutation linked to cancer. It could then be argued that the study offered a screening service without compensating the patent holder.

According to the explanatory memorandum for the Raising the Bar reforms, the first two scenarios are likely to be covered by the experimental exemption, provided the predominant purpose is to gain new knowledge or test the properties of the patented invention (Australian Government 2011b). In the third scenario, it appears the invention is being used as a teaching tool rather than to gain new knowledge. As such, it is unlikely to be exempted from infringement. The fourth scenario is considered in chapter 9 when assessing the case for legislating a right to personal genetic information. The Commission was not presented with any evidence of such a scenario having occurred in Australia. Moreover, existing privacy laws may already give people the right to see their test results if it were to occur.

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

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

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

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

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

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

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

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

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

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

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

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

Interaction with other forms of non-voluntary access

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

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

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

8.2 Regulatory approval exemption

In 2006, the Patents Act was amended to include an exemption from infringement for use of patented pharmaceutical products for the purposes of regulatory approval from the Therapeutic Goods Administration (s. 119A). The 'Raising the Bar' reforms extended the exemption to all products, processes or methods that require approval by law of the Commonwealth, state or territory (s. 119B) (box 8.2).

Examples of products that require regulatory approval are pharmaceuticals (by the Therapeutic Goods Administration) and agricultural and veterinary chemical products (Australian Pesticides and Veterinary Medicines Authority). The exemptions do not allow generic manufacturers to stockpile the patented product prior to the expiry date of the patent.

Box 8.2 **Regulatory approval exemption**

Section 119A of the *Patents Act 1990* (Cwlth) states:

(1) The rights of a patentee of a pharmaceutical patent are not infringed by a person exploiting an invention claimed in the patent if the exploitation is solely for:

  (a) purposes connected with obtaining the inclusion in the Australian Register of Therapeutic Goods of goods that:

    (i) are intended for therapeutic use; and

    (ii) are not medical devices, or therapeutic devices, as defined in the Therapeutic Goods Act 1989; or

  (b) purposes connected with obtaining similar regulatory approval under a law of a foreign country or of a part of a foreign country.

(2) Subsection (1) does not apply to the export from Australia of goods for purposes described in paragraph (1)(b) unless the term of the patent has been extended under Part 3 of Chapter 6 and the goods consist of or contain:

  (a) a pharmaceutical substance per se that is in substance disclosed in the complete specification of the patent and in substance falls within the scope of the claim or claims of that specification; or

  (b) a pharmaceutical substance when produced by a process that involves the use of recombinant DNA technology, that is in substance disclosed in the complete specification of the patent and in substance falls within the scope of the claim or claims of that specification.

Note: Part 3 of Chapter 6 provides for the extension of the term of standard patents claiming pharmaceutical substances.

(3) In this section:

pharmaceutical patent means a patent claiming:

  (a) a pharmaceutical substance; or

  (b) a method, use or product relating to a pharmaceutical substance, including any of the following:

    (i) a method for producing a raw material needed to produce the substance;

    (ii) a product that is a raw material needed to produce the substance;

    (iii) a product that is a pro-drug, metabolite or derivative of the substance.

(Continued next page)

Box 8.2 (continued)

Section 119B of the *Patents Act 1990* (Cwlth) states:

(1) A person may, without infringing a patent, do an act that would infringe the patent apart from this subsection, if the act is done solely for:

  (a) purposes connected with obtaining an approval required by a law of the Commonwealth or of a State or Territory to exploit a product, method or process; or

  (b) purposes connected with obtaining a similar approval under a law of another country or region.

(2) This section does not apply in relation to a pharmaceutical patent within the meaning of subsection 119A(3).

Rationale and assessment

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

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

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

and research exemptions in comparable markets are discussed in more detail in appendix C.

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

Interaction with other forms of non-voluntary access

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

8.3 Compulsory licences for pharmaceutical exports

In 2011, the Australian Government announced its intention to introduce legislation to allow the issuing of compulsory licences in Australia, for the purposes of exporting pharmaceuticals to developing countries (Carr and Emerson 2011). This would implement an agreement negotiated by the World Trade Organisation (WTO) (through a 2003 WTO General Council decision and the TRIPS Protocol) to address the issue of access to medicines in developing countries (appendix D).

Proposed amendments

A draft of the legislation, which contained proposed amendments to the Patents Act, was released in August 2012 for comment (IP Australia 2012e). The draft Bill proposes the creation of two classes of compulsory licences:

- general compulsory licences (the current provisions in the Patents Act)
- patented pharmaceutical invention (PPI) compulsory licences (box 8.3).

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

Box 8.3 **Proposed section 136D**

(1) After hearing an application under section 136C, the Federal Court may, subject to this Part, make the PPI order sought if the court is satisfied of all of the following matters:

(a) the application is made in good faith;

(b) the pharmaceutical product is to be imported:

(i) by the eligible importing country; or

(ii) on behalf of, and with the authorisation of, the eligible importing country;

(c) the proposed use of the pharmaceutical product is to address a public health problem in the eligible importing country:

(i) in circumstances of national emergency, or other circumstances of extreme urgency, in that country; or

(ii) in other circumstances—by the public non-commercial use of the pharmaceutical product in that country;

(d) working the patented pharmaceutical invention is necessary to enable the import and proposed use of the pharmaceutical product as mentioned in paragraphs (b) and (c);

(e) if subparagraph (c)(ii) applies:

(i) the PPI order applicant has given the patentee a notice in the approved form seeking from the patentee an authorisation to work the patented pharmaceutical invention for public non-commercial use; and

(ii) during the 30 days beginning when the notice was given, the PPI order applicant has tried, without success, to obtain such an authorisation from the patentee on reasonable terms and conditions;

(f) the notification requirements prescribed by the regulations in relation to the importation of the pharmaceutical product have been complied with;

(g) the PPI order applicant and the eligible importing country will take reasonable measures to prevent a pharmaceutical product that is exported from Australia in accordance with a PPI compulsory licence from being used for a purpose other than the purpose of addressing the public health problem mentioned in paragraph (c).

Without limiting the matters that the court may take into account in deciding whether it is satisfied of a matter mentioned in subsection (1), the court must take into account any matters prescribed by the regulations.

Source: IP Australia (2012e).

Rationale and assessment

The reforms are chiefly motivated by concerns about access to medicines in developing countries, and reflect changes made to the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS agreement) through the TRIPS Protocol (appendix D). The regulation impact statement for the proposed amendments stated that:

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

The reforms aim to address issues in the patents system that may be partly responsible for the limited availability of affordable medicine in developing countries:

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

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

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

Dr Matthew Rimmer (sub. 11; sub. 15) claimed that the agreement negotiated by the WTO, and hence Australia's proposed Bill to implement it, is ineffective in facilitating developing-country access to medicines. He argued that a better approach would be to exercise existing provisions in the TRIPS agreement, which he claimed Australia could use to legislate a system for exporting patented inventions on humanitarian grounds (including for products other than pharmaceuticals). However, the regulation impact statement argued that the legislative changes would implement the TRIPS Protocol 'in a simpler and more

efficient manner' than in other jurisdictions which have adopted it so far (IP Australia 2011b, p. 14).

The reforms seek to benefit developing countries by making medicines more accessible and affordable than otherwise. This includes by encouraging pharmaceutical companies to charge lower prices in eligible importing countries, rather than be subject to a compulsory licence. Evidence from South Africa indicates that competition from generic manufacturers, and threats to issue compulsory licences, prompted several multinational pharmaceutical companies to lower the prices of HIV/AIDS medicines (Schoofs and Waldholz 2001). The World Health Organisation found that competition from generic manufacturers lowered the annual per patient cost of HIV/AIDS medication from over US$10 000 in 2002, to US$100 in 2010 (WTO 2010). According to Health Action International, the flexibilities provided by the TRIPS Protocol are an important strategy for bringing the price of vital medicines down and improving the availability and affordability of essential medicines (Ewen 2010).

The Commission considers that an assessment of this issue is beyond the terms of reference for this inquiry. It was a matter for IP Australia to consider during its public consultation on the Bill (Dr Rimmmer also provided sub. 11 to IP Australia), and will also be open to scrutiny by Parliament when the Bill is tabled.

Interaction with other forms of non-voluntary access

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

9 Other alternative mechanisms

Key points

- The Commission has considered several new alternatives to existing compulsory licensing provisions, many of which focus on access to healthcare. This is where most concerns about the accessibility of patented inventions have arisen.
- Healthcare-specific approaches — including exclusion from patentability, exemption from patent infringement, or a special compulsory licensing regime — are not warranted because:
  - the benefits are likely to be small, given the few cases where there have been problems with accessing health-related patents
  - incentives for health-related innovation would be reduced
  - Crown use provisions can already be applied to healthcare and the Commission's proposed reforms (chapter 7) should increase clarity in this regard.
- The use of government purchasing power to ensure equitable and affordable access to patented health technologies currently occurs through the Medicare Benefits Schedule (MBS) and the Pharmaceutical Benefits Scheme (PBS). Where the processes associated with listing on the MBS and PBS are considered too slow, governments can resort to Crown use, as well as changes to the approval and funding arrangements to improve their efficiency and effectiveness.
- A licence-of-right mechanism would give patent holders the option of registering a commitment with IP Australia to license to all parties who wish to do so. However, experience with such a mechanism in other countries suggests that it would be rarely utilised. Moreover, its voluntary nature means that it would not address cases where patent holders are unwilling to license widely.
- Non-voluntary licensing by a collecting society, as currently occurs for copyrighted works, is not a suitable option for patents, primarily because the use of patents is much more diverse, and so is less amenable to standardised licensing by a central body.
- Model patent licences have not been very effective in facilitating voluntary licensing, because there is limited scope for a one-size-fits-all approach.
- Patent fee discounts to encourage voluntary licensing are unlikely to have much impact, given that patent fees are relatively small.

The terms of reference ask the Commission to consider alternatives to compulsory licensing. Existing alternatives, such as Crown use and acquisition powers, were examined in chapters 7 and 8. This chapter considers several other mechanisms, many of which focus on access to healthcare, given that this is primarily where concerns have arisen about the accessibility of patented inventions. The options

considered are: exclusions and exemptions for medical use; public-health specific compulsory licensing; use of government purchasing power in healthcare; a licence-of-right mechanism; collecting societies; and other measures to encourage more voluntary licensing.

9.1 Exclusions and exemptions for healthcare

As discussed in chapter 5, patents on human genes and related testing methods have raised concerns about equitable and affordable access to healthcare. Options to address these concerns include pre-grant measures (exclusions from patentability) and post-grant measures (exemptions from patent infringement). These are discussed below.

Exclusions for diagnostic, therapeutic and surgical methods

The Agreement on Trade-Related Aspects of Intellectual Property Rights 1994 (TRIPS agreement) generally prohibits member countries from implementing technology-specific exclusions from patentability, and as such, requires Australia to maintain a technology-neutral patents system. However, Article 27 of the TRIPS agreement does allow member countries to exclude from patentability diagnostic, therapeutic and surgical methods for the treatment of humans and animals (appendix D). This is based on public health considerations, leaving medical practitioners free to take the necessary action to diagnose or treat a certain disease.

Australia does not currently have an exclusion under Article 27. In its review of gene patenting, the Australian Law Reform Commission (ALRC 2004) considered that an Article 27 exclusion may be limited to methods performed on or inside the body (*in vivo* procedures). As gene patents often relate to products and processes for use outside the human body (*in vitro*), most notably in connection with gene sequencing and diagnostic testing, this implies that an exclusion under Article 27 may not address concerns about the effect of gene patents on access to diagnostic testing.

The European Union provides an example of where Article 27 has been used. The European Patent Convention states that methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised *on* the human or animal body are not patentable inventions. The exclusion does not apply to methods practised on substances that are removed from the body. For example, the treatment of blood for storage in a blood bank or diagnostic testing of blood samples is not excluded. In contrast, a treatment of blood by dialysis, where the

blood returns to the same body would be excluded (Basheer, Purohit and Reddy 2010).

Patentability exclusions for medical treatment have been applied in Canada, New Zealand, and the United Kingdom. However, these only relate to treatment or diagnosis on the human body, and not procedures carried out *in vitro* or exclusively outside the body. In Canada, methods of medical treatment, although not explicitly excluded, are not considered patentable subject matter, based on judicial interpretation of section 2 of the Canadian Patent Act 1985. As defence to an allegation of infringement, a defendant may argue that a patent claim is invalid on the basis that it covers subject matter that is a non-patentable method of medical treatment (CIPO, pers. comm., 24 October 2012).

The introduction of an Article 27 exclusion in Australia has been considered in several reviews of gene patents. The ALRC (2004) concluded that the *Patents Act 1990* (Cwlth) should not be amended to exclude from patentability genetic materials or methods of diagnostic, therapeutic or surgical treatment. It was concerned that this would be difficult to implement, could have adverse effects on investment in biotechnology, medical research and innovation in healthcare, and may not be consistent with Australia's international obligations under the TRIPS agreement. An inquiry by the Senate Community Affairs References Committee (SCARC 2010) considered excluding genes from patentable subject matter and also concluded that the Patents Act should not be amended to include an express prohibition on patents on human genes and genetic products at that time. This was based on international and national legal developments relating to the BRCA gene patents. It was considered that if the courts were to find that isolated genetic materials were discoveries rather than inventions, this would lessen the need for an express prohibition on gene patents.

As discussed in chapter 5, a private member's Bill was introduced to the Senate in 2010, which would have introduced an exclusion for human genes, biological processes and materials. However, the Bill did not pass following an inquiry by the Senate Legal and Constitutional Affairs Legislation Committee (SLCALC 2011**)** on the basis that it could have unintended consequences on the patents system with unknown effects on a range of industries and sectors.

The Australian Government (2011a) accepted the ALRC's view that genetic materials and technologies as well as methods of diagnostic, therapeutic or surgical treatment should not be excluded from patentable subject matter. However, it also accepted a more recent recommendation of the Advisory Council on Intellectual Property (ACIP 2010c) to include a general patentability exclusion in the Patents Act that would apply in exceptional circumstances to protect public order and

morality as permitted by Article 27(2) of the TRIPS agreement. ACIP (2010c, p. 18) recommended 'to exclude from patentability an invention, the commercial exploitation of which, would be wholly offensive to the ordinary reasonable and fully informed member of the Australian public'. A similar provision under Article 53(a) of the European Patent Convention has been used to reject patent claims. For example, in 2008, the European Patent Office denied a patent over the human embryonic stem cell, because the invention required the destruction of a human embryo, and this was found to be contrary to *orde public* or morality (ACIP 2010c).

The Commission notes that there have been no amendments to the Patents Act to give effect to the Australian Government's response to ACIP's recommendation. Moreover, it is uncertain whether the introduction of the general exclusion as recommended by ACIP could be used to prevent future patenting of diagnostic, therapeutic or surgical treatments in certain circumstances. Given it is intended to apply only in exceptional circumstances, it would seem likely that the courts would narrowly interpret the circumstances in which such an exclusion would be granted.

The Commission agrees with the Australian Government's acceptance of the arguments made in past reviews that the Patents Act should not be amended to include these technology-specific exclusions. The focus of the Commission's inquiry is on compulsory licensing and other forms of non-voluntary access after a patent is granted.

Exemptions for medical practitioner use

Another option is to introduce a specific exemption from infringement by medical practitioners and medical scientists for the limited purpose of screening and diagnosis. This would enable patients to access the results of screening and diagnostic tests to identify gene-related diseases through their medical practitioners.

A medical practitioner exemption might be similar in intent and design to the medical treatment defence under US law (box 9.1). However, this currently only applies to medical and surgical procedures performed on a body.

The ALRC (2004) concluded that there were potentially many difficulties in defining the scope of a new medical treatment defence in Australia. These included:

- what specific medical activities should be covered under the defence (in particular, whether it should apply to both procedures performed outside of the human body (*in vitro*) as well as procedures performed on, or inside of, the human body (*in vivo*))

- which persons or organisations should qualify to invoke the exemption from patent infringement.

Box 9.1 **US medical treatment defence**

In 1993, Dr Samuel Pallin launched legal action against Dr Jack Singer in relation to use of a patented surgical method for treating cataracts. In March 1996, the US District Court dismissed Pallin's infringement claims and invalidated the patent claims over the surgical method (as Singer was proven to have used the method prior to Pallin applying for the patent). In response to this case, the US Government introduced a limited statutory defence to claims of patent infringement asserted against a medical practitioner or related healthcare entity, where it occurs during performance of a medical activity (WIPO 2010b).

The defence is provided under section 35 of the United States Code (§287(c)(2)), which states that:

(A) the term 'medical activity' means the performance of a medical or surgical procedure on a body, but shall not include

(i) the use of a patented machine, manufacture, or composition of matter in violation of such patent,

(ii) the practice of a patented use of a composition of matter in violation of such patent, or

(iii) the practice of a process in violation of a biotechnology patent.

(B) the term 'medical practitioner' means any natural person who is licensed by a State to provide the medical activity described in subsection (c)(1) or who is acting under the direction of such person in the performance of the medical activity.

(C) the term 'related health care entity' shall mean an entity with which a medical practitioner has a professional affiliation under which the medical practitioner performs the medical activity, including but not limited to a nursing home, hospital, university, medical school, health maintenance organization, group medical practice, or a medical clinic.

Certain types of medical activity are expressly excluded from the ambit of the medical treatment defence, including most medical applications of genetic materials and technologies. The medical defence was subject to scrutiny by European Community member States in a review of the implementation of the TRIPS agreement in 1998 (ALRC 2004). There does not appear to be evidence of the medical defence being used in practice.

In 2002, a Bill was introduced into the US Congress, which would have extended the definition of a medical activity to include genetic diagnostic, prognostic or predictive testing. This would have exempted medical practitioners using genetic diagnostic tests (for example, tests performed on the BRCA genes) from patent infringement. However, the Bill was not passed because the primary sponsor lost her seat, and to date, there has been no further activity on this legislation.

The ALRC did not support any legislative amendment to enact either a general medical treatment defence or a defence specifically related to the use of patented genetic material and technologies. It concluded that this would be inconsistent with provisions of the TRIPS agreement that require technology neutrality, and would detract from patent rights, with potential adverse effects on innovation and investment in some areas of medical technology.

Clinical use exceptions have been suggested as a less arbitrary alternative to excluding genetic tests entirely from patentability than other mechanisms (including compulsory licensing and the application of antitrust law). Some have advocated for research exemptions to be extended to include clinical use exemptions for diagnostic testing with a research purpose (OECD 2002). However, the difficulty with such an approach is to clearly distinguish clinical use from commercial use to minimise any adverse effects on incentives for investment in health-related innovations.

One way to address this problem would be to introduce a clinical or medical use exemption that is similar in intent to the research exemption — that is, to allow for limited commercial use by medical practitioners and health care providers (for example, to earn professional consultation fees). However, the exemption would not apply where the main purpose is to commercialise the invention, or manufacture it for sale.

Clearly defining the scope of limited commercial use by medical practitioners would be difficult and the Commission is not aware of a similar approach being used in other jurisdictions. Moreover, as concluded by the ALRC, the adoption of a medical defence exemption would be a departure from technology neutrality, as required under the TRIPS agreement, and have unknown potential adverse effects on investment. Thus, the Commission does not support the introduction of a medical defence exemption on this basis.

9.2 The right of an individual to personal health information

One of the arguments raised against patents over genetic material is that they shift ownership of genetic material away from the individual from whom it was obtained, and may impede access to important health information. It has been argued that this is incompatible with the individual's self-determination, or right to make choices about how that person's body is used (ALRC 2004).

The Australian Government Department of Health and Ageing (DOHA) gave an example of where this issue could arise under existing legislation. Specifically, it was concerned that a person cannot be given the results of a genetic test if it is conducted without the patent owner's authorisation under a research exemption:

> Stakeholders have raised concerns that exemption from patent infringement for experimental (i.e. research) activities ... may be insufficient to protect researchers in situations where there may be an intersection between experimental and clinical purposes relating to a patent invention. For example, in clinical trials a researcher may be required to make available the results of a genetic test undertaken as part of the trial to the participant in accordance with NHMRC's National Statement on Ethical Conduct in Human Research. There is a concern that this type of research may be seen as involving a screening service and therefore may not be protected from claims of patent infringement under the research exemption. (sub. 22, p. 10)

If such a scenario were to eventuate, a compulsory licence would not be an effective means for the tested individuals to access their health records. This is because few people have the capacity to obtain a licence to work a patent themselves (that is, undertake their own genetic tests). Furthermore, the patent holder would not necessarily have engaged in conduct that would constitute grounds for the granting of a compulsory licence order.

The OECD (2006) noted that, while it does not appear to be general practice for patent holders to exert control over human genetic information derived from individuals, anecdotal evidence suggests this practice has occurred in certain situations. It recommended that human genetic information should be disseminated as widely as possible to provide valuable insight into the human body and the development and progression of disease. However, this dissemination of information should be subject to the need to protect the privacy of patients and to meet the legitimate business needs of licensors and licensees.

The *Privacy Act 1977* (Cwlth) and the National Privacy Principles (NPPs) require that, if an organisation holds personal information about an individual, it must provide the individual with access to the information on request by the individual. However, under NPP 6.1, there are some situations where access to medical records can be refused, including where 'providing access would be unlawful'.[1] According to the Office of the Australian Information Commissioner (OAIC, pers. comm., 12 February 2013), it appears to be possible that an individual could be denied access to their personal information under NPP 6.1(g), if it would infringe a patent.

[1] The exception under NPP 6.1(g) covers circumstances where providing access to personal information would be a breach of confidence under the law, for example a breach of professional privilege (OFPC 2001).

