9 Other alternative mechanisms

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| Key points |
| * The Commission has considered several new alternatives to existing compulsory licensing provisions, many of which focus on access to healthcare. This is where most concerns about the accessibility of patented inventions have arisen. * Healthcare-specific approaches — including exclusion from patentability, exemption from patent infringement, or a special compulsory licensing regime — are not warranted because: * the benefits are likely to be small, given the few cases where there have been problems with accessing health-related patents * incentives for health-related innovation would be reduced * Crown use provisions can already be applied to healthcare and the Commission’s proposed reforms (chapter 7) should increase clarity in this regard. * The use of government purchasing power to ensure equitable and affordable access to patented health technologies currently occurs through the Medicare Benefits Schedule (MBS) and the Pharmaceutical Benefits Scheme (PBS). Where the processes associated with listing on the MBS and PBS are considered too slow, governments can resort to Crown use, as well as changes to the approval and funding arrangements to improve their efficiency and effectiveness. * The Commission is seeking further input from inquiry participants on whether a licence-of-right mechanism is warranted. * This would give patent holders the option of registering a commitment with IP Australia to license to all parties who wish to do so. Where parties cannot reach agreement on the licence terms, this could be determined by arbitration. * A number of countries currently have licence-of-right provisions — including Germany, New Zealand, Singapore, Switzerland and the United Kingdom — but it appears that the take up of these provisions is low. * While a licence-of-right mechanism would not address cases where patent holders are unwilling to license widely, it may be useful in facilitating voluntary licensing when they are willing to do so. * Non-voluntary licensing by a collecting society, as currently occurs for copyrighted works, is not a suitable option for patents, primarily because the use of patents is much more diverse, and so is less amenable to standardised licensing by a central body. * Model patent licences have not been very effective in facilitating voluntary licensing because there is limited scope for a one-size-fits-all approach. * Patent fee discounts to encourage voluntary licensing are unlikely to have much impact, given that patent fees are relatively small. |
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The terms of reference ask the Commission to consider alternatives to compulsory licensing. Existing alternatives, such as Crown use and acquisition powers, were examined in Chapters 7 and 8. This chapter considers several other mechanisms, many of which focus on access to healthcare, given that this is primarily where concerns have arisen about the accessibility of patented inventions. The options considered are: exclusions and exemptions for medical use; public‑health specific compulsory licensing; use of government purchasing power in healthcare; licence‑of‑right mechanisms; collecting societies; and other measures to encourage more voluntary licensing.

## Exclusions and exemptions for healthcare

As discussed in chapter 5, patents on human genes and related testing methods have raised concerns about equitable and affordable access to healthcare. Options to address these concerns include pre‑grant measures (exclusions from patentability) and post-grant measures (exemptions from patent infringement). These are discussed below.

### Exclusions for diagnostic, therapeutic and surgical methods

The Agreement on Trade-Related Aspects of Intellectual Property Rights 1994 (TRIPS agreement) generally prohibits member countries from implementing technology-specific exclusions from patentability, and as such, requires Australia to maintain a technology-neutral patents system. However, Article 27 of the TRIPS agreement does allow member countries to exclude from patentability diagnostic, therapeutic and surgical methods for the treatment of humans and animals (appendix D). This is based on public health considerations, leaving medical practitioners free to take the necessary action to diagnose or treat a certain disease.

Australia does not currently have an exclusion under Article 27. In its review of gene patenting, the Australian Law Reform Commission (ALRC 2004) considered that an Article 27 exclusion may be limited to methods performed on or inside the body (*in vivo* procedures). As gene patents often relate to products and processes for use outside the human body (*in vitro*), most notably in connection with gene sequencing and diagnostic testing, this implies that an exclusion under Article 27 may not address concerns about the effect of gene patents on access to diagnostic testing.

