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]](#footnote-2) 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).

Table C.1 Grounds for use of compulsory licensing in selected countries

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| --- | --- | --- | --- | --- | --- |
|  | Non-working of patent | Dependent patent | Patent abuse | Public interest | Competitiona |
| 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 |
| Japanb | 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 |

aCompetition 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).

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| 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). |
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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.

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| 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). |
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##### 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).

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| 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). |
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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.

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| 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). |
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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).

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| 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). |
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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.

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| 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). |
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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.

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 …’. [↑](#footnote-ref-2)