This situation might arise if a particular gene sequence is identified in an individual that is associated with a disease or health problem by a tester who is not licensed to use the gene patent. However, the OAIC cautioned that it could not provide definitive advice on the interaction between the NPPs and patents law. Therefore, it is unclear whether an individual's right to access personal information under the Privacy Act, in this case, would override the exclusive rights of the patent holder.

However, it appears that a solution is being sought for a scenario that rarely, if ever, arises. Civil Liberties Australia (sub. 12) referred to one example in the United States in which it claimed that the holder of the BRCA gene patents had prohibited researchers from informing people about their test results. The Commission was not presented with any evidence of people in Australia having been denied access to their genetic test results because the testing was done as part of a clinical trial or experimental activity. Thus, it appears to essentially be a hypothetical scenario.

If the scenario were to become prevalent in the future, and existing protections in the Privacy Act proved to be inadequate, there may be a case for legislating a right to personal genetic information. Under this option, individuals would have a right to access information relevant to their own genome (their genetic make-up). It would also provide that a medical practitioner, scientist or their employer are exempt from infringement of gene patents where:

- they have used the information contained in the gene patent for the purpose of identifying a gene sequence in a particular genome which is associated with a medical disease or condition
- the genome belongs to an Australian individual
- the purpose of identifying the gene sequence is to provide information relevant to the provision of health services to that individual.

This approach would prevent gene patent holders from restricting individuals from obtaining information on sequences in their own genome that are relevant to their own health, without detracting from their rights, as use of the gene patent would not be for commercial gain.

To implement this option, the Australian Government would need to investigate whether a legislative amendment that provides individuals with the right to access personal information would comply with the TRIPS agreement and other relevant international obligations.

On balance, the Commission's view is that implementing a legislative change to this effect is not warranted at this stage. As discussed in chapter 8, the newly introduced experimental exemption aims to clarify the rights and obligations of researchers and

reduce uncertainty around patent infringement related to the use of patented inventions in research. However, the application of the exemption to medical research is yet to be tested by the courts. The development of case law in this area would provide more clarity to researchers on the legitimacy of providing personal health information to individuals that is derived from gene patents. Where an individual is concerned about accessing personal information in accordance with their rights under the Privacy Act, they can make a complaint to the Office of the Australian Information Commissioner, which has responsibility for investigating complaints about privacy issues covered under the Act.

9.3 Public-health specific compulsory licensing arrangements

In addition to generic compulsory licensing provisions, France, Belgium and Switzerland have introduced specially tailored compulsory licensing regimes to remedy patent licensing practices which are considered detrimental to public health. These were introduced following public debates about BRCA gene patents granted by the European Patent Office and concerns over restrictive licensing practices of the patent holder, Myriad. The intention was to overcome perceived deficiencies of generic compulsory licensing regimes, particularly the lack of a quick and effective remedy against unreasonable licensing behaviour with detrimental effects on public health.

In France, existing compulsory licensing provisions were amended to extend the application of *ex-officio* licences for public health to genetic diagnostics (box 9.2). In Belgium, public health was added as a new separate ground for granting a compulsory licence, and is intended to apply to the entire medical sector in a non-discriminatory way. The Swiss mechanism differs somewhat from the Belgian and French systems in that it only deals with inventions regarding diagnostic products or processes. The Swiss patent legislation was amended in 2008 to include a separate compulsory licence to apply in cases of anticompetitive practices contrary to the Swiss Cartel Act 1995 that relate to such inventions. The concept of 'public health' applied to specific compulsory licence regimes varies across these countries, as do the inventions subject to this form of compulsory licensing.

According to Van Zimmeren and Van Overwalle (2011), the specially tailored compulsory licensing regimes have never been used in practice. However, they argued that the regimes have several advantages over conventional compulsory licences issued on the grounds of failure to work, including:

- a shortening of the waiting period for applying for a compulsory licence (there is

no requirement to wait three years from the grant of the patent, or four years from the filing of the patent application, before applying for a compulsory licence)

- increased incentives for patent holders to provide the patented product or services on reasonable terms, or to license to third parties on reasonable terms (there is some anecdotal evidence from licensing experts that suggests the mechanisms may have an indirect, preventative effect on possibly unduly restrictive licensing behaviour by patent owners).

Box 9.2 **French public health licensing regime**

In France, an *ex-officio* licensing regime has been established with respect to patents issued for medicines, medical devices, *in vitro* diagnostic medical devices, related therapeutic products, and processes for obtaining such products, products necessary in obtaining these products, processes for manufacturing such products and *ex vivo* diagnostic methods.

The Minister responsible for industrial property and an advisory committee consider all the circumstances of the case, including the reasons for a patent holder's refusal to license. This occurs in two instances: prior to establishment of an *ex-officio* regime; and when individual applications for licences to work the patented invention are filed. Once the Minister responsible for intellectual property has ordered the establishment of an *ex-officio* licence regime, any qualified individual can apply for a licence to work the patent. The person has to be qualified from a legal, technical, industrial and financial point of view. A non-voluntary licence will only be granted if prior attempts to seek access on reasonable terms and conditions have been made.

Under the French Intellectual Property Code (FIPC) an *ex-officio* licence is legitimate if one of the following circumstances applies:

1. The quantity or the quality of the medicines or methods available to the public is insufficient.
2. The medicines or methods are only available at abnormally high prices.
3. The patent is exploited in a manner contrary to public health interests.
4. The patent is worked in a manner resulting in anticompetitive practices, qualified as such in a final administrative or court decision.

Sources: Van Zimmeren and Van Overwalle (2011); (Article L.613-16 FIPC).

There are also potential disadvantages of health-specific compulsory licensing regimes.

- The effectiveness of the mechanism may be uncertain if its use is dependent on the willingness of private companies to apply for compulsory licences (although

in France and Switzerland, the relevant Minister has the right to initiate proceedings).

- Despite reduced waiting periods compared to a conventional compulsory licence regime, there may be potentially long delays between application for, and granting of, a health-specific compulsory licence, which limit the effectiveness of the mechanism in emergencies.
- It may increase incentives, relative to conventional compulsory licence regimes, for firms to relocate their research activities to other countries.

The introduction of a similar health-specific compulsory licensing regime in Australia would need to be compliant with the TRIPS agreement. According to Van Zimmeren and Van Overwalle (2011), a compulsory licence for public health can be justified on the basis of Articles 8 and 30. However, it would be a move away from a technology-neutral patents system, as mandated by Article 27 of the TRIPS agreement.

The Commission considers that determining the grounds for the granting of a health-specific compulsory licensing regime is likely to be problematic. The objective of any new health-specific regime would need to be clarified. That is, whether the primary motivation for such an intervention in Australia is to address concerns about the potential for gene patents to inhibit patient access to diagnostic testing, or concerns that patents inhibit access to medical and health-related innovations more broadly. The National Coalition of Public Pathology submitted:

> Under an Ex Officio arrangement, the Health Minister could be granted the power to grant a licence where there are important public health reasons (which should be explicitly defined). Clear legislation should be developed about what an important public health reason is … To avoid every State and Territory Health Minister from having to grant a licence for every applicable patent on public health grounds, their powers may have to be referred to the Federal Health Minister on this matter. (sub. 25, p. 4)

The introduction of a compulsory licensing regime specifically tailored for gene patents could also be seen as a costly reaction to the BRCA gene case, where there are other more efficient and timely non-voluntary access mechanisms such as the Crown use provisions.

Moreover, public reaction to perceived restrictive licensing behaviour appears to have been effective in many countries in putting pressure on patent holders to license gene patents, as noted by the OECD (2002, p. 73):

> Industry representatives recognised that governmental and public pressure (particularly from patient groups and the medical establishment) have a powerful influence on their

licensing strategies. Public reaction against ill-conceived licensing and enforcement practices carries weight in corporate decision making.

Furthermore, a health-specific compulsory licence regime may have a number of unintended effects on investment and the allocation of resources to innovative effort. If a new regime has the effect of broadening the circumstances in which compulsory licences can be invoked (relative to conventional compulsory licences), a consequence of this is a reduction in the rights of the patent holder to exploit health-related patents. In turn, this could reduce the returns to health-related innovation, relative to areas not subject to specific compulsory licensing provisions, and may result in reallocation of investment funds into those areas at the expense of health-related innovation. In other words, the regime may introduce a distortion into the innovation market.

A key issue is whether such an approach might be more appropriate than current non-voluntary access mechanisms to address systemic or potentially unanticipated problems in the future that may arise as a result of restrictive licensing practices.

Crown use and government purchasing power (discussed below) provide the Australian Government with mechanisms that are sufficient to access future developments in healthcare technology. In light of this, and the potential unintended effects on technological development, the Commission considers that health-specific compulsory licensing would not improve the overall effectiveness and efficiency of the Australian patents system.

9.4 Use of government purchasing power in health

A number of participants to this inquiry (for example, AusBiotech sub. 21; WEHI sub. 13) and previous reviews into gene patents (ACIP 2010c; ALRC 2004; SCARC 2010) supported an arrangement for genetic testing similar to the Pharmaceutical Benefits Scheme (PBS). The Australian Government (2011a) rejected a recommendation from the ARLC (2004) that the Australian Health Ministers' Advisory Committee should examine further options for using government funding and purchasing power to control the cost of goods and services that are subject to gene patents and used in the provision of healthcare. This was on the basis that it did not see a need for an additional mechanism to address the cost of medical goods and services beyond the existing funding mechanisms under the Medicare Benefits Schedule (MBS) and the PBS. This section examines whether the current arrangements provide a suitable alternative to compulsory licensing.

Current arrangements

The Australian Government controls and contributes to the cost of medical procedures and pharmaceuticals using funding mechanisms under the MBS and the PBS. The Government also contributes to the funding of public hospitals, including outpatient clinic services, which are generally provided by state and territory governments.

Genetic testing

In Australia, genetic testing is provided by:

- specialist genetic testing laboratories in the public hospital system (this is the usual route for complex testing, and is typically provided free of charge to public patients who are residents of that state, while interstate and private clinic patients may be charged)
- laboratories accredited to provide the genetic tests listed on the MBS, and thus eligible for a Medicare rebate
- research laboratories, either as part of research activities or on a fee-for-service basis
- small private laboratories on a fee-for-service basis (RCPA 2008).

Data are not available on the proportion of genetic tests provided in Australia that are patented. However, the Royal College of Pathologists of Australasia (sub. 16, attachment 5) noted that one major public sector laboratory estimated that at least 50 per cent of the genetic tests it offers could be covered by one or more Australian patents. A US study in 2005 found that 20 per cent of approximately 23 700 genes identified had been patented, with up to 20 patents and 12 patent holders for any one gene.

The majority of genetic tests in Australia are currently funded by state and territory health departments using a range of mechanisms, including cost recovery. Some genetic tests are only available if the patient pays directly. Others may not be available from an Australian laboratory, and so samples have to be sent overseas.

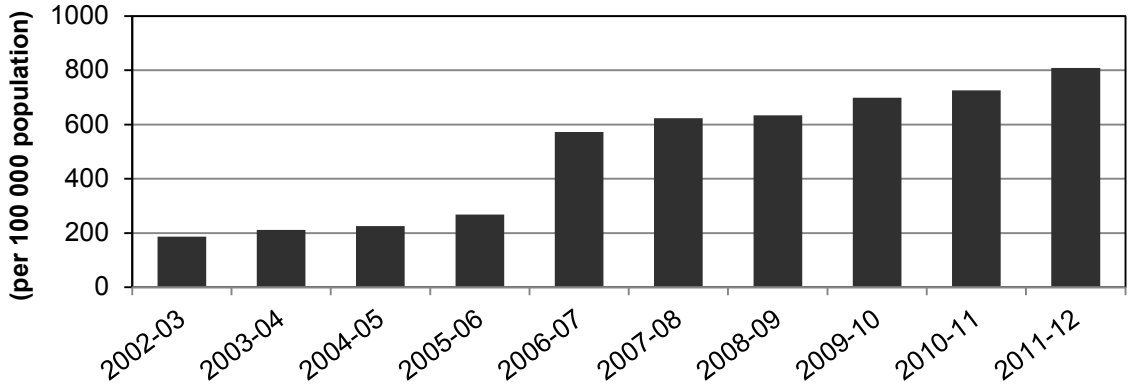
Only 23 distinct genetic tests are currently listed on the MBS.[2] However, there is evidence to suggest that these account for a sizeable proportion of the volume of

[2] On 1 March 2013. There were more than 23 MBS pathology items related to genetic tests, but this was because some items indicated a referral of the testing from one pathology laboratory to another (DOHA, pers. comm., 22 March 2013).

genetic tests conducted in Australia. The most recent data for all genetic tests undertaken in Australia show that, in 2007, 40 per cent attracted a Medicare rebate (RCPA, sub. 16, attachment 3). These data also show that the majority of genetic tests not listed on the MBS in 2007 were only available from a small number of laboratories in a single state or territory. The volume of many of these tests was low (less than 100 samples assayed each year).

More comprehensive and up-to-date data are only available for Medicare-rebated tests. This information indicates that the volume of MBS-listed genetic tests increased fourfold between 2002-03 and 2011-12 (figure 9.1). This was largely due to a more than doubling of the volume of tests in 2006-07. It appears that this was linked to the addition of several new genetic tests to the MBS in 2006 (RCPA, sub. 16, attachment 3). However, the volume of Medicare-rebated genetic tests has remained very small compared to the volume of other Medicare-rebated pathology tests (less than 0.5 per cent of all Medicare rebated pathology tests in every year from 2002-03 to 2011-12).

Figure 9.1 **Per capita level of Medicare-rebated genetic services, 2002-03 to 2011-12**[a]



a Genetic services include all MBS-listed items under the cytogenetics group (P7) of pathology services (category 6). These relate to analysis of abnormalities of whole chromosomes (each chromosome contains many different genes) and molecular genetic testing (analysis of gene mutations linked to specific diseases). The per capita level of services was calculated by dividing the number of services provided by a Medicare registered provider and processed by Medicare Australia in a month by the number of people enrolled in Medicare at the end of each month for the financial year ending 30 June.

Source: Medicare Australia (2013).

In 2011-12, only about $29 million was paid as Medicare benefits for genetic services (table 9.1). This accounted for 0.2 per cent of total Medicare item expenditure.

The number of Medicare-rebated genetic tests may increase significantly in future years. Australian Government decisions about the listing of new medical

technologies on the MBS (including genetic tests) and public funding are informed by the advice of the Medical Services Advisory Committee (MSAC).[3] Over one-third of applications currently being considered by the MSAC for listing on the MBS relate to genetic tests and/or associated services. In some cases, this includes a review of existing MBS items (DOHA, pers. comm., 5 November 2012).

Table 9.1 **Medicare services and benefits, 2011-12**

Type of service	*Services*		*Benefits*	
	No.	%	$ million	%
All genetic services	184 036	0.1	29.2	0.2
Other pathology services	114 510 230	34.4	2 207.5	12.5
Other Medicare services	217 915 465	65.5	15 460.5	87.3
All medical services	332 609 731	100.0	17 697.2	100.0

Source: Medicare Australia (2013).

The MSAC approval process for new genetic tests can be slow and there is no mechanism for determining which tests should be prioritised for Medicare funding (DOHA 2011a). However, the funding arrangements for pathology services funded through the MBS have recently been reviewed by the Department of Health and Ageing (box 9.3).

Box 9.3 **Funding Agreement for MBS pathology services**

In March 2011, the Department of Health and Ageing (DOHA) released its final discussion paper on the *Review of Funding Arrangements for Pathology Services*. This review, undertaken by the Medical Benefits Reviews Task Group, informed a five-year funding agreement between the Australian Government and the Australian Association of Pathology Practices, the Royal College of Pathologists of Australasia, and the National Coalition of Public Pathology. The agreement, which was signed in April 2011, sets the maximum and minimum government outlays relating to services in the Pathology Services Table (PST) of the MBS.

Among a number of objectives, the funding agreement is intended to promote:

- development of a more transparent mechanism for setting and reviewing schedule fees for PST items, based on better cost information
- competition in the pathology sector

(Continued next page)

[3] The MSAC provides advice to the Commonwealth Minister for Health and Ageing on the safety, clinical effectiveness and cost-effectiveness of new and existing medical procedures, including pathology services, which includes some genetic testing.

Box 9.3 (continued)

- development of a National Pathology Framework
- improvement of data collection through MBS payment arrangements
- implementation of electronic requesting and reporting of pathology across the sector
- development of appropriate policy and funding mechanisms for genetic testing.

The development of a national approach to the provision of genetic services, including financing, is currently being considered by a working party established by DOHA and comprised of representatives from the pathology sector, state and territory governments and consumers. The PST expenditure implications of any reforms may affect government outlays under the agreement. At the time of writing this report, it appeared the working party had not provided its advice to DOHA on possible reforms.

Sources: DOHA (2011a; 2011b).

Pharmaceuticals

The primary role of the PBS is to achieve the objective of the National Medicines Policy, endorsed by the Australian Government in 1999, to ensure the provision of timely access to the medicines that Australians need, at a cost that individuals and the community can afford. The Government uses several mechanisms to contain the cost of the scheme, including reference pricing, exercising countervailing buyer bargaining power, and use of prescription guidelines.

Once a prescription drug is approved for marketing by the Therapeutic Goods Administration (TGA) and included in the Australian Register of Therapeutic Goods (ARTG), the producer or sponsor usually applies to have the drug listed on the PBS.[4] Similar to the MBS process, the Pharmaceutical Benefits Advisory Committee (PBAC) makes recommendations to the Australian Government on the suitability of drugs and medicinal preparations for subsidy under the PBS and the vaccines for listing under the National Immunisation Program. The recommendations are based on comparative clinical effectiveness and cost effectiveness. Following this, the Pharmaceutical Benefits Pricing Authority (PBPA) negotiates prices paid with the sponsor and makes recommendations to the Minister on pricing determinations for drugs recommended for listing on the PBS.

4 Under parallel processing arrangements for new drug evaluations, submissions to the Pharmaceutical Benefits Advisory Committee (PBAC) may be lodged at the same time as applications to the TGA for inclusion on the ARTG. However, the PBAC cannot recommend listing on the PBS until the outcome of the TGA's consideration is known.

The Australian Government considers the advice of both the PBAC and the PBPA and makes a decision on whether the drug will be listed on the PBS.[5] The PBPA may also recommend revised prices where the use of a drug is extended or changed. In addition, the PBPA reviews prices of all brands of pharmaceutical items listed on the PBS at least once each year. The PBPA's approach to pricing determinations under the PBS is based on cost-effectiveness criteria and comparative price referencing (box 9.4). It does not take into account the patent status of a drug or include a price premium to provide compensation for patent rights (ALRC 2004).

Box 9.4 **Pricing of drugs under the PBS**

In making recommendations to the Australian Government on the prices that should be paid for items recommended for listing on the PBS (and in reviewing the price of items already listed on the PBS), the Pharmaceutical Benefits Pricing Authority (PBPA) is required to take account of:

- the advice of the Pharmaceutical Benefits Advisory Committee (PBAC) on clinical and cost-effectiveness
- prices of alternative brands
- comparative prices of drugs in the same therapeutic group
- cost data information
- prescription volumes, economies of scale and product stability
- prices of items containing the drug in reasonably comparable overseas countries
- other factors the applicant may wish the PBPA to consider
- any directions of the Minister.

The PBPA uses a number of pricing methods in making its recommendations. Most commonly used are the Cost-Plus method, Reference Pricing and Weighted Average Monthly Treatment Cost. It may recommend either a ceiling price or price range for an item that has been approved by the PBAC following negotiation. Under the PBS, patient contributions towards medication costs at pharmacies are capped.

Sources: DOHA (2010); PBPA (2009).

Where there are two or more brands of the same drug on the PBS schedule (which generally only occurs if the patent has expired), the Government subsidises each

5 Following an Australian Government decision in 2010-11, all recommendations made by the PBAC and PBPA to approve new and amended listings, and price increases that have a financial impact for the Australian Government, are required to be considered by Cabinet prior to PBS listing. Previously, Cabinet consideration was only required for the listing of medicines with a net cost greater than $10 million per year (DOHA 2012a).

brand to the same amount, up to the cost of the lowest-price brand (DOHA, sub. 22).

If a drug manufacturer cannot agree with the Government on a price, it may sell the drug on the private prescription market. However, this is generally an unattractive option, given the provision of a subsidy through the PBS and the fact that doctors generally confine their prescribing to the PBS list.

The extent to which the PBS suppresses the price of different categories of drugs is likely to depend on the prevalence of competing medicines (including substitutes) in the market. Price disclosure and statutory price reductions are used to reduce the price of off-patent PBS-listed medicines when there are generic or competitor brands on the PBS. The price disclosure program brings the subsidised price of some older PBS medicines in line with the market price paid by pharmacies, as reported by manufacturers (DOHA 2013a). Producers of unique or breakthrough drugs that are the only form of treatment or cure for a particular disease (and are often patented) have a monopoly position in the market, at least for a period of time. In such cases, the Government is in a relatively weaker bargaining position (IC 1996).

The ALRC (2004) found there was evidence that the PBS allows relatively low prices for drugs to be maintained because the Government acts as a monopsony — a single buyer in a market with a number of sellers. However, while the Government is the only purchaser of many drugs in the Australian market, this monopsony does not extend to international markets, and its buying power is weakened by pharmaceutical companies that use their global market power to influence prices.

There are a number of cases where utilisation of a drug, medicinal preparation or vaccine listed on the PBS is likely to be targeted to a small population with a particular disease. DOHA (2011c) noted that of the total number of applications submitted, approximately one-third of sponsors predicted an estimated use of less than 2000 prescriptions in the first 12 months of listing. A number of products are supplied to eligible patients through arrangements outside of the PBS as part of the Life Saving Drugs Program. However, the costs to the Australian Government of subsidising patient access to these products can be significant because of high unit costs.