The European Union provides an example of where Article 27 has been used. The European Patent Convention states that methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised *on* the human or animal body are not patentable inventions. The exclusion does not apply to methods practised on substances that are removed from the body. For example, the treatment of blood for storage in a blood bank or diagnostic testing of blood samples is not excluded. In contrast, a treatment of blood by dialysis, where the blood returns to the same body would be excluded (Basheer et al. 2010).

Patentability exclusions for medical treatment have been applied in Canada, New Zealand, and the United Kingdom. However, these only relate to treatment or diagnosis onthe human body, and not procedures carried out *in vitro* or exclusively outside the body. In Canada, methods of medical treatment, although not explicitly excluded, are not considered patentable subject matter, based on judicial interpretation of section 2 of the Canadian *Patent Act 1985*. As defence to an allegation of infringement, a defendant may argue that a patent claim is invalid on the basis that it covers subject matter that is a non-patentable method of medical treatment (CIPO pers. comm., 24 October 2012).

The introduction of an Article 27 exclusion in Australia has been considered in several reviews of gene patents. The ALRC (2004) concluded that the *Patents Act 1990* (Cwlth) (Patents Act) should not be amended to exclude from patentability genetic materials or methods of diagnostic, therapeutic or surgical treatment. It was concerned that this would be difficult to implement, could have adverse effects on investment in biotechnology, medical research and innovation in healthcare, and may not be consistent with Australia’s international obligations under the TRIPS agreement. An inquiry by the Senate Community Affairs References Committee (SCARC 2010) considered excluding genes as patentable subject matter and also concluded that the Patents Act should not be amended to include an express prohibition on patents on human genes and genetic products at that time. This was based on international and national legal developments relating to the BRCA gene patents. It was considered that if the courts were to find that isolated genetic materials were discoveries rather than inventions, this would lessen the need for an express prohibition on gene patents.

As discussed in chapter 5, a private member’s Bill was introduced to the Senate in 2010, which would have introduced an exclusion for human genes, biological processes and materials. However, the Bill did not pass following an inquiry by the Senate Legal and Constitutional Affairs Legislation Committee (SLCALC 2011**)** on the basis that it could have unintended consequences on the patents system with unknown effects on a range of industries and sectors.

The Australian Government (2011a) accepted the ALRC’s view that genetic materials and technologies as well as methods of diagnostic, therapeutic or surgical treatment should not be excluded from patentable subject matter. However, it also accepted a more recent recommendation of the Advisory Council on Intellectual Property (ACIP 2010) to include a general patentability exclusion in the Patents Act that would apply in exceptional circumstances to protect public order and morality as permitted by Article 27(2) of the TRIPS agreement. ACIP (2010, p. 18) recommended ‘to exclude from patentability an invention, the commercial exploitation of which, would be wholly offensive to the ordinary reasonable and fully informed member of the Australian public’. A similar provision under Article 53(a) of the European Patent Convention has been used to reject patent claims. For example, in 2008, the European Patent Office denied a patent over the human embryonic stem cell, because the invention required the destruction of a human embryo, and this was found to be contrary to *orde public* or morality (ACIP 2010).

The Commission notes that there have been no amendments to the Patents Act to give effect to the Australian Government’s response to ACIP’s recommendation. Moreover, it is uncertain whether the introduction of the general exclusion as recommended by ACIP could be used to prevent future patenting of diagnostic, therapeutic or surgical treatments in certain circumstances. Given it is intended to apply only in exceptional circumstances, it would seem likely that that the courts would narrowly interpret the circumstances in which such an exclusion would be granted.

The Commission agrees with the Australian Government’s acceptance of the arguments made in past reviews that the Patents Act should not be amended to include these technology-specific exclusions. The focus of the Commission’s inquiry is on compulsory licensing and other forms of non‑voluntary access after a patent is granted.

### Exemptions for medical practitioner use

Another option is to introduce a specific exemption from infringement by medical practitioners and medical scientists for the limited purpose of screening and diagnosis. This would enable patients to access the results of screening and diagnostic tests to identify gene-related diseases through their medical practitioners.

A medical practitioner exemption might be similar in intent and design to the medical treatment defence under US law (box 9.1). However, this currently only applies to medical and surgical procedures performed on a body.

