# 5 Specific concerns about patent access

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| 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. |
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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).

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| 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). |
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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).

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| 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). |
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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]](#footnote-2) 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 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).

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| 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. |
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| 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. |
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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).

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| 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). |
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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).

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| 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). |
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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]](#footnote-3) Among other things, this included making the 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)

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| 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. |
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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).

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| 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. |
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1. This figure includes patents over human and animal genes. [↑](#footnote-ref-2)
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. [↑](#footnote-ref-3)