The Australian Government has initiated a review of the system of patents for pharmaceuticals (IP Australia 2012k). The review is considering a number of issues, including whether the current arrangements are being used to extend pharmaceutical monopolies at the expense of generic pharmaceuticals entering the market. The review, which is scheduled to be completed in May 2013, will look at the

pharmaceutical extension of term provisions (introduced to the Patents Act in 1998), and the current approach to granting patents for new formulations and new methods of manufacturing.

Is government purchasing power a suitable alternative?

The ALRC (2004) and others have previously recommended that governments use their purchasing power in health to address concerns about equitable and affordable healthcare. The ALRC considered that in some cases intervention in the patent process by government health departments is warranted:

> In some circumstances, health departments should be willing to challenge patents, or their exploitation, in the public interest. Patent holders will have an incentive to ensure that the exploitation of their patent rights does not prejudice public healthcare or medical research if they face the realistic prospect that their patents will face detailed scrutiny by government authorities. (p. 480)

As noted, the Australian Government rejected proposals for the introduction of new arrangements because it already uses its purchasing power through the MBS and the PBS. It accepted a recommendation by the ALRC that, where gene patents have an adverse impact on medical research or the cost-effective provision of healthcare, governments should consider exercising existing legal options to seek access, including:

- challenging a patent, requesting re-examination, or applying for revocation of a patent under the Patents Act
- making a complaint to the ACCC regarding a potential breach of Part IV of the *Competition and Consumer Act 2010* (Cwlth)
- exploiting or acquiring a patent under the Crown use and acquisition provisions
- seeking the grant of a compulsory licence under the Patents Act.

The Commission's view is that, as discussed in chapter 5, gene patent owners are not typically placing unreasonable restrictions on access to their technologies. From the evidence available to the Commission, the BRCA gene case is not representative of industry behaviour. This is supported by the preliminary results of a recent survey of managers of Australian genetic testing laboratories. As noted in chapter 5, few respondents to the survey indicated that they paid licence fees or royalties (other than those included in the price of a commercial kit), or had since 2010 received a cease and desist letter or a letter of notification from a patent holder about its patent rights (Nicol and Liddicoat 2013).

Moreover, gene patenting appears to have already peaked as an issue raising public concern. As noted by Pfizer (sub. 5), the majority of the earlier broad patents, which include the BRCA patents, are nearing the end of their patent life and patent offices have been increasing the novelty and inventiveness threshold in issuing patents.

Nevertheless, the Peter McCallum Cancer Centre observed:

> There remains … a public perception, and indeed a possibility, that there may be isolated occasions where patent holders may … attempt to enforce their rights unreasonably and either not supply patented materials in the Australian market or apply unreasonable licensing provisions to their use. (sub. 14. p. 1)

As noted in chapter 5, concerns regarding the effect of patents on the affordability of medical treatment are broader than the BRCA case, and rapid development in medical science and biotechnology could present future challenges for the patents system. Inquiry participants (for example, NHMRC, sub. 33) noted that increasingly, many diseases and conditions require analysis of multiple genes and whole-genome sequencing will be important to provide more personalised medicine. There is uncertainty as to whether patents over specific isolated genes will be infringed by whole-genome sequencing. Concerns have been raised that this presents a potential barrier to the future development of technology, as noted in a report by the US Secretary's Advisory Committee on Genetics, Health, and Society:

> As multiplex testing and whole-genome sequencing become commonplace in medicine, challenges to innovators in obtaining access to licensing information may discourage the development of advanced tests and their application to medicine. (SACGHS 2010, p. 62)

The Commission considers that wholesale changes to existing arrangements to ensure equitable and affordable healthcare are unlikely to be warranted purely on the basis of concerns related to the BRCA case. Moreover, it is evident that gene-related diagnostic and therapeutic services are being funded more extensively under the MBS and PBS. There has been an increase in the number and complexity of applications to the MSAC for genetic diagnostic tests (DOHA 2012b). This seems inevitable, as healthcare becomes increasingly reliant on gene-related technologies, and new treatments are often hybrid and co-dependent. For example, genetic tests are often used to help determine whether a particular medicine may be suitable for use by an individual. This may require assessments by both the MSAC and the PBAC and the provision of coordinated advice to the Australian Government. The existing MBS and PBS processes provide mechanisms for negotiating the supply and price of new medical technologies with producers, regardless of whether they are patented. The Commission, therefore, does not see a compelling case for changing the important checks and balances built into the Australian Government's funding arrangements for healthcare.

There have been concerns that the current evaluation processes for listing on the MBS and PBS may not be capable of responding quickly enough to some rapidly developing fields of medical technology (SCARC 2010; DOHA 2012b). The Commission notes that the Australian Government has recently reviewed health technology assessment (HTA) processes involving a number of Commonwealth agencies, including the TGA, MSAC and PBAC (DOHA 2009). Following this, measures have been introduced to improve the coordination and efficiency of HTA processes. This includes the alignment of MSAC and PBAC meeting dates and the establishment of a single entry point to assist potential applicants with a co-dependent or hybrid technology eligible for funding under the MBS, PBS and/or Prostheses List, or with a technology where the assessment pathway through existing HTA processes is uncertain (DOHA 2013b). Further, a number of changes have been proposed to improve the timeliness of the MSAC's processes for public funding applications for diagnostic tests (DOHA 2012b).

In situations where existing mechanisms associated with government purchasing power are considered too slow or are not effective in facilitating access to important health-related technologies, governments could resort to Crown use provisions (particularly in emergencies). Governments could also consider changes to the approval and funding arrangements, if necessary.

9.5 Non-voluntary licensing by a collecting society

As discussed in chapter 4, there are several cooperative mechanisms used by firms to facilitate licensing of multiple patents and enable greater access to technology, such as cross licensing, patent pools and clearing houses. For example, the MPEG-2 and Medicines Patents Pools have been established to reduce costs associated with negotiating licences for multiple patents and, in some cases, to facilitate competition from generic manufacturers. Van Overwalle et al. (2006) suggested a 'compulsory patent pool' could be applied in public healthcare and genetics to overcome access problems between multiple patent holders and technology users. This would require the creation of a patent pool entity to seek compulsory licences from owners of patents over essential technology that do not voluntarily engage in the pool.

Collecting societies, such as copyright collectives, are a type of licensing clearinghouse. Copyright Agency Limited (CAL) has been established as a collecting society with the authority to license copyrighted works, collect royalties from users (as part of compulsory licensing arrangements or individual licences negotiated on behalf of its members) and distribute the proceeds to copyright owners (box 9.5). Where a collecting society, representing one or a number of copyright holders, is unable to negotiate a licence agreement with a potential

licensee, the Copyright Tribunal has the power to make orders on the charges and conditions it considers to be 'reasonable in the circumstances'.

Box 9.5 **Copyright Agency Limited and the Copyright Tribunal**

Copyright Agency Limited (CAL) is a non-profit rights-management organisation that collects and distributes copyright fees for text and images to holders of copyrights. CAL was appointed by the Commonwealth Attorney-General in 1990 to manage the statutory licence in the *Copyright Act 1968* (Cwlth) for educational use of text and images (educational statutory licence), and by the Copyright Tribunal in 1998 to manage the statutory licence for government use of text and images (government statutory licence). These statutory licences allow use of content without a copyright clearance, provided fair payment is made to rights holders. CAL was also appointed by the Australian Government in May 2010 to manage the artists' resale royalty scheme. It also distributes payments to Australian copyright holders for works used overseas where licence fees have been collected by a collecting society in that country.

The basis of licence fees negotiated by CAL varies depending on the type of licence. However, they generally comprise a fee for the volume and type of use, rather than the use of specific works.

Unlike the Patents Act, there are no explicit compulsory licensing provisions in the Copyright Act. However, s. 183 of the Copyright Act allows the Crown to use copyright material for the services of the Commonwealth or a state after paying compensation to the owner, making this a type of compulsory licence. The licence terms are agreed between the parties, or set by the Copyright Tribunal if parties do not reach an agreement.

The Copyright Tribunal has jurisdiction with respect to both:

- statutory licences when specified conditions are satisfied (essentially statutory exclusions from infringement of copyright for the reproduction of certain materials by educational institutions or institutions assisting persons with disabilities)
- voluntary licences negotiated between a copyright holder or its representative, such as a collecting society, and the licensee. Licences granted under licence schemes are often referred to as blanket licences and cover all works in the particular collecting society's repertoire.

The Copyright Tribunal has jurisdiction to confirm, or vary, a licence scheme or proposed licence scheme. It may also substitute a new scheme for the one referred to it (ss. 154-156 of the Copyright Act). Section 157 provides for various kinds of applications to the Tribunal by licensors and prospective licensees where there has been a failure to agree on the grant of a licence. This may include cases where a licence scheme applies. The Tribunal has the power to make orders as to the charges and conditions it considers 'reasonable in the circumstances'.

Sources: CAL (2012); Copyright Tribunal of Australia (2009).

The Commission has considered the option of establishing a collecting society, under the Patents Act, to compel a patent holder to grant licences for a specific

purpose, such as access to specific gene patents for diagnostic testing. The collecting society's role could be to administer licences and negotiate some of the terms on behalf of patent holders, including licence fees. It could also be responsible for collecting royalties and distributing these to patent holders. Patent holders (or the collecting society acting on their behalf) and potential licensees could have the option of making an application to a court or tribunal for independent price adjudication if the parties fail to reach agreement on a licence.

The objective of a collecting society would be to provide a means to access specific patents and facilitate the licensing of multiple patents by a single body. In doing so, it may overcome some of the difficulties parties face when developing their innovation requires access to many other patents. DOHA stated that:

> … such a mechanism could allow much quicker, cheaper and less cumbersome access to patents which need to be utilised in a health or broader context. However, there may be insufficient demand to justify the establishment and maintenance of such a body by Government. (sub. 22, p. 9)

The Centre for Law and Genetics (sub. 3) noted that it had previously supported the creation of a statutory licensing scheme for some types of patents, particularly in the field of genetic technology. It considered that these would be most appropriate for technologies that are newly emerging, or where patent thickets have the capacity to interfere with incremental innovation. It suggested that non-voluntary schemes should be restricted to specific sectors, for example, the public research and public health sectors.

However, there are important differences between copyright works and patents that potentially limit the effectiveness of using collecting societies as a mechanism to facilitate access to patents. Specifically, these relate to their use and the characteristics of licensing agreements. Spence (2009) outlined a number of differences in the purpose and features of copyright collecting societies and patent royalty clearinghouses in the context of gene patents.

- It is easier to determine the scope and use of copyright works relative to patents. Copyright collecting societies control the use of particular types of work in specific contexts (mostly musical and literary works in relation to public performance and reproduction). The determination of licence conditions is, therefore, more straightforward for copyright than gene patents that may be used for a variety of different purposes.
- Gene patents are most frequently used for upstream inventions, while copyright usually protects works that are finished products. Therefore, there may be an available substitute if the collecting society sets unreasonable prices for a copyright work. In contrast, there may be no substitute for a gene patent where it

is an upstream patent for a research tool, and consequently, this may hinder downstream development of technology.

Patent licences are heterogeneous and technology-specific compared to copyright, where there is more scope for standard terms of use. Therefore, patents are less amenable to standard licensing by a central body.

Most inquiry participants did not support non-voluntary licensing of patents by a collecting society, primarily because of the inherent differences between copyright and patents. For example, the Institute of Patent and Trade Mark Attorneys and FICPI Australia submitted that:

> A collecting society may have a place in administering the rights of copyright owners where the rights are limited to reproduction of a copyright work. However, such societies have no place in administering granted rights such as patents, where the value of each granted right and the potential for exploitation under the Patents Act must be individually determined according to a unique combination of factors intrinsic and extrinsic to the patented technology. (sub. 18, p. 6)

Similarly, the Law Council of Australia observed:

> While there are examples of industries (including aspects of computer technology) where widespread non-exclusive licensing, including bulk pricing of patents, is known, we are not aware of any examples of a successful collecting scheme for patents anywhere in the world. It is likely that the reason for that is quite fundamental. In particular, the variable nature and value of patent rights would mean that the determination of price to users and the distribution of royalties to patentees would frequently need to be assessed on a case by case basis. The ability to determine a standard general charging mechanism and a fair general method of splitting the revenue among IP owners, which are the key to collecting schemes, are not present. Administrative costs and disputes at both levels are likely to consume any return. (sub. 32, p. 11)

In summary, copyright and patents are sufficiently different to mean that collecting societies are not an appropriate vehicle for administering non-voluntary access to patents. Moreover, it could be costly to establish and maintain a collecting society for patents. Introducing a legislative requirement to grant compulsory licences for patents in a specific area, like other mechanisms considered in this chapter, would also create a technology-specific mechanism in the patents system. This may have unintended adverse impacts on investment and the allocation of resources. In light of the above, the Commission does not support non-voluntary licensing of patents by a collecting society.

9.6 Licences of right

The ALRC (2004) identified a voluntary 'licence-of-right' (LOR) system used in the United Kingdom as a useful model to facilitate access to patented genetic inventions, should the need for a statutory licensing scheme arise in the future. Such a LOR system would be applicable to all patents. LOR provisions also exist in national patents legislation in Germany, New Zealand, Singapore, Switzerland and a number of developing countries.

A LOR is a legally enforceable mechanism by which a patent holder voluntarily chooses to provide access to a patented invention to anyone who is willing to accept the conditions. This can include payment of an 'appropriate return' determined by a public undertaking (for example, a court) (Schovsbo 2009). This means the patent holder effectively loses the ability to enter into exclusive licences. In most countries, LORs entitle a patent holder to pay a reduced level of patent fees.

The main benefit of a LOR mechanism is to facilitate access to patented inventions by reducing the cost of identifying licensees and negotiating licence agreements. By registering a LOR, patent holders flag their willingness to license. To assist prospective licensees, some intellectual property offices maintain a publicly available list or database of granted patents that are endorsed LOR. Thus, a LOR can benefit inventors who are uncertain of the potential users of their invention or ways to promote it. A LOR might also be attractive to small businesses that do not have the financial resources required to defend their IP rights, or organisations such as universities which rely on non-exclusive licensing (STOA 2007).

Licence-of-right provisions in other countries

Under the UK Patents Act 1977, once a patent is granted, the patent holder may apply to the Comptroller of Patents for an entry in the patent register that its patented invention is available as a LOR. The Comptroller will check if the patent holder is precluded by a contract from offering their patent as a LOR. Once entered into the register, the invention is available for licensing to any party. The parties must agree on the licence terms or, failing agreement, the Comptroller of Patents can set them. Renewal fees are halved for patents made available as a LOR. At any time during the life of a patent, the patent holder may apply to have a LOR removed, provided there is no existing licence under that patent. If a LOR is removed, the patent holder must repay the fee discounts they received.

Similarly, in New Zealand and Singapore, the terms of a LOR are negotiated between the patent holder and the licensee or, in the event that the parties fail to

reach agreement, the Commissioner of Patents (for New Zealand) and the Registrar of Patents (for Singapore) may be asked to settle the terms. In both countries, renewal fees are halved for patents registered as a LOR (NZ Ministry of Business Innovation and Employment, pers. comm., 21 November 2012; IPOS 2012a).

In Germany, a patent holder can declare a 'willingness to license' — equivalent to a LOR — to the German Patent and Trade Mark Office (DPMA). The process and terms and conditions in Germany are similar to those in the United Kingdom and other countries with LORs. However, licence fees are generally set by a court or the DPMA, rather than by negotiation. Patent holders in Germany can also declare an 'interest in licensing', which is non-binding (DPMA, pers. comm., 4 December 2012).

A LOR system has been foreshadowed as part of a Community Patent across the European Union (Schovsbo 2009). Regulations for the Community Patent, which were passed by the European Parliament in December 2012, state that:

> The proprietor of a European patent with unitary effect may file a statement with the EPO to the effect that the proprietor is prepared to allow any person to use the invention as a licensee in return for appropriate consideration. (European Parliament 2012b)

It appears that LOR mechanisms are only used for a small proportion of patents. In the United Kingdom, Schovsbo (2009) attributed this to a lack of awareness of the possibility of a LOR, and unattractiveness of negotiating licensing agreements because no model licence was available. The number of UK LOR applications has fluctuated over time (figure 9.2). As of 22 November 2012, 9622 LORs (about 2.5 per cent of patents in force) were registered on the UK patents register (UK IPO pers. comm., 23 November 2012). It would be difficult to measure the impact of LORs in the United Kingdom, as patent holders are not required to register licences.

Figure 9.2 **UK licence of right applications, 2002 to 2011**

Source: UK IPO (pers. comm., 31 October 2012).

In Singapore, there were almost 200 patents registered as a LOR in 2012 (about 0.5 per cent of patents in force) (IPOS 2012a; IPOS 2012b). In New Zealand, of approximately 37 000 patents in force in 2012, only four were registered as LORs (NZ Ministry of Business Innovation & Employment, pers. comm., 21 November 2012). In Germany, the number of new declarations of willingness to license made in each year fluctuated between 3000 and 7000 during 2005 to 2012, which is a small proportion of the roughly 500 000 patents in force (DPMA, pers. comm., 4 December 2012; WIPO 2011c). The limited use of LORs in these countries suggests that they have had a small impact on the number of voluntary licences negotiated.

The term 'licence of right' is sometimes used to refer to non-voluntary measures to access patents. For example, under Swiss law, research tools fall outside the scope of the research exemption. A LOR was introduced to safeguard access to essential research tools. If an owner of a patent related to a research tool refuses to grant a licence, a judge will grant a non-exclusive licence and determine the terms and conditions (Van Zimmeren and Van Overwalle 2011).

A number of countries have removed LOR provisions from their patents legislation. Prior to 1992, Canadian law imposed a non-voluntary LOR on all patented pharmaceutical products marketed in Canada. Generic manufacturers could produce and market patented medicines in return for paying a royalty, which the Commissioner of Patents typically set at 4 per cent of revenue (Reichman 2010). According to Reichman, critics argued that, although it helped to establish the generics industry, the Canadian LOR discouraged the establishment of a research-based sector. In the early 1990s, the US Government pressed the Canadian Government to abandon its LOR scheme in exchange for US producers contributing a share of their profits to support medical research in Canada. The Canadian LOR approach was later prohibited by the North American Free Trade Agreement (Reichman 2010).

In France, a special LOR provision was removed from the Intellectual Property Code in 2005 because it had not been used (National Industrial Property Institute, pers. comm., 16 January 2013; Van Zimmeren and Van Overwalle 2011). The LOR provision in the Indian Patents Act 1970 was removed in 2002 to make the Indian patents regime compliant with the TRIPS agreement (IELRC 2002; Indian Government 2002).

The New Zealand Parliament is currently considering a Bill that, as part of a major revamp of that country's patents legislation, would repeal its LOR provisions (appendix B). According to the NZ Ministry of Business Innovation & Employment (pers. comm., 21 November 2012), the reason for this is that very few New Zealand

patents have been endorsed with a LOR, which suggests they are not fulfilling any useful purpose.

Is a licence-of-right mechanism warranted in Australia?

Adopting a LOR mechanism in Australia would not address cases where patent holders are unwilling to license widely, but it may be useful in facilitating voluntary licensing when they are willing to do so. It would be desirable for such a mechanism to be technology neutral, as occurs in other countries, rather than being specific to a particular area such as gene patents.

It appears that the cost of introducing a voluntary LOR mechanism would be low, particularly if changes are introduced as part of a package of other legislative changes. There would be some costs involved in maintaining a register of LORs, but they would be relatively small. Maintaining an arbitration mechanism for cases where the parties cannot agree on licence terms would be more problematic.

The Commission has not identified any research on LOR mechanisms in other countries that would be useful in determining whether the adoption of such a mechanism in Australia would deliver a net benefit. A request for information from inquiry participants and foreign patents agencies did not yield any assistance in this regard. However, the limited use of LOR mechanisms overseas, and their abolition in some cases, suggests that the benefits are small and probably do not outweigh the costs. In light of this, the Commission does not support introducing a LOR mechanism in Australia at this time.

9.7 Other measures to encourage voluntary licensing

A perceived benefit of compulsory licensing is its deterrent effect against refusals to licence on reasonable terms. Consideration could also be given to measures that facilitate voluntary licensing, as noted above for a LOR mechanism. This section examines whether voluntary licensing should be encouraged through model licences and discounted patent fees.

Model licensing agreements and guidelines

The cost and complexity of drafting and negotiating licence agreements is a major obstacle to licensing patents, as found in an OECD survey of European and Japanese firms (Zuniga and Guellec 2009). Patent licensing agreements are generally negotiated on an individual contract basis. Firms often have complex

licensing strategies and use the expertise of patent attorneys in negotiating patent licensing agreements. Nonetheless, the development of model agreements and interpretative guidelines for patent licensing, particularly for small business, could facilitate voluntary licensing.

As discussed in chapter 10, a number of industry organisations (for example, AusBiotech Ltd, the Australian Institute for Commercialisation, and the Licensing Executives Society) have programs and activities that provide information, education and training related to licensing of intellectual property and technology commercialisation practices. However, this does not generally include model agreements and guidelines for patent licensing.

Model patent licence agreements such as that published by Creative Commons (2012) serve as potential examples of model agreements. This is a standard model licence to use in a public licence offer that aims to provide a 'science commons' to facilitate research. A licensee can use a public offer to publicise its willingness to license patent rights in a reasonable and non-discriminatory manner. The agreements are intended to attract potential licensees who might otherwise not have been aware that certain patent rights were available for licence, or who might be unwilling to approach the licensor because of the expected large transaction costs associated with negotiating a licence.