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| Box 1 US medical treatment defence |
| In 1993, Dr Samuel Pallin launched legal action against Dr Jack Singer in relation to use of a patented surgical method for treating cataracts. In March 1996, the US District Court dismissed Pallin’s infringement claims and invalidated the patent claims over the surgical method (as Singer was proven to have used the method prior to Pallin applying for the patent). In response to this case, the US Government introduced a limited statutory defence to claims of infringement of patents over diagnostic, therapeutic and surgical methods (WIPO 2010b).  The provisions provide a defence for medical activities performed by a medical practitioner or a related health care entity. Section 35 of the United States Code (USC) (§287(c)(2)) states that:  (A) the term ‘medical activity’ means the performance of a medical or surgical procedure on a body, but shall not include  (i) the use of a patented machine, manufacture, or composition of matter in violation of such patent,  (ii) the practice of a patented use of a composition of matter in violation of such patent, or  (iii) the practice of a process in violation of a biotechnology patent.  (B) the term ‘medical practitioner’ means any natural person who is licensed by a State to provide the medical activity described in subsection (c)(1) or who is acting under the direction of such person in the performance of the medical activity.  (C) the term ‘related health care entity’ shall mean an entity with which a medical practitioner has a professional affiliation under which the medical practitioner performs the medical activity, including but not limited to a nursing home, hospital, university, medical school, health maintenance organization, group medical practice, or a medical clinic.  Certain types of medical activity are expressly excluded from the ambit of the medical treatment defence, including most medical applications of genetic materials and technologies. The medical defence was subject to scrutiny by European Community member States in a review of the implementation of the TRIPS agreement in 1998 (ALRC 2004). There does not appear to be evidence of the medical defence being used in practice.  In 2002, a Bill was introduced into the US Congress, which would have extended the definition of a medical activity to include genetic diagnostic, prognostic or predictive testing. This would have exempted medical practitioners using genetic diagnostic tests (for example, tests performed on the BRCA genes) from patent infringement. However, the Bill was not passed because the primary sponsor lost her seat, and to date, there has been no further activity on this legislation. |
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The ALRC (2004) concluded that there were potentially many difficulties in defining the scope of a new medical treatment defence in Australia. These included:

* what specific medical activities should be covered under the defence (in particular, whether it should apply to both procedures performed outside of the human body (*in vitro*) as well as procedures performed on, or inside of, the human body (*in vivo*))
* which persons or organisations should qualify to invoke the exemption from patent infringement.

The ALRC did not support any legislative amendment to enact either a general medical treatment defence or a defence specifically related to the use of patented genetic material and technologies. It concluded that this would be inconsistent with provisions of the TRIPS agreement that require technology neutrality and would detract from patent rights, with potential adverse effects on innovation and investment in some areas of medical technology.

Clinical use exceptions have been suggested as a less arbitrary alternative to excluding genetic tests entirely from patentability than other mechanisms, including compulsory licensing and the application of anti-trust law. Some have advocated for research exemptions to be extended to include clinical use exemptions for diagnostic testing with a research purpose (OECD 2002). However, the difficulty with such an approach is to clearly distinguish clinical use from commercial use to minimise any adverse effects on incentives for investment in health-related innovations.

One way to address this problem would be to introduce a clinical or medical use exemption that is similar in intent to the research exemption — that is, to allow for limited commercial use by medical practitioners and health care providers (for example, to earn professional consultation fees). However, the exemption would not apply where the main purpose is to commercialise the invention, or manufacture it for sale.

The Commission considers that clearly defining the scope of limited commercial use by medical practitioners would be difficult and is not aware of a similar approach being used in other jurisdictions. Moreover, the Commission agrees with the ALRC that the adoption of a medical defence exemption would be a departure from technology neutrality, as required under the TRIPS agreement, and have unknown potential adverse effects on investment. Thus, it does not support the introduction of a medical defence exemption on this basis.