Other examples are the model research collaboration agreements published by the UK Intellectual Property Office in 2005, following the Lambert Review of Business-University Collaboration (box 9.6). These were developed as a mechanism to foster technology transfer between universities and business, and have been used by a number of organisations, including SMEs, to reduce the costs, time and uncertainty of negotiating collaboration agreements (HM Treasury 2006). While there is limited evidence of the use and impact of the agreements, one survey found that around 60 per cent of respondents believed the model agreements simplified the process of constructing contracts and has saved them time (UK IPO, pers. comm., 31 October 2012).

The Australian Government (2011a) accepted, in principle, a recommendation made by the ALRC (2004) that Biotechnology Australia, in collaboration with stakeholders, develop model materials transfer agreements for use by research organisations. The Australian Government also agreed to investigate options for developing model agreements and interpretative guidelines for patent licences involving genetic materials and technologies. These were to be non-binding model agreements developed in collaboration with Biotechnology Australia, state and territory governments, and other relevant stakeholders. However, Biotechnology

Australia was abolished in 2008, and it appears that the recommended model agreements were not developed.

Box 9.6 **UK model research collaboration and consortium agreements**

The UK Intellectual Property Office published the Lambert toolkit for universities and companies that wish to undertake collaborative research projects with each other. The toolkit includes:

- Model Research Collaboration Agreements — these are five different agreements which cover one-to-one projects, with each providing a different approach depending on which party is to own and have the right to exploit the intellectual property. The terms of the five model agreements vary based on whether the sponsor has exclusive rights to use intellectual property (IP) or may negotiate further licensing or assignment of some of the university's IP, or whether the university has the right to use the IP for non-commercial purposes.
- Model Consortium Agreements — these are four agreements that are used when more than two parties are collaborating. They use the same terminology and structure as the five research agreements, but contain additional provisions to cover some of the complications that arise as a result of having more than two parties.

Source: UK IPO (2012).

While model agreements have the potential to reduce the costs of patent licensing, it is questionable whether a one-size-fits-all approach can work in practice. The rapid pace of technological development and diversity of patent licensing arrangements might limit the usefulness of model licensing agreements, even for use within a specific field of technology. Licensing arrangements vary based on a wide range of characteristics such as: the licence type; duration; field of use; remuneration for the licensor; exclusivity of the licence; and obligations and rights of the licensee and licensor (chapter 4). The Centre for Law and Genetics submitted:

> While there have been attempts to draft standard licensing agreements for the licensing of genetic inventions, their success has been limited, probably due to the fact that so many different licence terms are used within the industry, and because the technology being licensed is in a constant state of development and modification. (sub. 3, p. 9)

Thus, the Commission does not consider that there is a strong case for requiring governments to develop model licences. However, interpretive licensing guidelines have been developed in some sectors with the aim of fostering more effective and efficient transfer of technology and delivery of new products to market. In response to concerns about how certain genetic inventions have been licensed and exploited, particularly for diagnostic genetic services, OECD member countries agreed to guidelines for the licensing of genetic inventions used for human healthcare purposes. The guidelines outline principles and best practice for business,

researchers and health providers that enter into licensing agreements and are intended to stimulate genetic research, while maintaining appropriate access to health products and services. While the guidelines outline basic licensing terms and concepts, they are not intended to cover all aspects of licensing, material transfer or technology transfer agreements (OECD 2006).

Discounted patent fees

Another potential mechanism to encourage voluntary licensing could be to provide financial incentives through discounted patent fees. For example, patent holders could pay a reduced level of patent renewal fees if they enter into licensing agreements.

IP Australia's patent fees include charges for patent application, examination and renewal. Renewal fees are charged annually by IP Australia, and rise during the term of a standard patent, from $300 on the 4th anniversary of the filing date, to $2300 on the 20th anniversary of the filing date (appendix B). Separate fees are charged for filing and examination processes associated with Patent Cooperation Treaty applications. The costs associated with applying for and maintaining a patent generally include both the official application fees and patent attorney fees. Based on a study of international patenting costs, Australian patent renewal fees accounted for about 60 per cent of total patent costs, and patent attorney fees accounted for about 35 per cent (not including patent litigation costs) (appendix B). Renewal fees accounted for about 95 per cent of total official and maintenance fees.[6]

The extent to which discounted patent fees increase incentives for patent holders to enter into licensing agreements will depend on the magnitude of these fees relative to other costs of patenting, as well as the potential economic benefits from licensing a patent. Reducing official patent fees (at least maintenance and renewal fees) is unlikely to encourage voluntary licensing when they are small in proportion to potential licensing revenue.

As discussed in chapter 4, some firms may choose to license out patents for strategic reasons, for example, to prevent others from infringing on a patent or to establish a patented technology as a defacto industry standard. Some firms may decline to licence their patents to avoid disclosure of commercially sensitive information to third parties and create a barrier to imitation by potential competitors

6 Official and maintenance fees include charges for filing, examination, granting and renewal of patents. Maintenance fees are patent renewal fees or annuities that are estimated as the non-discounted sum across 20 years of protection (Park 2010).

to maintain market share. In such cases, reducing patent fees is unlikely to affect firm incentives to license their patents.

Moreover, reducing patent fees would compromise IP Australia's ability to fund its activities, which is based on a cost-recovery model. Given these considerations, there do not appear to be strong grounds for lowering patent fees.

10 Awareness-raising measures

Key points

- Lack of awareness of compulsory licensing is unlikely to be a significant reason for its limited use. Other factors — including the few cases where it is needed, and the costly and time-consuming process in applying — appear to be more important.
- Various government bodies, industry organisations, law firms and private individuals already provide information on Australia's intellectual property system. However, very little of the information provided by any of these bodies is specific to compulsory licensing.
- There may be a small number of businesses that would benefit from compulsory licensing awareness-raising measures focused on the provision of general information.
- To raise awareness of compulsory licensing, IP Australia and the ACCC should jointly develop a plain English guide on compulsory licensing and make it available on their websites.

The terms of reference ask the Commission to recommend measures to raise awareness of the compulsory licensing provisions, particularly among small businesses and the healthcare sector. This reflects a concern that the limited use of compulsory licensing in Australia to date may be partly due to a lack of awareness. This chapter examines the evidence supporting that view and, in light of the evidence, considers what new awareness-raising measures are appropriate.

10.1 The case for awareness-raising measures

As noted in chapter 1, the compulsory licensing provisions of the *Patents Act 1990* (Cwlth) have been seldom used. This may partly be the result of limited awareness of the provisions. However, other factors — particularly the few cases where the provisions are needed (chapters 4 and 5), the uncertain language of the provisions, and costly and time-consuming processes in applying (chapter 6) — appear to be more important.

The Centre for Law and Genetics observed that a lack of awareness did not appear to be an issue in the biomedical/biotechnology industry:

> It would appear that parties involved in patent licensing transactions are aware of the compulsory licensing provisions, at least in the biomedical/biotechnology industry in which we have conducted empirical research. The problem is not so much awareness of the provisions, as their cumbersome and expensive nature. (sub. 3, p. 26)

It also appears that awareness of compulsory licensing is not a problem among intellectual property (IP) professionals, including those that work in, or with, the small business and healthcare sectors. The Walter and Eliza Hall Institute of Medical Research questioned the purpose of awareness-raising measures for those sectors:

> ... we do not understand why ... there should be specific awareness and promotion activities directed to small businesses and the healthcare sector. Is the purpose to encourage litigation when it has not previously been required? Why promote litigation opportunities to the segments that can least afford or justify such action? (sub. 13, p. 8)

More generally, many businesses — particularly small businesses — are unlikely to have the capacity to 'work' a patent and may not be involved in patent licensing. Hence, compulsory licensing is not relevant to their operations.

Where compulsory licensing is relevant, an organisation may prefer not to use it. For example, the CSIRO (sub. 26) stated that, while it was aware of compulsory licensing, it prefers to use other options to resolve potential patent-related impediments to research.

Nevertheless, there may be a case for some awareness-raising initiatives about compulsory licensing. Limited awareness can be an impediment to the use of compulsory licensing, along with other factors. Potentially there are businesses who either currently, or in the future, experience difficulty negotiating a patent licence and may benefit from information on compulsory licensing. This is more likely to be the case for small businesses, which would not usually have the resources to develop specific expertise on compulsory licensing. Thus, while the number of businesses that would benefit from information on compulsory licensing is likely to be very small, it may still be worthwhile to raise awareness, provided the benefits exceed the costs.

10.2 Existing awareness-raising measures

There are a number of organisations in Australia that publicise aspects of Australia's IP system. However, little of this information is specific to compulsory

licensing per se. IP Australia is the main government body engaged in measures to raise awareness of Australia's IP system.

- It provides information on forms of IP rights that can be registered, access to searchable patent databases and a range of IP programs for small business, exporters and other industry sectors.
- Its Education, Awareness and International Engagement sub-program seeks to 'deliver public education and awareness programs, which promote the importance of IP and provide Australians with the tools they require to make informed decisions regarding IP' (DIISRTE 2012, p. 37). The program had a budget of around $8.7 million in 2011-12.

Its website provides some basic information on Crown use of IP under the Patents Act and the *Designs Act 2003* (Cwlth). This information includes a description of Crown use, the justification for Crown use, who is able to use the Crown use provisions, and the rights of patent holders under the Crown use provisions. IP Australia also provides information on mechanisms to resolve patent disputes, including court action and alternative dispute resolution (ADR) options. The parties can initiate ADR to resolve a dispute over IP infringement without going to a court or tribunal, or it may be a court decision that parties undertake ADR before returning to court. The body with primary responsibility for raising the profile of ADR in Australia is the National Alternative Dispute Resolution Advisory Council (NADRAC 2012).

There are also several Australian, State and Territory government publications intended to educate people about Australia's IP system, including:

- *Biotechnology Intellectual Property Manual*, released in 2008 as a joint initiative between the Victorian Government, AusBiotech and Spruson & Ferguson
- *Intellectual Property and Biotechnology: A Training Handbook*, published in 2001 by the Department of Foreign Affairs and Trade
- the *Australian Code for the Responsible Conduct of Research*, jointly published by the National Health and Medical Research Council, the Australian Research Council and Universities Australia contains limited advice on IP, focusing on protecting the confidentiality and management of IP by researchers (NHMRC 2007).

In addition to government sponsored awareness raising of IP law, a number of industry organisations (for example, AusBiotech Ltd, the Australian Institute for Commercialisation, the Institute of Patent and Trade Mark Attorneys of Australia and the Licensing Executives Society of Australia and New Zealand) provide information, education and training related to licensing of intellectual property and

technology commercialisation practices. Such organisations play an important role in monitoring developments in international law and licensing practices.

As noted, there is very little awareness-raising that is specific to compulsory licensing. For example, the Commission found that the primary reference to compulsory licensing on IP Australia's website was a news feature about this inquiry (IP Australia 2012l). Moreover, the Commission understands that IP Australia has not engaged in any awareness-raising initiatives on the compulsory licensing provisions with professional bodies or other groups. This is consistent with the view that compulsory licensing is a safeguard only to be used in exceptional circumstances. Given this, other issues would have a higher priority for IP Australia's limited awareness-raising resources.

While the Commission is not aware of any compulsory licensing awareness-raising measures undertaken by industry organisations, there are a small number of private initiatives that may increase awareness. For example, Freehills (2012) published a short article on compulsory licensing for the pharmaceuticals industry. Additionally, legal experts may choose to make research they have undertaken on compulsory licensing freely available (for example, Lawson 2008b and Lindgren 2004).

10.3 Potential new awareness-raising measures

Objectives of awareness-raising

Awareness-raising initiatives for compulsory licensing should focus on remedying the problem of deficient information about its availability and provisions. To avoid any perception of bias, awareness raising should provide a balance of information for both patent holders and potential licensees. The Institute of Patent and Trade Mark Attorneys (IPTA) and the Australian Federation of Intellectual Property Attorneys (FICPI) supported such an approach:

> Awareness of compulsory licensing among small businesses and the healthcare sector is not considered by IPTA or FICPI to be a significant problem. However both IPTA and FICPI would support a balanced approach to raising awareness of the compulsory licensing provisions as they apply to small businesses and the healthcare sector (as well as other industries) as both patentees and potential licensees. (sub. 18, p. 16)

Awareness-raising initiatives should also recognise that compulsory licensing is part of a suite of mechanisms available to resolve disputes over patent access, including Crown use and ADR. Thus, existing information that IP Australia provides on these mechanisms should be cross-referenced. Raising awareness of compulsory licensing in isolation may not lead to better outcomes if it leads to compulsory licence

applications being undertaken in circumstances where other options would provide a more efficient solution.

The information provided about compulsory licensing by IP Australia should be general in nature. The intended audience would be firms and organisations seeking a non-technical overview of compulsory licensing. Industry or firm-specific information is best provided by an IP specialist.

Targeting information provision

Given the limited number of situations for which compulsory licensing is likely to be a useful safeguard, the benefits of a widespread awareness-raising campaign may be small. Thus it would not be cost effective for awareness-raising measures to seek to engage directly with every small business and healthcare provider.

One potential option is to target awareness-raising initiatives at company directors and senior managers. This could be done through a professional body such as the Australian Institute of Company Directors, which provides direct education and development on director issues and governance (Australian Institute of Company Directors 2012). The small business and healthcare sectors could also be targeted through their relevant professional bodies. These professional organisations could be supplied with information on compulsory licensing that could then be passed on to their members through relevant training programs or direct communications.

However, this approach may not be sufficiently targeted, as it may include many individuals who do not have any substantial involvement or interest in patent licensing.

In most cases, small businesses or healthcare organisations would be expected to consult an IP expert or industry body when dealing with patent disputes, so it may be unnecessary to target these sectors for specific awareness raising. For instance, the Walter and Eliza Hall Institute of Medical Research stated that:

> In our experience Australian companies, small and large, universities and medical research institutes use such [IP] professionals on a routine basis and would therefore be directly or indirectly aware of options for IP exploitation. (sub. 13, p. 8)

It is reasonable to expect that IP professionals would be aware of the IP system, including the compulsory licensing provisions, through formal training and professional experience. Nevertheless, awareness-raising measures may be useful in facilitating their acquisition of this knowledge. These measures could also alert other individuals with an interest in IP licensing to the existence of the compulsory licensing provisions.

Who should be responsible for general awareness raising?

General information on compulsory licensing can be considered a public good, and hence will tend to be underprovided by the private sector, because its use by one person does not affect the amount available to others, and it is difficult to exclude people who do not pay for the information. Thus, while private organisations — such as legal firms and industry associations — will continue to have a role in providing general information about compulsory licensing, this is primarily a responsibility of government.

Given its role in administering the patents system, the Australian Government is best placed to take on this role. As noted, IP Australia already provides general information on matters covered by the Patents Act, including on Crown use and ADR. The ACCC has a similar role in informing the public about the *Competition and Consumer Act 2010* (Cwlth), which is relevant to the competition test for a compulsory licence (chapter 6).

In light of the above, the Commission proposes that a plain English guide to compulsory licensing be developed jointly by IP Australia and the ACCC. This guide should cover both the public interest and competition grounds for issuing a compulsory licence.

Participants in this inquiry were generally supportive of the development of a plain English guide to compulsory licensing.

> Cancer Voices also supports the suggestion that information about compulsory licensing provisions should be readily accessible, written in plain English, and located on a logical Australian Government website. (Cancer Voices, sub. DR44, p. 2)

> ... [we] support the proposed strategy of the development of a plain English guide to be made available on the IP Australia website. This guide should be written so that it can be understood by those with limited knowledge of patent law ... (Consumer Health Forum of Australia, sub. DR38, p. 2)

> ... Medicines Australia supports the recommendation for IP Australia to develop a plain English guide on the compulsory licensing provisions ... (Medicines Australia, sub. DR43, p. 2)

The plain English guide should be made freely available on both the IP Australia and ACCC websites. This is likely to be the most cost-effective option relative to other awareness-raising options, and will also be the most readily accessible to the intended audience.

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.

A Conduct of the inquiry

In keeping with its standard practice, the Commission actively encouraged public participation in this inquiry.

- Following receipt of the terms of reference on 29 June 2012, the Commission placed notices in the press and on its website inviting public participation in the inquiry. Information about the inquiry was also circulated to people and organisations likely to have an interest in it.
- The Commission released an issues paper in August 2012 to assist inquiry participants with preparing their submissions. A total of 35 written submissions were received prior to the release of the draft report (table A.1).
- The draft report was released on 14 December 2012, and a further 17 submissions were received (denoted in table A.1 with the prefix 'DR'). All submissions are available online at: www.pc.gov.au/projects/inquiry/patents.
- As detailed in table A.2, the Commission met with a wide range of stakeholders.
- Public hearings were held in Melbourne in February 2013 (participants are listed in table A.3).

The Commission is grateful to all inquiry participants for their input.

Table A.1 **Submissions**[a]

Participant	*Submission number*
Australian Competition and Consumer Commission (ACCC)	DR50
Advisory Council on Intellectual Property	35
Alliance for Clean Technology Innovation	9
Alphapharm	30, DR48, DR51
Association of Australian Medical Research Institutes	17
Ausbiotech	21, DR39
Australian Fair Trade and Investment Network	23
Biotechnology Industry Organisation	27
Bouvier, Scott	2#
Business SA	20
Cancer Voices Australia	DR44
Centre for Law and Genetics	3
Civil Liberties Australia	12
Commonwealth Scientific and Industrial Research Organisation (CSIRO)	26, DR47
Croplife	6, DR42
CSL	5
Department of Health and Ageing (Australian Government)	22
Dwyer Lawyers	1, DR37
FB Rice	7
Federal Court of Australia	29
Generic Medicines Industry Association	34
GM Holden Ltd	19
Health Forum of Australia	DR38
Hoad, Richard	DR49
Human Genetics Society of Australasia	DR40
Institute of Patent and Trade Mark Attorneys and the Australian Federation of Intellectual Property Attorneys	18, DR41
Janssen Cilag Pty Ltd	28
Law Council of Australia	32
Lawson, Dr Charles	DR36
Medicines Australia	10, DR43
Moir, Dr Hazel	31#, DR46
National Coalition of Public Pathology	25
National Health and Medical Research Council	33
Peter MacCallum Cancer Centre	14
Pfizer Australia	24
Public Health Association of Australia	4, DR52
Rimmer, Dr Matthew	11, 15
Royal College of Pathologists of Australasia	16#
Telstra Corporation Limited	8
The Walter and Eliza Hall Institute of Medical Research	13
Treloar, Peter	DR45

[a] # indicates that the submission includes attachments.

Table A.2 **Visits**

Participant and location

Canberra
CropLife Australia
Department of Health and Ageing (Australian Government)
Department of Industry, Innovation, Science, Research and Tertiary Education (Australian Government)
Department of Foreign Affairs and Trade (Australian Government)
Ergas, Henry
IP Australia
Medicines Australia
The Treasury (Australian Government)

Melbourne
Advisory Council on Intellectual Property
Alphapharm
Australian Competition and Consumer Commission (Australian Government)
Commonwealth Science and Industrial Research Organisation (CSIRO)
Davies Collison Cave
Heath, Ian
Institute of Patent and Trademark Attorneys
Intellectual Property Research Institute of Australia
Law Council of Australia
Licensing Executives Society of Australia and New Zealand
Melbourne Business School
Melbourne Law School
Middleton, Justice John
Review of Pharmaceutical Patents in Australia
Walter and Eliza Hall Institute of Medical Research

Sydney
Australian Law Reform Commission
Cancer Voices Australia
CSIRO
Westmead Hospital

Table A.3 **Public Hearings**

Individual or organisation

Melbourne – 20 February 2013
Public Health Association of Australia
Medicines Australia
Dr Matthew Rimmer

B More detail on the patents system in Australia and comparable markets

This appendix provides more detail on the patents system in Australia and comparable markets than is included in the chapters of this report. Non-voluntary access arrangements to patents in comparable markets are discussed in appendix C.

What constitutes a comparable market is a complex issue that depends on a range of factors, such as a country's industrial structure, geography, form of government, and human and physical capital, and the purpose of the analysis at hand. The fact that Australia and many other countries grant the majority of patents to non-residents is particularly relevant for this inquiry. For example, in 2010, 91 per cent of patents granted in New Zealand and 90 per cent in Canada were to non-residents (WIPO 2012a). Australia's status as a developed economy is also relevant, given the importance that places on attracting suppliers of advanced technologies. Hence, the United States is included in the comparison. Australia's significant trading relationship with Asian countries, such as China, has been a further consideration.

This appendix has three sections:

- features of the patents system in Australia and comparable markets
- measures of patent strength and quality
- reforms of patents systems.

B.1 Features of the patents system in Australia and comparable markets

This section discusses key features of patents systems including the patent application process in Australia and comparable markets.

Patentability criteria

Patents systems, and patentability criteria, are influenced and constrained by international agreements. Almost all countries in the world, and all developed countries, are signatories to the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS agreement), which is one of the key international intellectual property (IP) agreements. It was negotiated and came into force in the 1990s. Article 27 of the TRIPS agreement states:

> [subject to certain allowable exclusions] patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application.

In patents systems internationally, patents are made available for inventions in all fields of technology. Patents tend not to be available for discoveries, although the distinction between an invention and a discovery is not always clear. As a result, abstract ideas, natural phenomena and laws of nature are usually excluded from patentability. Patentability criteria in Australia are outlined in box B.1.

Box B.1 **Patentability criteria**

Under the *Patents Act 1990* (Cwlth), an invention is eligible for a patent if it:

- is a 'manner of manufacture', such that the invention must relate to an 'artificial state of affairs', that is a product, process or method that arises through a form of human intervention with nature to bring about some physical change
- is novel, such that the invention has not been publicly disclosed in any form, anywhere in the world (for example, published patent specifications, textbooks, technical journals and internet sites) or sold or used in a public area
- is an inventive step for a standard patent, such that the invention is not obvious to someone with knowledge and experience in the technological field of the invention
- is an innovative step for an innovation patent such that there must be a difference between the invention and what is known about that technology, and this difference must make a substantial contribution to the working of the invention
- is useful, such that the invention must have a specific, substantial and credible use and must be capable of achieving the result that the patentee claims it can achieve
- is sufficiently well disclosed or described
- is not the subject of a specific exclusion in the Patents Act.

Source: IP Australia (nda).

Patentability criteria are similar in comparable markets. As part of its study into patentable subject matter, the Australian Council on Intellectual Property

(ACIP 2010c) examined international definitions of inventions. ACIP noted that New Zealand's patent laws, like Australia's, included a 'manner of manufacture' test, linked to the *Statute of Monopolies 1623*. Patent laws in other countries were not directly linked to this statute, but include similar tests and language. Table B.1 presents language on patentable subject matter from patents legislation worldwide.

Table B.1 **Patentable subject matter**

Country	*Language on patentability*
Australia	'[An] invention is a patentable invention … if the invention … is a manner of manufacture … is novel … involves an inventive step … is useful … [and] was not secretly used [in the past]'
Canada	'[An invention means] any new and useful art, process, machine, manufacture or composition of matter, or any new and useful improvement in any art, process, machine, manufacture or composition of matter'
China	'[An invention means] any new technical solution relating to a product, a process or improvement thereof'
European Patent Convention	'European patents shall be granted for any inventions, in all fields of technology, provided that they are new, involve an inventive step and are susceptible of industrial application'
Japan[a]	'[An invention means] a highly advanced creation of technical ideas by which a law of nature is utilized'
South Korea[a]	'[An invention means] the highly advanced creation of a technical idea using the law of nature'
Malaysia	'An invention is patentable if it is new, involves an inventive step and is industrially applicable'
New Zealand[b]	'Invention means any manner of new manufacture the subject of letters patent and grant of privilege within section 6 of the *Statute of Monopolies* and any new method or process of testing applicable to the improvement or control of manufacture; and includes an alleged invention'
United Kingdom	'A patent may be granted only for an invention … [if] the invention is new … involves an inventive step … [and] it is capable of industrial application [and not subject to exclusions]'
United States	'Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent …'

[a] From an English language translation of local patents legislation. [b] In 2008, a new Patents Bill was introduced to replace and repeal the Patents Act. At the time of writing the Bill had not been passed.

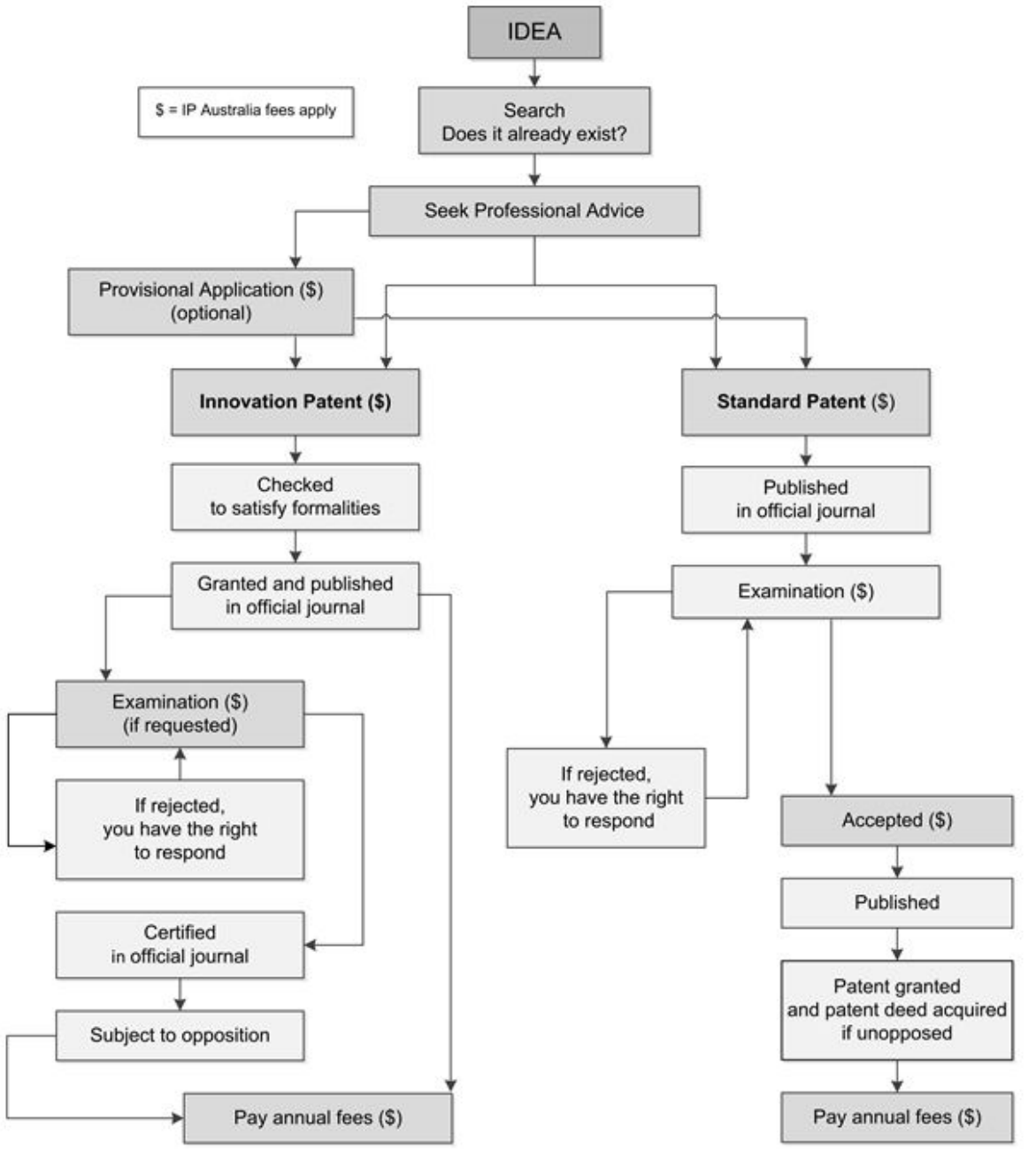
Sources: *Patents Act 1990* (Australia), p. 16; Patent Act (Canada), p. 9; SIPO 2012; European Patent Convention, p. 106; JPO (2012c, p. 1); WIPO (2012c, p. 2); Patents Act 1983 (Malaysia), p. 13; Patents Act 1953 (NZ), p. 5; Patent Act 1977 (UK), p. 8; 35 U.S.C., appendix L — Patent Laws, p. L-21.

Patent application process

Figure B.1 outlines the patent application process in Australia. As a first step, applicants are advised to perform a search to determine whether the invention is novel, to keep their invention secret so that it would meet the novelty requirement, and to seek professional advice due to the complexity of the IP system. If the

applicant wishes to proceed, the second step is to decide whether to apply for a standard or innovation patent. Innovation patents are discussed in more detail below in the 'utility models' section.

Figure B.1 **Patent application process in Australia**



Source: Based on IP Australia (nda).

Three types of applications can be submitted:

- Provisional application — an application prior to a complete application. This enables applicants to get the earliest possible priority date, which is the date from which novelty is assessed, and important for applicants in competitive industries. A provisional patent application does not provide patent protection. A complete application must be filed within 12 months of a provisional application or the priority date lapses.
- A complete application — necessary for a patent to be granted. Complete applications are published in the *Australian Official Journal of Patents*, and must include:
  - a full description of the invention
  - one or more claims on the invention, which outline what the invention is and what it can do, and determine the scope of exclusive rights claimed by an applicant.
- International application — an application for patent protection overseas. Many inventors wish to apply for international protection since an Australian patent only provides protection in Australia. Applicants have two choices:
  - Patent Cooperation Treaty application — this allows an applicant to file a patent application with IP Australia and elect for protection in over 100 countries.
  - Paris Convention application — if protection is only sought in a few countries, it might be cost effective for an applicant to make separate patent applications in each country.

Patent application process in comparable markets

Application processes for a patent in comparable markets are broadly similar to the process in Australia. All comparable markets have a 'first-to-file' system, like Australia. Until recently, the United States was the exception, as it had a 'first-to-invent' system. The United States moved to a first-to-file system in March 2013. In some comparable markets (for example, New Zealand and the United States) provisional applications are available. Grace periods (where an applicant can apply for a patent when the invention has already been disclosed subject to conditions) apply in many countries including the United States, Japan and Canada. Grace periods do not apply in most European countries (IP Australia 2012g).

Selected features of patents systems in Australia and comparable markets are discussed in more detail below.

Utility models

In some comparable markets, inventions can be protected under a 'utility model' or short-term patent, equivalent to innovation patents in Australia. Utility models have a maximum term of six years in France, 10 years in both China and Germany, 10–15 years in Japan and 15 years in both South Korea and Malaysia. In these markets, utility models have less stringent requirements for patentability, lower fees and a more streamlined application process. Examination requirements for utility models only exist in some comparable markets. In many countries, a patent application can be converted into a utility model application. In France, failure to request examination for a patent will automatically lead that application to be converted into a utility certificate (Richards nd).

Utility model applications worldwide have grown rapidly in recent years — from 313 000 in 2008, to 496 000 in 2010. Applications received by the Chinese IP Office make up most of these applications (83 per cent in 2010). In 2010, applications to the German, South Korean, Russian, Ukrainian and Japanese patent offices were the next most common, comprising collectively about 12 per cent of applications worldwide. Applications to other patent offices were negligible. Utility model applications are more likely to be by domestic applicants than applications for standard patents. This is particularly the case in China, where in 2010, 99 per cent of applications were domestic (WIPO 2012a). Between 2009 and mid-2012, IP Australia received between 1000 and 2000 applications for innovation patents per year (IP Australia 2012j) relative to about 25 000 standard patent applications per year (chapter 4).

Features of standard and innovation patents in Australia are outlined in table B.2.

Table B.2 **Features of standard and innovation patents**

	Standard patent	*Innovation patent*
Patentability criteria	The invention must be new, useful and involve an inventive step	The invention must be new, useful and involve an innovative step
Examination requirements	Mandatory. Substantive requirements must be met before a patent is granted	Optional. Examination can be requested by a patentee or a competitor to clarify the patentee's legal right
Protection period	20 years if annual fees paid (up to 25 years for pharmaceuticals)	8 years if annual fees are paid
Application processing time	6 months — several years (depending on circumstances)	1 month for grant
Renewal fees	Yes	Yes

Source: IP Australia (nda).

Examination requirements

Examination requirements apply to patents, and fees apply. In Australia, examinations are performed by IP Australia to determine whether an invention meets patentability criteria (outlined above in box B.1) and is sufficiently well disclosed. As part of the process, examiners will search for 'prior art' to determine if the invention is novel. An applicant for a standard patent must request examination within five years of the application being filed in Australia. Standard patent applications must be examined before rights can be enforced. In contrast, innovation patents are not examined unless requested by the patentee or a third party. Twelve months after requesting examination, IP Australia advises applicants if their application does not meet patentability requirements. Applicants can modify and resubmit their application. Once an application has passed examination and opposition proceedings have been resolved a patent is granted.

Examinations of patents are required in comparable markets. Time limits for examination vary. For example, request for examination must occur within six months of publication of a European patent, which occurs 18 months after filing. A request for examination is required within three years of filing date in China (EPO 2012a), three years in Japan (JPO 2012a) and five years in Canada (CIPO 2012). In the United States, applicants do not request examination. Once applications meet requirements they are examined in due course.

Opposition periods

Pre- and post-grant patent review provisions, where the validity of patents can be challenged, exist in Australia and most comparable markets.

In Australia, an application for a standard patent is published 18 months after it is accepted by IP Australia. Once the application has been published, third parties have three months to start 'opposition proceedings' and challenge the validity of the application. The Federal Court has noted:

> … the purpose of pre-grant opposition proceedings is to provide a swift and economical means of settling disputes that would otherwise need to be dealt with by the courts in more expensive and time consuming post-grant litigation; that is, to decrease the occasion for costly revocation proceedings by ensuring that bad patents do not proceed to grant. (Federal Court of Australia quoted in IP Australia 2009b, p. 4)

Grounds for filing opposition include:

- the applicant is not the person entitled to the patent

- the invention is not a 'manner of manufacture', novel nor involves an inventive step
- the patent is not sufficiently well disclosed
- the patent relates to human beings or the biological processes for their generation.

Innovation patents can also be opposed, but only after the patent is granted. Filing an opposition to a standard or innovation patent costs $600. In the past decade, between 100 and 200 oppositions have been filed each year, which is very small in comparison to the number of patent applications in recent years (about 25 000 per year) (IP Australia 2012j; chapter 4).

After an application has passed examination and any opposition proceedings have been resolved, an application is sealed and becomes a granted patent, but can still be challenged through re-examination or revocation. Requests for re-examination can be made to IP Australia on more limited grounds than for opposition proceedings. An application for revocation can be made to the Federal Court of Australia on broader grounds than for opposition proceedings or re-examination.

Opposition proceedings are available in some comparable markets subject to time limits, which are similar across countries. For example, notices of opposition can be filed within three months of a patent being published in New Zealand and within nine months in the European Union. Opposition proceedings have been abolished in a number of other countries. For example, opposition proceedings were abolished in Japan in 2004 because the system was considered redundant given invalidation proceedings were available (Okuyama 2007). Post-grant procedures for challenging patents exist in almost all comparable markets. For example, in the United States, a request for re-examination of a patent can be made by anyone at any time during the term of a patent (USPTO 2012a).

Patent fees

Once a patent is granted, the patent holder must pay annual renewal (maintenance) fees to keep the patent in force. Table B.3 provides a non-exhaustive list of fees through the life cycle of patents in Australia. Standard, innovation and Patent Cooperation Treaty (PCT) applications are considered. Applicable fees vary considerably depending on events that occur during the life cycle of a patent.

Table B.3 **Patent fees in Australia**[a]

	Standard	*Innovation*
Provisional patent application request	$110	..
Complete patent application	$370	$180
Acceptance fee	$250	..
Patent examination fee	$490	$500[b]
Excess claims — per claim, in excess of 20	$110	..
Request for re-examination	$800	$800
Renewal fees	$300–$2 300[c]	$110–$220[d]
Patent Cooperation Treaty (PCT) fees[e]		
Transmittal fee	$200	..
International search fee	$2 200	..
International filing fee	$1 375	..
PCT international preliminary examination	$590	..
Additional international preliminary examination	$590	..

[a] By approved means. These fees apply from 1 October 2012. [b] The fee is paid by the patentee if the patentee requests examination. If a third party requests examination, the fee is shared between the patentee and that third party. [c] Renewal fees are annual and rise during the term of a standard patent from $300 on the 4th anniversary of the filing date to $2300 on the 20th anniversary of the filing date. [d] Renewal fees are annual and rise during the term of an innovation patent from $110 on the 2nd anniversary of the filing date to $220 on the 7th anniversary of the filing date. [e] Only one class of patent (equivalent to a standard patent) is available under the Patent Cooperation Treaty. .. not applicable.

Source: IP Australia (2012f).

It is difficult to compare patent costs across comparable markets as patent application processes and types of fees charged by patents offices differ, and change over time. Fees are charged in the local currency, which makes comparison more difficult. Variation in patent attorney fees might also be considered in any analysis.

Park (2010) provided a sample of patent fees across countries — by destination, not origin of the patent. The cost of a patent 25 pages in length, with five pages of drawings and 15 claims, for a full 20 year term was analysed. Costs in 2010 were examined, from an English language applicant's perspective, and included application fees, patent attorney fees, translation fees (into English) and renewal fees. Park found that the total cost of such a patent in Australia was about US $20 000. Renewal fees accounted for about 60 per cent of the costs and patent attorney fees accounted for about 35 per cent of the cost. Application fees accounted for less than 5 per cent of the costs. Among key comparable markets, Park found that, relative to Australia, total costs were about 50 per cent higher in Germany and Japan and between 10 and 20 per cent lower in Canada, China, the United Kingdom and the United States. The mix of fees also varied. The United States had the highest proportion of official fees and patent attorney fees, and the lowest proportion of renewal fees.

De Rassenfosse and van Pottelsberghe (2010) also found that patent fees varied greatly across countries both in the level and mix of fees charged. The authors used three metrics for patent fees; absolute fees (fees in $US); fees weighted by the size of the market (measured by population, which influences the value of patent protection); and the affordability of patents for local applicants (measured by absolute fees relative to GDP per capita). In most countries, application fees were lower than renewal fees. Among key comparable markets, absolute fees were much higher in the European Union than Japan or the United States, in large part due to translation requirements.

Another complication is that many inventors apply for patents in multiple countries. As mentioned above, Australian inventors can apply for patent protection in other countries through the PCT or applications through foreign patents offices. PCT application fees are standardised across countries.

Subject matter exclusions

Most patents systems have subject matter exclusions, which are permitted under international agreements such as TRIPS. Typical subject matter exclusions include discoveries, scientific theories or mathematical methods, inventions contrary to public policy or morality, business methods and methods of medical treatment and diagnosis (for example, Patents Act 1977 (UK)).

Many subject matter exclusions are health related. Some of these specifically concern biological material, access to pharmaceuticals and access to healthcare. In Australia, human beings, and the biological processes for their generation, are not patentable inventions. European law and practice excludes 'animal varieties' and 'plant varieties' from patentability. In Canada, exclusions exist for medical treatment and higher (multi-cellular) life forms. However, Canadian law expressly states that unicellular microorganisms and processes to produce life forms are patentable. South Korean law excludes mixing two or more medicines. US law does not provide explicit *statutory* health-related exclusions. An exception for patenting humans exists but is not defined in statute (Barbosa and Grau-Kuntz 2010).

The desirability of computer software and business method patents is debated. Objections to these patents are based on the effects on innovation and the obviousness of some of these inventions. ACIP (2010c) found considerable variation internationally on the patentability of computer software. ACIP also noted recent court decisions in Australia and the United States that found that abstract ideas are not patentable, but there was no general bar on business method patents.

In the past, many developing countries excluded pharmaceuticals from patentability. At the beginning of the Uruguay Round of trade negotiations about 50 countries did not recognise pharmaceutical patents (Correa 1999). Most of these countries now recognise pharmaceutical patents in order to be compliant with TRIPS.

A number of exclusions exist in patents legislation related to inventions contrary to public order or morality. For example, the United States prohibits patents 'useful solely in the utilization of special nuclear material or atomic energy in an atomic weapon' under the Atomic Energy Act of 1954 (cited in ACIP 2010c, p. 77).

Objects clauses

Objects clauses, also referred to as 'statements of objectives', are included in some pieces of legislation to outline the purpose of the legislation. As discussed in chapter 6, the *Patents Act 1990* (Cwlth) does not have an objects clause, but some commentators have recommended one be included. ACIP (2010c) noted that it is important that the patents system take into account economic and ethical matters, and for this reason recommended that an objects clause be inserted into the Patents Act. The proposed objects clause describes the purpose of the Act as being to enhance the wellbeing of Australians by balancing competing interests of patent holders, users of technology and Australian society. The Australian Government (2011a) accepted this recommendation, but did not introduce an objects clause into the Patents Act as part of the 'Raising the Bar' reforms (discussed in more detail later in this appendix). At the time of writing this report, the Government had not yet developed legislation to introduce an objects clause.

Article 7 of the TRIPS agreement describes the objective of an IP system:

> The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.

Objects clauses are included in the patents legislation in other comparable markets, including Japan, South Korea and the New Zealand Patents Bill, which is currently being debated. Language from these clauses is contained in box B.2. Canadian, US and UK patents legislation do not have an objects clause.

Box B.2 **Object clauses in selected other countries**

An English language translation of the Japanese objects clause is:

> The purpose of this Act is, through promoting the protection and utilisation of inventions, to encourage inventions, and thereby to contribute to the development of industry (JPO 2012c).

An English language translation of the South Korean objects clause is similar:

> The purpose of this Act is, through protecting and encouraging inventions and promoting the utilisation of inventions, to accelerate the development of technology, and thereby to contribute to the development of industry (WIPO 2012c).

The objects clause in the proposed new NZ Patents Act is more extensive:

> The purposes of this Act are to—
>
> [a] Provide an efficient and effective patent system that—
>
> (i) promotes innovation and economic growth while providing an appropriate balance between the interests of inventors and patent owners and the interests of society as a whole (NZ Parliament Commerce Select Committee 2010).

B.2 Measures of patent strength and quality

There has long been interest in the 'strength' and the 'quality' of patents systems. A body of literature measuring the strength and quality of patents systems in different countries has developed in recent decades (Ginarte and Park 1997; Lerner 2002; Park 2008; Rapp and Rozek 1990).

Strength and quality of patents systems are difficult concepts to define. Definitions of strength usually relate to the coverage and duration of patents, enforcement mechanisms available to patent holders and safeguards on patents, such as compulsory licensing. Definitions of quality tend to relate more to the stringency and transparency of the patent process. The effects of strength and quality on innovation and growth are also disputed. For example, a 'strong' patents system might have perverse effects and discourage innovation due to difficulties accessing patented materials to develop incremental inventions. A strong patents system might also put strain on the relevant patent office due to a large number of applications, which might lead to delays in the patent process and other problems. A high quality patents system might mean patent applications have to pass a high inventive threshold, and therefore that granted patents are of 'high quality'. However, the degree to which the quality of a patents systems impacts on the quality of patents is uncertain. Care must be taken when comparing countries because there has been much patent reform in recent years. Many of these reforms were designed to improve the strength and/or quality of patents systems, which has altered world rankings.

Park (2008) found that, in 2005, most developed countries had strong patents systems and that almost all strong patents systems were in developed countries. Park measured the strength of patents systems on a five point scale based on: coverage (inventions that are patentable); membership of international treaties; duration of protection; enforcement mechanisms; and safeguards. On this scale, in 2005, the United States had a score of 4.9; Japan had a score of 4.7; and most European Union members had a score of about 4.5. Australia had a slightly lower score (4.2).

The International Property Rights Index, which includes IP rights as one of three core components, shows that developed countries provided the strongest IP protection. In 2012, Finland had the highest score on the IP measure of 8.6 out of 10. Japan and the United States were in equal fourth position and the United Kingdom was in ninth position. Australia was ranked equal 18th with a score of 7.8 (Tiwari 2012).

The desirability of a strong patents system is contested. For example, de Saint-Georges and van Pottelsberghe (2011) argued that most literature on patent strength overlooks the quality and transparency of patents systems. The authors argued that patents systems typically classified as 'stronger' were more 'applicant friendly', rather than high quality, and developed a quality index for 32 countries based on nine components outlined in table B.4.

Table B.4 **Components of patent quality index**

Component	*Assumed effect on quality*
First-to-file system	A first-to-file patents system increases patent quality because it encourages earlier disclosure
Published search report	A published search report for prior knowledge increases patent quality
Time limit to request examination	A shorter time limit to request examination after filing increases patent quality
Length of post-grant opposition period	A longer post-grant opposition period increases quality since more time is allowed to challenge 'poor quality' patents
Grace period	A shorter grace period increases patent quality
Time period patent application is hidden	A shorter period of time where a patent application is hidden increases patent quality
Continuation-in-part application	Existence of continuation-in part applications (related to previously granted patents) decreases patent quality.
Incentives to patent examiners	Greater incentives, based on salaries, increase patent quality through higher quality examination.
Workload of patent examiners	Greater workload, measured by claims per examiner, decreases patent quality.

Source: de Saint-Georges and van Pottelsberghe (2011).

After calculating indices, countries were ranked as having a high, medium-high, medium-low or low quality patents system. The authors' results showed variation in rankings for comparable markets to Australia. The European Patent Office (EPO) and the United Kingdom and Scandinavian countries had the highest rankings. Australia had a medium-low ranking. Comparable countries including Canada, New Zealand and the United States had a low ranking (table B.5). These rankings do not take into account recent patent reforms. For example, Australia, New Zealand and the United States have made reforms to their patents systems (discussed in detail in section B.3) that might improve their rankings on this index.

Table B.5 **Quality of patents systems**[a]

Ranking	*Countries*
High	European Patent Office, United Kingdom, Sweden, Norway, Denmark, Finland
Medium-high	Austria, Poland, China, The Netherlands, France, Japan, Switzerland, Chile, Russia, Colombia, South Korea, Turkey, Malaysia
Medium-low	Australia, Greece, Germany, Singapore, Spain, Brazil, Thailand, Mexico
Low	India, New Zealand, South Africa, Canada, United States

[a] Countries within a category are listed in order of their scores based on the author's preferred index.

Source: de Saint-Georges and van Pottelsberghe (2011).

Patent grant rates are used by some authors as a measure of patent quality. Grant rates appear to be broadly similar in key comparable markets:

- In 2011, among applications to the EPO: 22 per cent were abandoned after search; 31 per cent were stopped during examination; and 47 per cent were granted (EPO 2012b).
- In 2011, about 535 000 patent applications were made to the United States Patent and Trademark Office. About 250 000 patents were granted, which implies a grant rate of about 45 per cent (US Patent and Trademark Office 2012c).
- In 2011, about 220 000 patents were granted by the Japanese Patent Office. About 60 per cent of applications were granted and about 40 per cent were rejected (JPO 2012b).

In 2010, the ratio of patent applications to grants was about 60 per cent in Australia. This ratio fluctuated between 35 and 80 per cent between 1995 and 2010 (chapter 4).

B.3 Reforms of patents systems

There have been many patent reforms in Australia and comparable markets in recent years. Australia and comparable markets are signatories of the Paris Convention, TRIPS and other international IP agreements, which means that there are many similarities between patents systems. Many recent reforms involve further harmonisation of patents systems.

Worldwide, patent applications have grown markedly in the past decade, which has led to considerable pressure on patent offices and consequent backlogs of applications. Many recent reforms aim to address this issue through greater cooperation between patent offices, including by sharing resources. As part of these reforms, a number of multilateral forums have been established.

Other key themes include raising the threshold for patentability of inventions, introducing accelerated examination processes and providing fee discounts for small and medium enterprises.

Recent reforms in Australia

There has been much debate about Australia's patents system and broader IP system in recent years, especially with respect to gene patents. The Australian Government established a number of inquiries into the patents system including:

- Review of Intellectual Property Legislation Under The Competition Principles Agreement (IPCRC 2000)
- Genes and Ingenuity: Gene Patenting and Human Health (ALRC 2004)
- Review of Crown Use Provisions for Patents and Designs (ACIP 2005a)
- Gene Patents (SCARC 2010)
- Patentable Subject Matter (ACIP 2010c).

The Intellectual Property Competition Review Committee (IPCRC 2000) recommended that s. 135 of the Patents Act, concerning the 'reasonable requirements of the public' test for compulsory licensing, be repealed and replaced with a competition test. The Government partly agreed with this recommendation, agreeing to introduce a competition test but decided to retain the 'reasonable requirements of the public' test. A competition test was introduced as part of amendments to the Patents Act in 2006. The competition test is discussed in more detail in chapter 6.

Raising the Bar

In 2011, the Australian Government provided a combined response to the ALRC (2004), SCARC (2010) and ACIP (2010c). Recommendations from these reports were part of the latest package of reforms to the patents system — titled 'Raising the Bar'. These reforms have led to extensive changes, but left compulsory licensing untouched. These reforms are discussed in more detail in box B.3.

Box B.3 **'Raising the Bar' reforms**

The intellectual property (IP) system was significantly changed with the passage of the *Intellectual Property Laws Amendment (Raising the Bar) Act 2012* (Cwlth). The amendments apply to the *Patents Act 1990* (Cwlth) and other IP legislation. The changes addressed six key areas:

- Patent standards — raises the standard of Australia's patents to align more closely with higher patent standards in comparable markets. It does this by:
  - raising standards for information provided in patent applications and specifications, and requiring that the patent has a credible use consistent with the information provided
  - raising the standard for inventiveness, including by taking into account common general knowledge from overseas
  - ensuring that a consistent standard of proof is applied by the Commissioner of Patents.
- Research freedom — distinguishes between research and commercial activities, leaving researchers free to conduct their experiments without having to gain approval from a patent holder. It also introduces an exemption for activities undertaken solely for the purpose of gaining regulatory approval to market or manufacture a patented technology.
- Application process — introduces changes aimed at making the patent and trade mark application process more efficient, in part through preventing 'gaming'. These changes target two key areas — opposition proceedings and divisional applications.
- Attorney profession — permits patent and trade mark attorneys to conduct all aspects of their business through a corporate structure and extends the definition of 'privileged' communications within the IP field.
- Trade mark and copyright infringement — introduces changes aimed at improving the ability of trade mark and copyright owners to enforce their rights.
- Technical improvements in the IP system — introduces changes aimed at modernising aspects of Australia's IP system, increasing transparency in the decision making process, and generally making the system easier to use.

Source: Carr (2011).

Most provisions came into effect on 15 April 2013. However, the regulatory use exemption (for non-pharmaceutical patents) and the experimental use exemption were introduced immediately.

There have been a number of other amendments to the Patents Act in recent years. For example, amendments as a result of the Australia–United States Free Trade Agreement. More changes are in prospect:

- ACIP is investigating the effectiveness of innovation patents (ACIP 2011) and might recommend changes to the innovation patents system.
- The Australian Government announced its intention to implement a TRIPS Protocol, which allows compulsory licensing for export of patented pharmaceuticals to developing countries, and has released an exposure draft of the Bill (discussed in more detail in appendix D).

Multilateral reforms

TRIPS Protocol

A number of countries have implemented the above mentioned TRIPS Protocol (discussed further in chapter 8).

International cooperation between patent offices

Cooperation between patent offices can reduce the costs of the patent process through sharing resources. The greater the harmonisation between patents systems, the greater the scope for cooperation. Cooperation is especially important since patent applications have been rising in recent years. Two projects are outlined below. Many other forums and projects to promote cooperation have also been established in recent years.

Five IP Offices forum

The heads of the five largest IP offices — European Patent Office, Japan Patent Office, South Korean Intellectual Property Office, State Intellectual Property Office of the People's Republic of China, and United States Patent and Trademark Office — met in South Korea in 2008. Together these offices account for about 90 per cent of patents filed worldwide. After the meeting, these five offices established the Five IP Offices forum. The foundation projects agreed to were developing common staff training policies, application processes and examination practices. The offices also agreed to establish a shared set of literature to assess novelty and improve machine

translation services to assist users of the IP system. The forum has continued to develop. For example, the fourth IP5 Examiners' Workshop was held in October 2012 in Beijing. These workshops have provided opportunities for patent examiners from different offices to learn from each other and enhance cooperation between offices (Five IP Offices 2012).

Patent Prosecution Highway

Many inventors apply for patents in multiple countries. Under the Patent Prosecution Highway (PPH), an applicant for a patent may, in participating countries, request that the office of second filing fast track examination of corresponding claims when the office of first filing ruled that the application included at least one patentable claim. The PPH speeds up examinations by allowing examiners in one national office to reuse search and examination results from another office.

Recent reforms in other markets

There have been many reforms of patents systems in comparable markets in recent years. This section examines some key reforms.

EU reforms

European patent law is relevant when considering comparable markets in Europe, as these countries have both national patent laws and are affected by European laws.

European patents and unitary patents

The Convention of the Grant of European Patents, commonly referred to as the European Patent Convention (EPC), was signed by 16 countries in 1973 and came into force in 1977. The EPC allows for European patents to be granted. To obtain a European patent, a single patent application in one language can be filed at the EPO or at a national patent office. European patents are essentially a group of independent, nationally-enforceable and nationally-revocable patents. At the time of writing, all 27 EU member states as well as 11 other European countries offered European patents. Once a European patent is granted it has to be validated in each member state (EPO 2012c).

In 2011, the European Union Council decided to allow 25 member states to establish a unitary patents system. Enabling EU legislation was approved by the

European Parliament in December 2012 and will come into force on 1 January 2014. Unitary patents, also known as 'community patents', will be automatically valid in all participating countries, unlike European patents. Advantages of unitary patents include fewer translation and renewal requirements. European patents will continue to be available (EPO 2012c; European Parliament 2012a).

European Patent Office 'Raising the Bar' initiatives

In response to criticism from stakeholders, the EPO launched a series of measures in 2010 to 'raise the bar'. The aims of the measures were to clarify the scope of the search for prior knowledge, save time in the application process and increase the chance of worthy applicants being granted robust patents (EPO 2009).

The first series of reforms included:

- introducing time limits for filing divisional applications (applications related to a previously filed application)
- where it is unclear to the patent examiner what subject matter should be searched for, the applicant will be invited to file a statement indicating relevant subject matter
- examiners will only search one independent claim per category.

Kossonakou (2009) suggested that these reforms are likely to encourage higher-quality applications, lead to an earlier focus on the scope of the patent application and assist applicants to decide whether to enter the examination phase.

US reforms — Leahy-Smith Act (US)

The Leahy-Smith Act America Invents Act was passed by the US Congress in September 2011 and came into force in March 2013. The Act:

- moved the US patents system to a 'first-to-file' system from a 'first-to-invent' system
- introduced a prioritised examination procedure known as 'Track one', available for a fee at the time of filing a patent application
- aimed to reduce litigation. Interference proceedings, where two parties claim identical or substantially similar inventions, were eliminated and post-grant opposition, where third parties can challenge the validity of a patent, was introduced
- allowed the USPTO to set its own fees rather than the US Congress.

Japanese reforms

The JPO has put in place measures to improve the quality of the patents system. For example, the Quality Management Office was established in 2007 (JPO 2012b). Japan has also made changes to expedite its patent application process by providing applicants with a facility to search for prior art, shortening the time limit for requests for examination from seven to three years and introducing an accelerated examination system.

In 2012, amendments made to the Japanese Patents Act came into force, which aimed to provide:

- greater protection for licensing agreements, by making it easier to register a licence with the JPO and be protected by registration
- appropriate protection to inventors in relation to results from joint research and development programs
- greater convenience for users of the IP system and reduced burdens on small and medium enterprises, through extending fee reductions for these enterprises from three to 10 years
- quick and efficient settlement of IP disputes (METI 2012).

New Zealand reforms

New Zealand Patents Bill

A Bill was introduced into the New Zealand Parliament in July 2008 to repeal and replace the Patents Act 1953 (NZ). The Patents Bill was designed to increase patent standards in New Zealand and harmonise with the rest of the world. Commentary in a report by Parliament on the Bill noted that New Zealand has a low threshold for patentability compared to other countries, which can disadvantage New Zealand, since technology freely available in other countries can be subject to patents in New Zealand (NZ Parliament Commerce Select Committee 2010). The new Bill includes an 'absolute novelty' standard which considers worldwide, rather than local, prior knowledge. As part of these changes, more patent examiners will be employed and higher fees will be charged.

The Bill was introduced into Parliament prior to an election in late 2008 and was reintroduced after that election. The first reading of the Bill was in May 2009 and it was then passed to the NZ Parliament Commerce Select Committee and opened for submissions. The Committee reported back to Parliament in 2010 and recommended two key changes — that both computer software and methods of

medical treatment of human beings not be patentable and that a separate bill be developed to regulate patent attorneys. On 12 September 2012, the New Zealand Parliament held a second reading debate for the Bill. At the time of writing, the Bill had not yet been passed.

Trans-Tasman integration

The Trans-Tasman Outcomes Implementation Group, jointly chaired by representatives of the Australian Treasury and NZ Ministry of Business, Innovation and Employment, recently authored a progress report on integration between the Australian and New Zealand economies. The report noted that governments have agreed to a single regulatory framework for patent attorneys, a single trade mark regime, a single application and examination process for patents filed in both countries, and a single plant variety right regime. Progress is on track for all outcomes except the plant variety rights regime (TTOIG 2012).

South Korean reforms

In October 2008, the KIPO launched the Three-Track Patent Examination system, which, as the name suggests, gives applicants the opportunity to select from three different types of examinations:

- an accelerated examination (which is performed within three months of an examination request)
- a regular examination
- customer-deferred examination (which is performed within three months of the date specified by the applicant).

From 2008 to 2010, between 10 and 15 per cent of applicants selected an accelerated examination (KIPO 2012).

South Korea also amended its patents legislation in 2010 to implement the TRIPS Protocol and to introduce a regulatory approval exemption for pharmaceutical products.

In December 2012, the KIPO signed a memorandum of understanding with the EPO on simplifying the process for South Koreans applying for patents in Europe.

Chinese reforms

China's first Patents Law came into force in 1985, which included compulsory licensing provisions. The Law was amended in 1992, 2000 and 2008 (Ma 2011). The 2008 amendments came into force in 2009 and included:

- introducing an 'absolute' novelty standard, which considers worldwide prior knowledge
- removal of the requirement for Chinese applicants to file first in China
- amendments related to compulsory licensing.

C Non-voluntary access arrangements in comparable markets

Among other things, the terms of reference for this study ask the Commission to:

> Advise on the frequency, and impact, of the issue of compulsory licences in comparable markets and the common features in such compulsory licences.

The Commission was also asked to have regard to 'the range of international approaches'. This appendix examines arrangements for non-voluntary access to patents in comparable markets. As detailed in appendix B, the Commission has included a range of countries in its international comparisons, reflecting the many different factors that can define a comparable market.

Non-voluntary access arrangements examined in this appendix include compulsory licensing, government use, research and regulatory approval exemptions and other relevant arrangements. The features, frequency of use and impacts of such arrangements are examined in turn.

C.1 Features of non-voluntary access arrangements

As mentioned elsewhere in this report, there are many similarities between patents systems in Australia and comparable markets. These similarities are in part because comparable markets are signatories to key international intellectual property (IP) agreements, such as the Paris Convention for the Protection of Industrial Property and the Agreement on Trade-Related Aspects of Intellectual Property Rights 1994 (TRIPS agreement). Non-voluntary access to patents is permitted under these international treaties. Article 30 of TRIPS states:

> Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.

Compulsory licensing

The World Intellectual Property Organisation (WIPO 2008) defines a compulsory licence for a patent as a licence given to an entity or person on their request by a government authority (for example, a Patent Office) to 'work'[1] a patent without the patent owner's consent. International IP treaties explicitly permit compulsory licensing (discussed in more detail in appendix D). WIPO released a detailed study in 2010 which showed that compulsory licensing is a feature of IP legislation in almost all countries (WIPO 2010a). Compulsory licensing is not restricted to patents and is available for other types of IP in comparable markets.

WIPO (2010a) examined four grounds for use of compulsory licensing provisions for patents in Australia and selected countries:

- non-working of a patent (the patented product or process is not produced at all or not produced in sufficient quantities)
- dependent patent (where a patent cannot be worked without exploiting an earlier patented invention)
- patent abuse (for example, by 'refusing to deal' with an applicant for a licence to the patent)
- public interest (varies from country to country and commonly includes national emergencies).

In Australia, the grounds for compulsory licensing in the *Patents Act 1990* (Cwlth) include the 'reasonable requirements of the public' rather than the 'public interest' (discussed in more detail in chapter 6). Despite this difference in language, WIPO found that the above mentioned four grounds were available in Australia. These four grounds also exist in legislation in many comparable markets. For example, France, Germany, Japan, Korea and the United Kingdom have explicit public interest tests. In contrast, the United States does not have provisions for compulsory licensing in its patents legislation (although as explained later the United States uses compulsory licensing). As a result, none of the grounds are explicitly provided for in US patents legislation. Australia and most comparable markets also have competition grounds for granting compulsory licences (table C.1).

[1] Section 226 of the Patents Act states that 'work, in relation to a patented invention, means: where the invention is a product — [the patent holder] make[s] or import[s] the product; or where the invention is a method or process — [the patent holder] uses the method or process [to make or import] a product …'.

Table C.1 **Grounds for use of compulsory licensing in selected countries**

	Non-working of patent	*Dependent patent*	*Patent abuse*	*Public interest*	*Competition*[a]
Australia	Yes	Yes	Yes	Yes	Yes
Canada	Not explicitly provided	Not explicitly provided	Yes	Not explicitly provided	Yes
China	Yes	Yes	Yes	Yes	Yes
France	Yes	Yes	Not explicitly provided	Yes	Yes
Germany	Yes	Yes	Not explicitly provided	Yes	Yes
Japan[b]	Yes	Yes	Not explicitly provided	Yes	No
Korea	Yes	Yes	Yes	Yes	No
Malaysia	Yes	Yes	Yes	Not explicitly provided	Yes
New Zealand	Yes	Not explicitly provided	Not explicitly provided	Not explicitly provided	No
United Kingdom	Yes	Yes	Yes	Yes	Yes
United States	Not explicitly provided	Not explicitly provided	Not explicitly provided	Not explicitly provided	Yes

[a] Competition grounds typically relate to breaches of competition law. [b] Japan does not have competition grounds for compulsory licensing of a patent. However, if a court finds a patent was used to breach Japanese competition law, the court can revoke that patent. To date, no patents have been revoked for this reason.

Sources: WIPO (2010a); WIPO (2011b); national legislation.

Typical conditions for a compulsory licence include:

- the licence is non-excludable and non-assignable
- if the licence is not used within a set period, the patent owner can request that the licence be cancelled
- the licence is predominantly for the supply of the domestic market
- compensation is paid to the patent owner (WIPO 2011b).

In most countries, an applicant for a compulsory licence must have made a genuine effort to negotiate with the patent owner for a licence on reasonable terms. In countries where non-working of a patent is a ground for compulsory licensing, patent owners are given a time limit to work the patent before this ground can be used. This is typically three years after the date the patent was granted.

Reichman (2006) noted there were at least six types of compulsory licences recognised around the world — compulsory licences:

1. to rectify abuses of the patent owner's exclusive rights

2. issued in the public interest, to address environmental, public health, national security or economic development concerns by promoting third-party production of the patented products (at a lower price)
3. issued on behalf of owners of dependent patents, that is, to allow holders of improvements patents to make use of dominant patents that would otherwise block technical progress
4. to rectify violations of competition law
5. for export of pharmaceutical products to developing countries that lack the capacity to manufacture needed drugs
6. imposed by governments to permit them and their contractors to make non-commercial public use of the patents without consent of the patent holder.

The first three types of compulsory licensing noted by Reichman are allowed in most comparable markets, as demonstrated in table C.1. The fourth and fifth types of compulsory licensing are discussed in more detail below. The sixth type of compulsory licensing — use by governments — is considered separately to other forms of compulsory licensing (specifically, chapter 7 considers Crown use). WIPO (2010a) found that the distinction between government use of patents and compulsory licensing is not always clear. Some other forms of compulsory licensing are also briefly considered below.

Competition issues

In a survey on the compulsory licensing provisions of 34 countries, WIPO (2011b) found that in most countries these provisions were not specifically designed to address anticompetitive uses of IP rights. Most compulsory licensing provisions in national IP laws did not contain language addressing anticompetitive uses of IP rights. However, some countries address anticompetitive uses of IP rights in competition legislation. Australia stands in contrast to most comparable markets as it has a competition test in its patent law (discussed in more detail in chapter 6).

Among developed economies, the United States appears to be relatively unusual in the emphasis it places on using compulsory licensing to remedy antitrust violations and open markets to competition, compared to other public interest grounds (Reichman and Hasenzahl 2003; WIPO 2011b; Yosick 2001).

The ‘essential facilities doctrine’ has been applied to IP in comparable markets, most notably in the European Union and, in some cases, in the United States. This doctrine refers to the principle that a firm’s general right to refuse to deal with others may need to be limited in some cases to ensure competition.

Provisions to use compulsory licences for exports to developing countries

In November 2001, the World Trade Organisation (WTO) published the 'Declaration on the TRIPS agreement on public health' (WTO 2001). Following this declaration, a protocol to amend TRIPS was adopted by the WTO. This protocol allows compulsory licensing for the purpose of exporting pharmaceuticals to developing countries.

In 2011, the Australian Government announced its intention to implement this protocol (Carr and Emerson 2011). This follows several other countries, including Canada, EU members and South Korea, which have already implemented the protocol. Discussion of the draft Australian Bill, including background to, and rationale for, the TRIPS Protocol, is included in chapter 8. TRIPS and other international agreements are discussed in appendix D.

Other types of compulsory licensing

Sector-specific compulsory licensing provisions

Internationally, a number of public-health-specific compulsory licensing provisions exist. The French, Belgian and Swiss governments have adapted their patents legislation to introduce specific compulsory licences to address concerns raised by gene patents (Van Zimmeren and Van Overwalle 2011). Public-health-specific compulsory licensing is examined as an alternative mechanism to more general compulsory licensing in chapter 9.

An amendment to the Swiss patents legislation in 2008 allowed for automatic compulsory licences on certain 'research tools'. This allows anyone to use a patent for a biological invention as a tool or means for research (Schovsbo 2009).

In the past, sector-specific compulsory licences were provided for in Canada and the United Kingdom for food, medicines and surgical and curative devices (Correa 1999).

In the United States, provisions similar to compulsory licensing exist in legislation outside of IP and competition legislation. 'Mandatory licensing' of patents is allowed for in the Clean Air Act, and appears equivalent to compulsory licensing. However, the grounds for use of this provision appear narrow and it has not been used to date. Under the Atomic Energy Act of 1954, a person may apply to the US Atomic Energy Commission for a licence for a patent without the patent owner's consent, provided that certain conditions are met (Yosick 2001). This provision appears not to have been used either.

Some commentators are of the view that provisions in the following pieces of US legislation are also equivalent to compulsory licensing: Energy Storage Competitiveness Act of 2007; Federal Insecticide, Fungicide and Rodenticide Act; and Plant Variety Protection Act of 1970 (Correa 2012; Barbosa and Grau-Kuntz 2010; WIPO 2011a). The Commission is not aware of any uses of these provisions.

Government conditions on publicly-funded research

Concerns about the limited use of inventions resulting from publicly-funded research in the United States led to the Patent and Trademark Law Amendments Act of 1980 (Bayh-Dole Act) (box C.1).

Box C.1 **The US Bayh-Dole Act**

The Patent and Trademark Act Amendments 1980 (Bayh-Dole Act) was enacted in December 1980. Prior to the enactment of the Act, there was no government-wide policy on ownership of inventions made by government contractors and grantees receiving federal funding. Companies did not have exclusive rights under government patents to manufacture and sell resulting products. Consequently, there was limited interest by private industry in licensing government-owned patents.

The Bayh-Dole Act allows for the transfer of exclusive control over government-funded inventions to universities and businesses operating with federal contracts for the purpose of further development and commercialisation. The contracting parties and businesses are then permitted to exclusively licence the inventions to other parties.

The US Federal Government retains 'march-in' rights to license the invention to a third party, without the consent of the patent holder or original licensee where it determines the invention was not brought to practical use within a reasonable time, if health and safety issues arise, if public use of the invention was in jeopardy, or if other legal requirements were not satisfied. March-in rights are equivalent to compulsory licensing.

Since the enactment of the Bayh-Dole Act, there is evidence of a substantial increase in technology transfer from universities to industry, and ultimately the public.

Source: COGR (1999).

Legislation similar to the Bayh-Dole Act does not exist in other developed countries. However, countries including China, Brazil, Malaysia and South Africa have passed laws on the patenting of publicly-funded research, modelled in part on the Bayh-Dole Act (Rai et al. 2008).

Government use

Provisions for non-voluntary government use of patents exist in almost all comparable markets. The distinction between government use of patents and compulsory licensing is not always clear.

The Australian Law Reform Commission (ALRC 2004) found that patents legislation in Canada, the United Kingdom and New Zealand contained Crown use provisions, equivalent to government use. The ALRC found these provisions were similar to those in Australia. In these countries, governments could use a patent without the permission of the patent holder in certain circumstances, subject to notification and remuneration of the patent holder.

The Australian Council on Intellectual Property (ACIP 2005a) found that government use of patents did not require ministerial approval in Canada, the United Kingdom or New Zealand. However, the Canadian Government was required to apply to the Commissioner of Patents for a compulsory licence to use a patented invention, subject to compensation determined by the Commissioner of Patents. These provisions could be used by various government departments and at different levels of governments. However, exactly which bodies had access to government use provisions was uncertain.

In the United States, government-use provisions are not found in its patents legislation. However, the US Government has powers to use patented inventions. Reichman and Hasenzahl (2003) noted that the US Government has broad powers to seize and use any invention without incurring liability for infringement, subject to payment of reasonable compensation (28 U.S.C. § 1498). The patent holder has a right to challenge any royalty awarded by the court.

Government-use provisions exist in most European countries. In contrast, government-use provisions are not explicitly provided for in patents legislation in China, Japan, Korea and Malaysia (WIPO 2011b).

Research and regulatory approval exemptions

Research and regulatory approval exemptions provide defences against patent infringement, and can affect research activity and, consequently, affect innovation. These exemptions were recently strengthened in Australia (discussed in detail in chapter 8). These exemptions also exist in comparable markets, and are discussed in turn.

Research exemption

WIPO (2010a) noted that the rationale for research exemptions was explained as follows by the WTO in a previous case (WTO 2000):

> … a key public policy purpose underlying patent laws is to facilitate the dissemination and advancement of technical knowledge. [A]llowing the patent owner to prevent experimental use during the term of the patent would frustrate part of the purpose of the requirement that the nature of the invention be disclosed to the public WIPO (2010a, p. 21).

WIPO (2010a) also noted that the general objectives of research exemptions were similar across countries, but interpretation of research provisions, and language used, differ. Some countries have broad research exemptions, while others have much narrower exemptions and, for example, allow 'scientific research only', or require that research be 'without commercial or gainful intent'. In some countries, research tools are not covered by this exemption. The research exemption in the United States appears to be particularly narrow (Miller 2003).

Many countries — including Japan, Korea and the United Kingdom — have research exemptions in their national laws. In other countries — including Canada, New Zealand and the United States — research exemptions are not contained in national laws but are recognised in case law (WIPO 2010a). The scope of research exemptions varies across countries, and is sometimes difficult to determine given limited jurisprudence. Examples of language used in national laws follow. Section 60 of the Patents Act 1977 (UK) states that:

> (5) An act which, apart from this subsection, would constitute an infringement of a patent for an invention shall not do so if— …
>
> (b) it is done for experimental purposes relating to the subject-matter of the invention

Research exemptions also exist in Japan and Korea. An English language translation of the Japanese Patents Act notes '[a] patent right shall not be effective against the working of the patented invention for experimental or research purposes' (JPO 2012a). An English language translation of the Korean Patents Act notes:

> (1) The effect of a patent right does not extend to any of the following subparagraphs:
>
> (i) working a patented invention for research or experimental purposes (including researches and experiments for item permits and reports of medical supplies under the Pharmaceutical Affairs Act and for registration of agrochemicals under the Agrochemical Management Act) (WIPO 2012a).

Regulatory approval exemption

In the United States, *Roche Products v Bolar Pharmaceuticals* was a landmark court decision in 1984. Bolar, a generic manufacturer of pharmaceuticals, was developing a generic version of Valium, made and sold by Roche. Bolar planned to sell this generic version once the patent for Valium expired. Bolar used patented chemicals in experiments to determine whether its generic was bio-equivalent to Valium. The court found that the experimental use exemption did not apply because Bolar planned to sell its product in competition with Valium once Roche's Valium patent expired.

The Drug Price Competition and Patent Term Restoration Act of 1984 (also known as the Hatch-Waxman Act) overturned this decision and made it legal for a generic producer to import, manufacture and test, but not sell, a patented product prior to expiry of the patent in order to obtain regulatory approval. So-called regulatory approval exemptions can reduce delays in competing products coming to market once a patent has expired. These exemptions are also referred to as Bolar or Roche-Bolar provisions. These exemptions exist in most comparable markets (WIPO 2010a).

The WTO confirmed that these exemptions are legal in 2000 in a case brought by the EU against Canada (Commission on Intellectual Property Rights 2002).

C.2 Use and impacts of non-voluntary access arrangements

Use of compulsory licensing

Use of compulsory licensing in comparable markets dates back many decades, but appears to have been infrequent in most countries.

The ALRC (2004) found that few compulsory licences appeared to have been granted internationally, noting that in the United Kingdom, prior to 1998, only two compulsory licences had been issued under the Patents Act 1977 (UK). The ALRC also found that compulsory licences had rarely been used in New Zealand. Likewise, the Commission has found few recent examples of compulsory licensing provisions in most comparable markets. The Commission has found the greatest use of practices similar to compulsory licensing has occurred in the United States. Compulsory licensing has also been used regularly in Canada, but rarely in recent years. Discussion about compulsory licensing in these two countries follows. Compulsory licensing in Asia and the European Union is also discussed.

Use in the United States

US patents law does not provide for compulsory licensing *per se*. Yosick (2001, p. 1277) noted that 'the US patent system has generally been hostile toward the practice of compulsory licensing' and referenced the US Supreme Court, which in *Chemical Co. v Rohm & Haas Co* commented that '[c]ompulsory licensing is a rarity in our patent system'. Similarly, Reichman (2006, p. 4) noted that 'courts and commentators frequently expressed pro-patent sentiments hostile to the very concept of non-voluntary licensing'. Despite pro-patent sentiments, practices similar to compulsory licensing appear to have been used more frequently in the United States than in other comparable markets. Reichman (2006, p. 3) commented that 'the United States takes a dim view of the compulsory licences that other countries prefer to employ, but it loves the compulsory licences it routinely continues to impose'.

Competition issues

Compulsory licensing appears to have been used extensively to address competition issues in the United States. Reichman and Hasenzahl (2003) noted that US courts have the power to impose non-voluntary licences on patent holders to remedy a broad range of actual, or in the case of mergers, potential antitrust (anticompetitive) violations. These practices appear very similar to compulsory licensing (competition issues in comparable markets are also discussed in chapter 6).

There is a long history in the United States of using compulsory licensing as a remedy for antitrust conduct. In 1958, Scherer found that compulsory licensing had been used in roughly 100 antitrust settlements (cited in Scherer 2010). There are more recent examples. In 2002, Microsoft was required to license patents on reasonable and non-discriminatory terms to software companies developing products to be interoperable with Microsoft Windows (*United States of America v Microsoft Corporation*).

Compulsory licensing has also been used in the United States in a number of merger review cases. Some key cases are discussed in box C.2.

Box C.2 **Compulsory licensing in US merger review cases**

In 1998, the Department of Justice approved agricultural company Monsanto's acquisition of DeKalb Genetics Corporation after Monsanto agreed to address its competition concerns. Monsanto agreed to spin off its claims to technology used to introduce new genetic traits in corn seeds to the University of California. Monsanto also made commitments to license particular patented corn genetic material (US Department of Justice 1998).

In 1999, the Department of Justice reached a settlement allowing Halliburton Company to merge with competitor Dresser Industries Inc. As part of the settlement, Halliburton subsidiary HESI (Halliburton Energy Services Inc.) was required to grant worldwide, royalty-free, irrevocable, non-exclusive licences covering particular tools and related IP (US Department of Justice 1999).

In 2002, the FTC announced a consent agreement for Amgen Inc.'s proposed acquisition of Immunex Corporation, which required the companies to divest certain assets and license certain IP rights. Approval was conditional on the companies granting a license for IP rights to two other pharmaceutical companies (FTC 2002).

Rulings in patent infringement cases

Rulings in some patent infringement cases in the United States appear to be similar to compulsory licensing.

In the United States, like in other comparable markets, patent owners may sue for patent infringement, which includes unauthorised making, using, offering for sale, selling, or importing of a product which falls within one of the claims of a patented invention. In a patent infringement case, the patent owner (plaintiff) may apply for injunctive relief, which, if granted, requires the infringer to cease infringing the patent. A key question is on what grounds injunctive relief should be granted. Some argue that patent owners should be entitled to automatic injunctive relief if their patent is found to be valid and has been infringed.

In 2006, in a landmark decision, the US Supreme Court denied injunctive relief in the case of *eBay v MercExchange, L.L.C.* Prior to this case, there was a general rule in favour of granting injunctive relief if it was found that patent infringement had occurred (box C.3).

Box C.3 **eBay v MercExchange, L.L.C**

In 2000, online auction company eBay initiated negotiations to purchase patents from another online auction company, MercExchange. After eBay abandoned its efforts to obtain these patents, MercExchange sued eBay and a subsidiary for infringement of three patents. The jury in the US District Court of the Eastern District of Virginia found that the patents in question were valid and had been infringed. However, the District Court did not grant an injunction against eBay because:

> [MercExchange's] willingness to license its patents [and] its lack of commercial activity in practising its patents … are sufficient to rebut the presumption that it will suffer irreparable harm if an injunction does not issue.

On appeal, the US Court of Appeals for the Federal Circuit overturned the District Court's decision noting that there was a 'general rule' that injunctive relief should be granted if patent infringement had occurred.

An appeal was made by eBay. The US Supreme Court agreed to hear the case and overturned the Federal Circuit's approval of an injunction, finding that courts should apply a well-established four-factor test to determine whether to award injunctive relief in patent infringement cases:

> That test requires a plaintiff to demonstrate: (1) that it has suffered an irreparable injury; (2) that remedies available at law are inadequate to compensate for that injury; (3) that considering the balance of hardships between the plaintiff and defendant, a remedy in equity is warranted; and (4) that the public interest would not be disserved by a permanent injunction.

The Supreme Court found that neither the District Court nor the Court of Appeals applied these principles fairly. The District Court had mistakenly concluded that patent owners who license their inventions cannot apply for injunctive relief. The Supreme Court also dismissed the Federal Circuit's 'general rule'.

The Supreme Court sent the case back to the District Court. In 2007, the District Court again denied an injunction, based on MercExchange's history of licensing the patents, and determined that $30 million in damages was a sufficient remedy.

In 2008, the parties announced a settlement. As part of this settlement MercExchange assigned patents to eBay.

Sources: de Wit (2010); Fues (2007); Orozco and Conley (nd).

There was much speculation after this case about its effects. Fues (2007) found that in post-eBay rulings, many courts employed the four-factor test and granted injunctive relief. Some courts denied injunctive relief, particularly when the plaintiffs did not use the patented inventions. A survey of post e-Bay cases, published in 2009, found that denial of injunctive relief occurred in about 30 per cent of cases (Larson cited in de Wit 2010).

Denying injunctive relief when patent infringement has been found to have occurred appears to be equivalent to compulsory licensing. In a number of recent cases, the relevant court has allowed use of a patent without the patent holder's consent to continue, and determined appropriate compensation. Judge Rader (in *Paice v Toyota*) noted that 'calling a compulsory license an "ongoing royalty" does not make it any less a compulsory license'. However, this view is contested. Key post-eBay cases are discussed in box C.4.

Box C.4 **Denial of injunctive relief in selected post-eBay cases**

z4 Technologies v Microsoft Corporation — In 2006, Microsoft was found to have wilfully infringed z4's patent on product activation software. The court denied z4 injunctive relief and rejected its argument that its licensing program would be irreparably harmed by ongoing infringement. The court found z4 would lose no market share or name recognition because Microsoft did not offer product activation software separate from its own products. It was also noted that the infringing feature was a small part of Microsoft's products and that it planned to phase out this software. In weighing up the balance of hardships, the court commented that 'turning off' the activation software in Microsoft's products would flood the market with pirated software and cause Microsoft irreparable harm.

Paice v Toyota — In 2006, Toyota was found to have infringed Paice's patent on drive train technology for hybrid electric vehicles. The court denied injunctive relief and found that Paice has not suffered irreparable harm since it did not compete for market share with these vehicles. The court also found that Paice's problems licensing its technology were not due to Toyota's infringement.

Telcordia v Cisco Systems — In 2009, Telcordia, a telecommunication research and development company, argued that it would suffer irreparable harm if Cisco Systems continued to infringe its patent. The court found that Cisco had wilfully infringed Telcordia's patents but denied injunctive relief, noting that Telcordia's 'lifeblood' was its ability to enforce its patents.

In each of these three cases the defendants were allowed to continue using relevant patents, subject to paying compensation.

Source: FTC (2011).

For some, these cases highlighted their concerns about the effects of non-practising entities (so-called patent trolls). In his report in *eBay v MercExchange L.L.C.*, Justice Kennedy drew a distinction between cases where the patent holder does not practise the invention and cases where he or she actually uses the invention. Justice Kennedy noted:

> An industry has developed in which firms use patents not as a basis for producing and selling goods but, instead, primarily for obtaining licensing fees. ... For these firms, an injunction, and the potentially serious sanctions arising from its violation, can be

> employed as a bargaining tool to charge exorbitant fees to companies that seek to buy licenses to practice the patent (Supreme Court of the United States 2006, p. 2).

Injunctive relief has also been denied in a number of standard essential patents cases where patent infringement was found to have occurred. A standard essential patent is a patent on an invention that is required to practise an industry standard. Owners of these patents are often required to license their patent on fair, reasonable and non-discriminatory terms (FRAND) terms. In a number of patent infringement cases, courts have found infringement, but denied injunctive relief because the infringer had been prepared to license the patent on FRAND terms but had been denied by the patent holder. Standard essential patents are discussed further in chapter 5.

March-in rights

As discussed above, march-in rights equivalent to compulsory licensing are available under the Bayh-Dole Act. Prior to 2012, there had been four requests to the National Institutes of Health (NIH) for the Government to use march-in rights. All requests were denied. On 25 October 2012, the American Medical Students Association, Knowledge Ecology International, the U.S. Public Interest Research Group and the Universities Allied for Essential Medicine, requested that the NIH use march-in rights for patented AIDS medication. This was on the grounds that the patent was developed using federal funding and the medication is more expensive in the United States than in other developed countries. At the time of writing the NIH had not responded to this request (KEI 2012).

Use in Canada

Prior to 1992, Canadian law imposed a non-voluntary licence of right (LOR), equivalent to compulsory licensing, on all patented pharmaceutical products marketed in Canada. This scheme also covered food. Under this scheme, generic pharmaceutical manufacturers could produce and market patented medicines in return for paying a royalty, which the Commissioner of Patents typically set at 4 per cent of revenue (Reichman 2010). Reichman (2003) noted that this scheme was 'instrumental in the establishment of a generic medicine industry' (p. 4) and led to some of the lowest pharmaceutical prices among developed countries. From 1969 to 1992, 613 compulsory licences were granted to manufacture or import pharmaceuticals under this scheme (Reichman 2003).

From 1965 to the present, there were 56 unique applications for a compulsory licence in Canada on the ground of patent abuse. Ten of these applications were

granted. Most applications were in the 1970s or 1980s. All but one application was for a mechanical or chemical invention (CIPO, pers. comm., 6 November 2012).

According to Reichman (2010), critics argued that, although it helped to establish the generics industry, the Canadian LOR scheme discouraged the establishment of a research-based sector. In the early 1990s, the US Government pressed the Canadian Government to abandon its LOR scheme in exchange for US producers contributing a share of their profits to support medical research in Canada. The Canadian LOR scheme was later prohibited by the North American Free Trade Agreement (Reichman 2010).

Compulsory licensing has been less common in the past two decades in Canada, but has been used in a small number of cases.

- In 2001, Health Canada overrode Bayer's patent on ciprofloxacin, an anthrax treatment, and authorised production of a generic equivalent. In response, Bayer offered to donate 200 000 tablets to frontline Canadian Government workers.
- In 2007, Canadian company Apotex was awarded a compulsory licence to make an AIDS medication, *TriAvir*, in Canada for export to Rwanda. In addition, a small number of such requests made in Canada have been denied. At the time of writing, only one compulsory licence had been issued worldwide for export of pharmaceuticals to developing countries.

Licensing of IP has been used as a remedy in merger review cases in Canada. For example, the Canadian Competition Bureau issued a consent order for Bayer's acquisition of Aventis Crop Science which required Bayer to divest certain assets and grant an irrevocable and non-exclusive licence of certain IP relating primarily to its canola seed treatment business (Competition Bureau Canada 2006).

Use in Asia

Compulsory licensing of patents has occurred infrequently in Asia. It has not been used in Japan and has not been used in the past 20 years in Korea. However, there have been a small number of applications in recent years in Korea, which have all been rejected. No compulsory licence has yet been granted in China. However, there have been significant changes to Chinese patent law in recent years, including to compulsory licensing provisions. There has been speculation that China will soon use these provisions, especially after recent comments by a Chinese Government spokesperson that if China were to grant compulsory licences it would likely start with pharmaceutical patents (cited in Ma 2011). No compulsory licences have been applied for in recent years in New Zealand (Ministry of Business, Innovation & Employment, pers. comm., 21 November 2012).

There has been one instance of compulsory licensing in Malaysia in the past decade. In 2004, the Malaysian Government issued a compulsory licence to an Indian firm for the supply of patented HIV/AIDS medication (Feldman 2009, p. 150).

Use in Europe

Compulsory licensing of patents appears to have occurred rarely in Europe in recent years. Italy appears to have been the most active country.

- In 2006, the Italian Competition Authority (AGCM) closed its investigation into GlaxoSmithKline's (GSK) refusal to license patents over the active ingredients for migraine medicines to Fabbrica Italiana Sintetici (FIS). In its press release the AGCM noted that GSK had agreed to license to FIS on terms and conditions that remedied the earlier refusal to license. Those conditions included granting a number of additional licences which would save FIS time in developing an efficient manufacturing process for the active ingredient (AGCM 2006).
- In 2007, the AGCM made a decision finalising an earlier order requiring Merck to grant a licence over an active ingredient to an Italian pharmaceutical manufacturer Dobfar, which would allow production of a generic antibiotic (UNCTAD 2011).
- In 2007, the AGCM required Merck to grant free licences to allow the manufacture and sale in Italy of an active ingredient and related medicines, used to treat hypertrophy and cancer of the prostate and male baldness. These royalty free licences were remedies to earlier refusals to license these patents to Italian manufacturers (Ibanez Colomo 2007).

In the United Kingdom, there has been one application for a compulsory licence for a patent since 1998 — *Swansea Imports Limited v Carver Technology Limited*. The case concerned two patents related to water heaters in caravans. Heaters using the patents had been sold for many years in the United Kingdom. Following a takeover of the patentee company, production of the heater ceased, and a new design was used, which did not fall within the scope of the two patents. Swansea Imports sought permission from the patent holder to produce and sell heaters and spare parts using the old (patented) design, and were refused. Swansea applied to the Comptroller of Patents for a compulsory licence. This was on the ground that demand for products to replace or repair worn out heaters was not being met by the new design or the limited stock of the old design, which were available at an increased price. The Comptroller denied Swansea's application for a compulsory licence because Swansea did not prove that demand was not being met on reasonable terms. In the decision, it was noted that if the price being charged by the

patent owner is reasonable, and that demand is fully met at that price, then it is irrelevant whether demand would be greater at a lower price (IPO UK 2004).

Competition issues

Compulsory licensing of IP appears to have been used less frequently in the European Union than the United States to address competition issues. Temple Lang (2002, p. 7) noted that 'the question of compulsory licensing of [IP] rights has arisen very seldom in European antitrust law'. Compulsory licensing appears to have occurred more frequently in the European Union for copyright than for patents or other types of IP. Two important copyright cases include *Radio Telefis Eireann (RTE) and Independent Television Publications Ltd (ITP) v Commission*, also known as the Magill case, and *IMS Health v NDC Health* (discussed in box C.5). The essential facilities doctrine was considered in these cases.

In both *Magill* and *IMS Health* the European Courts held that, in exceptional circumstances, a dominant company's refusal to license its IP could constitute abuse of its dominant position (Kanter 2006). Specific conditions which constitute abuse were established in *Magill* and reaffirmed in *IMS Health* as being that:

- the information in question is indispensable to compete in the relevant secondary market
- the refusal of access to essential elements would prevent the emergence of a new product which is not offered by the dominant firm and for which exists a demand
- there is no objective justification for the refusal (Pil Choi 2010).

While these cases concern copyright rather than patents, precedents from these cases can be applied to patents.

Interoperability of computer software has been another issue relevant to competition policy and IP rights in the European Union. For example, the European Commission (EC) has had a series of disputes with Microsoft. In 2004, the EC found that Microsoft had abused its near monopoly position in two respects. First, Microsoft was found to have deliberately restricted interoperability between its Windows operating system and non-Microsoft work group servers. Second, the EC found that Microsoft had bundled together its Windows software and Windows Media Player to prevent competition from rival media players.

To remedy these abuses, the EC required Microsoft to supply all necessary interface information to allow non-Microsoft work group servers to achieve interoperability and to produce a version of Windows without Windows Media Player. For copyrighted information, the EC made compulsory licences with 'reasonable

royalties' available. The EC imposed a fine of €497 million (Anderman and Schmidt 2007). In 2007, Microsoft lost its appeal against the EC's case (Court of First Instance 2007). In 2008, the EC found that the royalty rates Microsoft requested for interoperability information were not on reasonable terms, and imposed an additional €899 million fine (European Commission 2008). This fine was upheld in 2012, but reduced slightly (General Court of the European Union 2012).

Box C.5 **Key competition cases involving compulsory licensing of IP in the European Union**

Magill — In the 1980s, most Irish and Northern Irish homes were able to receive television programs from the Irish State Broadcaster (RTE), ITV and the BBC. Under Irish and UK copyright law these broadcasters owned the copyright for lists of their programs, and provided this information free of charge to newspapers. However, there was no comprehensive TV guide. In 1985, Mr Magill decided to produce a TV guide, but the broadcasters refused to provide him with a list of their programs. Magill complained to the European Commission (EC) that the broadcasters were abusing their dominant position, and therefore breaching Article 86 of the Treaty of Rome. Despite the general presumption that IP rights allowed IP holders to refuse to license their IP, the European Court of Justice found that the broadcasters had abused their dominant position because they held information which was 'essential' and by refusing to license they had prevented competition. The Court found in Magill's favour and required the broadcasters to provide lists of their programs to Magill.

IMS Health v NDC Health — For many years, Intercontinental Marketing Services Health Inc. (IMS) was the sole supplier of regional sales data to the pharmaceutical industry in Germany. IMS supplied data to its customers using a specific format — based on geographical units, known as 'bricks'. This format had been developed over decades through collaboration with the pharmaceutical industry. In 1999, two competitors — National Data Corporation (NDC) and AzyX — tried to enter the market. When these competitors used the brick system, IMS successfully sued for copyright infringement and was granted an injunction. IMS subsequently refused to license its format to competitors. In 2000, NDC complained to the EC, arguing that the brick structure was an industry standard, and it could not compete without using this standard. In 2001, the EC issued a preliminary ruling finding that IMS had abused its dominant position in the German market and required it to license its brick system to NDC and AzyX. The matter was further considered by a series of German and European courts.

Sources: Delrahim (2004); Glazer (2006); Hull, Atwood and Perrine (2002).

Ezrachi and Maggiolino (2012) argued that the concept of indispensability formulated in *Magill* and *IMS Health* was broadened in the Microsoft cases to include 'economic indispensability', because although an alternative to using

Microsoft products was technically possible, any alternative would not be economically viable.

Impacts of compulsory licensing

There is much speculation about the impacts of compulsory licensing provisions. Lawson (2008, p. 145) noted 'there have been regular assertions that compulsory licensing encourages the licensing and working of inventions sooner'. These assertions often relate to the threat of compulsory licensing, and the consequent effect on behaviour. Reichman (2010, p. 596) noted that prior to 2006, when developing countries began using compulsory licensing provisions more regularly 'health ministries in a number of countries had quietly begun to use the threat of compulsory licenses to rein in the prices of selected medicines'. This followed similar threats in developed countries. Reichman noted that, in 2001, the United States threatened Bayer with a compulsory licence on ciprofloxacin, which the United States intended to stockpile as a defence against anthrax. Bayer drastically lowered its price after this threat. March-in rights, equivalent to compulsory licensing, also appear to have been used in licensing negotiations (ALRC 2004). Packard Love (2007) found that in 2001, Roche and Chiron reached agreement for a voluntary licence for a patent owned by Chiron for a blood screening HIV probe. This followed Roche's request for a compulsory licence to the German Government in 2000.

As discussed in chapter 2, there is limited literature which measures the effects of compulsory licensing. Moser and Voena (2009) estimated the effects of compulsory licensing on inventions using data on the changes in patents for chemical inventions by domestic inventors differentially affected by the Trading with the Enemy Act of 1917 (US). The authors estimated that compulsory licensing in the United States increased domestic invention by at least 20 per cent. In the 1950s, Scherer and others conducted a survey of companies in the United States which were subject to compulsory licensing (cited in Scherer 2010). Scherer noted that they found few negative effects of compulsory licensing on innovation. He further studied this issue in 1977 and found that research and development to sales ratios were 36 per cent higher for companies affected by compulsory licensing. Scherer noted that the impacts of compulsory licensing were likely to vary by industry, with those industries with large research and development expenditures, such as pharmaceuticals, likely to be most impacted. Taylor and Silberston (1973) examined the economic impacts of a worldwide regime of compulsory licensing where patents could be accessed provided 'reasonable royalties' were paid to the patent holder. The authors used a survey of English companies in the chemicals (including pharmaceuticals), mechanical engineering and electrical engineering

industries. The authors predicted that compulsory licensing would lead to an eight per cent decrease in R&D expenditure, on average, for the three industries. However, this figure masked variation within industries. A 64 per cent decrease in R&D expenditure was predicted in the pharmaceutical industry.

Government use

ACIP (2005a) found that government-use provisions in Canada, New Zealand and the United Kingdom had rarely been exercised and that their main function appeared to be for military purposes. Reichman and Hasenzahl (2003) noted that the US Government makes extensive use of other powers to seize and use inventions protected by privately-owned patents for defence and other purposes.

Non-voluntary use of patents by government has a long history in the United States. For example, the US Government confiscated thousands of patents after World War I under the Trading with the Enemy Act of 1917, discussed in more detail in box C.6.

Box C.6 Trading with the Enemy Act of 1917 (US)

During World War I, the US Congress passed the Trading with the Enemy Act of 1917 (TWEA) which permitted US firms to violate enemy owned patents to assist the military. The TWEA was part of a broader strategy to restrict trade with wartime enemies and seize property owned by them. One week prior to the Armistice of 11 November 1918, Congress amended the TWEA to seize all enemy-owned patents. On behalf of the US Government, the Chemical Foundation issued non-exclusive licences of enemy patents in 1919, and continued to do so until 1926. The US Government confiscated over 4 500 patents. Of these patents, 699 were licensed during this period.

At the time of writing, Cuba was the only country still affected by the TWEA.

Source: Moser and Voena (2009).

A more recent example relevant to US Government use of patents was when the US Government made a statement of interest in a private patent infringement action filed by NTP Inc., a patent holding company, against Research in Motion Ltd, makers of the BlackBerry device. In its statement, the US Government noted it was a major user of the BlackBerry device and stated that 'it is imperative that some mechanism be incorporated that permits continuity of the federal government's use' (US Government 2003, p. 2). The Department of Defense also commented on the case, and noted that it was critical for national security that the BlackBerry network continued to be operational (IPRIA 2008).

Government-use provisions have not been used in Canada (CIPO, pers. comm., 22 October 2012). Government-use provisions appear to have been infrequently used in EU member states and in Asia.

As mentioned above, there is much speculation about the impacts of compulsory licensing, but little estimation or measurement of impacts. Non-voluntary use of patents by governments has many similarities with compulsory licensing, and many commentators consider government use to be a type of compulsory licensing. Therefore, many of the speculated impacts of compulsory licensing could also apply to government use. Little literature specifically on the impact of government use of patents has been located.

Research and regulatory approval exemptions

As noted above, many countries have research and regulatory approval exemptions, which can be used as a defence against claims of patent infringement. These exemptions appear to have been used rarely in comparable markets (Cook 2006). An example of use was in *Madey v Duke University*, a 2002 patent infringement case in the United States. John Madey was the exclusive owner of patents over free electron laser (FEL) devices. He was later employed with Duke University and brought his FEL devices with him. Duke continued to use these devices after Madey had resigned. Madey subsequently initiated legal action. The District Court found that Duke's use was covered by the research exemption. However, on appeal the Federal Circuit noted the research exemption was narrow and referred the matter back to the District Court. The District Court then found that Duke's use of the patent was for educational purposes — its core business — and therefore did not qualify for the research exemption.

As discussed in chapter 8, research exemptions might increase research activity, and consequently increase innovation and lead to novel inventions, which can increase community welfare. Regulatory approval exemptions are likely to increase competition, by reducing the time taken for competing products to come to market once a patent for a product has expired. On the other hand, both of these exemptions might reduce incentives to innovate and therefore reduce innovation in the long term.

There is no register of research activity, so it would be difficult to comprehensively measure the impact of these exemptions. However, there is some survey evidence on the effects of patents on research activity. For example, Cho (2006) surveyed US laboratories conducting genetic testing and found that most of these laboratories believed patents had a negative impact on their ability to research. About

one-quarter of laboratories had been contacted by a patent holder or licensee and subsequently prevented from continuing to offer a testing service.

A limited number of authors have estimated the impacts of these exemptions on research and innovation. For example, Moschini and Yerokhin (2008) found that research exemptions reduced community-wide welfare when the cost of establishing a research program was high, due to reduced incentives to innovate. The authors found that research exemptions increased community-wide welfare when the costs of establishing a research program was low, relative to expected profits.

For many countries, including Australia, it has been argued that a de facto research exemption existed prior to a formal research exemption being introduced into legislation. It has also been argued that it was too difficult for researchers to check whether their research activities infringed on patents, so in practice patent infringement was not considered. For these reasons, the impacts of formal research exemptions might be minimal.

D International agreements

Australia is a party to several international agreements relating to intellectual property, which among other things, require harmonisation of certain aspects of Australia's patents system with those in other countries. This appendix presents a brief overview of the agreements that explicitly address non-voluntary access to patents (including the use of compulsory licensing arrangements). These are the:

- Paris Convention for the Protection of Industrial Property 1883 (Paris Convention)
- Agreement on Trade-Related Aspects of Intellectual Property Rights 1994 (TRIPS agreement)
- Australia-United States Free Trade Agreement (AUSFTA).

Australia is also a party to several other treaties relating to intellectual property which do not mention non-voluntary access to patents. These are the Patent Cooperation Treaty 1970, the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure 1977, the Patent Law Treaty 2000, and the Australia-Chile Free Trade Agreement.

D.1 Paris Convention

The Paris Convention dates back to 1883 and has undergone several changes since then. In 1925, an amendment was made to Article 5(A), allowing countries to issue compulsory licences. This provided an alternative to forfeiture of patents to prevent abuses that might arise from the exclusive rights conferred by a patent, including non-working of a patented invention. Article 5(A)(2) of the Paris Convention states:

> Each country of the Union shall have the right to take legislative measures providing for the grant of compulsory licenses to prevent the abuses which might result from the exercise of the exclusive rights conferred by the patent, for example, failure to work.

In addition to providing for compulsory licensing, the Paris Convention also established the concept of national treatment with regards to intellectual property and minimum thresholds for patent eligibility.

D.2 TRIPS Agreement

The TRIPS agreement was negotiated as part of the Uruguay Round, and came into effect in 1995. The agreement is administered by the World Trade Organisation (WTO), and being a signatory to the agreement is mandatory for WTO members. The aim of the agreement is to reduce distortions and impediments to international trade and ensure that intellectual property laws are not trade barriers themselves.

Patentable subject matter

Article 27 of the TRIPS agreement states that patents will generally be made available for any inventions, in all fields of technology, provided they are novel, useful and involve an inventive step. However, Article 27 also gives members the option to exclude particular inventions from patentability such as:

- inventions where preventing commercial exploitation is necessary to protect public order or morality
- diagnostic, therapeutic or surgical methods for treating humans or animals
- plants and animals, other than microorganisms, and the biological processes for their generation (other than non-biological and microbiological processes).

Where a decision has been made to forfeit or revoke a patent, the TRIPS agreement requires that judicial review of the decision is available.

Non-voluntary access to patents

Article 30 of the TRIPS agreement allows members to provide limited exceptions to the exclusive rights conferred by a patent. However, such exceptions are only permissible if they 'do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the interests of third parties'.

Other use without the authorisation of a patent owner is allowed under Article 31 of the TRIPS agreement. In the Australian context, this includes compulsory licensing and Crown use. Article 31 states that, where a member's laws allow for use of a patented invention (by the government or a third party authorised by the government) without the authorisation of the patent holder, the following provisions shall be respected.

- Authorisation shall be considered on its individual merits (Article 31(a)).

- The proposed user has made efforts to obtain authorisation from the patent holder on reasonable commercial terms and for a reasonable period of time (waived during times of national emergency or other circumstances of extreme urgency) (Article 31(b)).
- The scope and duration of use will be limited to the purpose for which it was authorised (Article 31(c)).
- Such use is non-exclusive and non-assignable (Articles 31(d) and 31(e)).
- Such use is to be predominately for supply of the domestic market (Article 31(f)).
- The authorisation will be terminated if the circumstances that led to the initial authorisation of non-voluntary access cease to exist (Article 31(g)).
- The patent holder is paid adequate compensation (Article 31(h)).
- Decisions related to use and compensation are subject to judicial review (Articles 31(i) and 31(j)).
- Members are not obliged to apply Articles 31(b) and 31(g) when such use is intended to remedy anticompetitive behaviour by the patent holder (Article 31(k)).
- Where such use of an existing patent is for the purpose of registering a new patent, the following conditions apply.
  - The invention claimed in the new patent will represent an important technical advance, of economic significance, on the existing patented invention.
  - The holder of the existing patent will be entitled to a cross-license, on reasonable terms, to the invention claimed in the new patent.
  - Such use of the existing patent will be non-assignable, except where the new patent is assigned to a third-party (Article 31(l)).

While Article 31 of the TRIPS agreement imposes conditions on how to implement the non-voluntary use of patents, it does not specify the grounds for allowing such use (Lawson 2008b; Van Zimmeren and Van Overwalle 2011).

Access to pharmaceuticals

In 2001, the WTO Ministerial Conference published the 'Declaration on the TRIPS agreement and public health' (WTO 2001), in which it noted the gravity of a range of public health problems experienced in many countries (particularly developing countries). It also noted that property rights are likely to result in higher prices for patented goods. In the context of public health, patent rights are likely to increase

the costs of pharmaceutical products and might impair access to medicines (particularly in poorer countries). The declaration also affirmed the:

- right of member countries to determine the circumstances that constitute a national emergency
- right of member countries to determine the grounds on which a compulsory licence may be granted
- commitment of developed countries to encourage technology transfer to least-developed countries.

The declaration stated that, with respect to pharmaceutical products, the least-developed countries are not obliged, at least until 2016, to implement or apply sections 5 or 7 of Part II of the TRIPS agreement or enforce rights accorded under those sections.[1]

The Ministerial Conference also noted that countries with insufficient manufacturing facilities might face difficulties in effectively exploiting a compulsory licence over a pharmaceutical product. The Council for TRIPS was directed to find a solution to this and report to the WTO General Council in 2002.

A temporary response to this issue was adopted by the WTO in an August 2003 decision of the General Council (WTO 2003). The General Council recognised ongoing exceptional circumstances justifying the waiving of Articles 31(f) and 31(h) of the TRIPS agreement for situations where a developed (exporting) country produces and exports pharmaceutical products to a least-developed (eligible importing) country.

The obligations associated with Article 31(f) (production primarily used for supply of domestic market) were waived for an exporting country, upon compliance with the following conditions.

- A notification has been made to the Council for TRIPS by the eligible importing country that:
  - specifies the name and quantity of the pharmaceutical product
  - confirms that it does not have the capacity to manufacture the product itself
  - confirms that a compulsory licence for the product has been granted (if the product is patented in that country).
- The exporting country has granted a compulsory licence with the following conditions.

[1] Section 5 relates to patents and section 7 relates to protection of undisclosed information.

  - Production is limited to the amount needed by the eligible importing country.
  - Products produced by the exporting country shall be clearly identified as such through the use of specific marking or labelling, special packaging and/or special colouring/shaping of the products if it is feasible and does not have a significant impact on price.
  - Prior to export, the licenced manufacturer will publish on a website details of the quantity supplied and destination country, and the distinguishing features as detailed above.
- The exporting country shall notify the Council for TRIPS of the issue of a compulsory licence, providing relevant information about the conditions attached to that licence.

A developed country that issues a compulsory licence in order to export pharmaceuticals is still obligated to provide reasonable compensation to the patent holders (as stated in Article 31(h)). However, this obligation is waived for an eligible importing country that issues a compulsory licence, conditional on remuneration having been paid by the exporting country.

In 2005, a protocol to amend the TRIPS agreement was adopted by the WTO General Council (WTO 2005), and submitted to WTO members for approval. The amendments are intended to provide a permanent solution to the issue of access to medicines and once accepted, replace the temporary solution provided by the WTO (2003). Acceptance of the amendments requires approval by two-thirds of WTO members, and at present has not been accepted. Upon acceptance, the TRIPS agreement will be amended by inserting a new article, Article 31(bis), and a new annex to the TRIPS agreement.

Article 31(bis) would establish the right of a developed country to grant a compulsory licence in order to export a pharmaceutical product to an eligible importing country, and obligate the exporting country to provide reasonable remuneration to the patent holder. It would also allow the eligible importing country to export the pharmaceutical product to other developing countries that:

- share the health problem in question
- are party to a regional trade agreement with the eligible importing country.

The Annex to the TRIPS agreement would establish conditions for the grant of a compulsory licence.

The combined effect of Article 31(bis) and the Annex appears to provide at least the same rights and obligations as the temporary solution embodied in the decision of the General Council (WTO 2003).

In 2011, the Australian Government announced its intention to introduce legislation allowing Australian Courts to issue compulsory licences for the purposes of exporting pharmaceuticals to developing countries (Carr and Emerson 2011). A draft Bill was released in August 2012 (IP Australia 2012e).

D.3 Australia-United States Free Trade Agreement

The AUSFTA entered into force on 1 January 2005 and among other things, established Australia's obligations to the United States (and vice-versa) with respect to intellectual property. AUSFTA also establishes patentability criteria and minimum standards of patent protection which are in line with the TRIPS agreement.

Like the TRIPS agreement, AUSFTA allows either country to implement patentability exclusions where necessary to maintain public order or for diagnostic, therapeutic and surgical methods for the treatment of humans and animals. It also restricts the grounds on which a patent may be revoked to those that would have justified a refusal to grant a patent, or instances of fraud, misrepresentation or inequitable conduct.

Non-voluntary access to patents

Under Article 17.9(7) of AUSFTA, a patented invention can only be used without the owner's authorisation if it is to remedy a practice determined as anticompetitive by a judicial or administrative process, or in situations of public non-commercial use, national emergency or other circumstances of extreme urgency. This appears to be more restrictive than the Paris Convention and TRIPS agreement.

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