## Legislating a right to personal genetic information

One of the arguments raised against patents over genetic material is that they shift ownership of genetic material away from the individual from which it was obtained, and may impede access to important health information. It has been argued that this is incompatible with the individual’s self determination or right to make choices about how that person’s body is used (ALRC 2004).

The Australian Government Department of Health and Ageing (DOHA) gave an example of where this issue could arise under existing legislation. Specifically, it was concerned that a person cannot be given the results of a genetic test if it is conducted without the patent owner’s authorisation under a research exemption:

Stakeholders have raised concerns that exemption from patent infringement for experimental (i.e research) activities ... may be insufficient to protect researchers in situations where there may be an intersection between experimental and clinical purposes relating to a patent invention. For example, in clinical trials a researcher may be required to make available the results of a genetic test undertaken as part of the trial to the participant in accordance with NHMRC’s National Statement on Ethical Conduct in Human Research. There is a concern that this type of research may be seen as involving a screening service and therefore may not be protected from claims of patent infringement under the research exemption. (sub. 22, p. 10)

In such cases, a compulsory licence could not be used as an effective remedy because the individual seeking access to their genetic information is not seeking to work the patent, and the patent holder has not necessarily engaged in conduct that would constitute grounds for the granting of an order.

The OECD (2006) noted that, while it does not appear to be general practice for patent holders to exert control over human genetic information derived from individuals, anecdotal evidence suggests this practice has occurred in certain situations. It recommended that human genetic information should be disseminated as widely as possible to provide valuable insight into the human body and the development and progression of disease. However, this dissemination of information should be subject to the need to protect the privacy of patients and to meet the legitimate business needs of licensors and licensees.

The *Privacy Act 1977* (Cwlth) (Privacy Act) and the National Privacy Principles (NPPs) require that, if an organisation holds personal information about an individual, it must provide the individual with access to the information on request by the individual. However, under NPP 6.1, there are some situations where access to medical records can be refused, including where ‘providing access would be unlawful’.[[1]](#footnote-2) This could potentially include situations where providing an individual information about their human genome or results of a genetic test would constitute patent infringement under the Patents Act. This situation might arise if a particular gene sequence is identified in an individual that is associated with a disease or health problem by a tester who is not licensed to use the gene patent. The Commission has sought advice from the Office of the Australian Information Commissioner on whether an individual’s right to access personal information under the Privacy Act in this case would override the exclusive rights of the patent holder. This will be an input into the Commission’s consideration of the issue in its Final Report.

Legislating a right to personal genetic information might address concerns that gene patents prevent test results from being received by the person tested. Under this option, individuals would have a right to access information relevant to their own genome (their genetic make-up). It would also provide that a medical practitioner, scientist or their employer are exempt from infringement of gene patents where:

* they have used the information contained in the gene patent for the purpose of identifying a gene sequence in a particular genome which is associated with a medical disease or condition
* the genome belongs to an Australian individual
* the purpose of identifying the gene sequence is to provide information relevant to the provision of health services to that individual.

This approach would prevent gene patent holders from restricting individuals from obtaining information on sequences in their own genome that are relevant to their own health, without detracting from their rights, as use of the gene patent would not be for commercial gain. However, the subject of the gene patent defined in the legislative provision should be limited to ‘bare gene patents’ — that is, patents over isolated and purified gene sequences and methods of associating the genotype with a phenotype.

To implement this option, the Australian Government would need to investigate whether a legislative amendment that provides individuals with the right to access personal information would comply with the TRIPS agreement and other relevant international obligations.

From the evidence available to the Commission, there does not appear to have been a large number of cases in Australia where persons have been unable to access the results of a genetic test because it was conducted without the patent holder’s consent under a research exemption. However, concerns related to patent infringement could become more apparent in the future with emerging biotechnologies related to genetic tests and personalised medicine. As discussed in chapter 8, the newly introduced experimental exemption aims to clarify the rights and obligations of researchers and reduce uncertainty around patent infringement related to the use of patented inventions in research. However, the application of the exemption to medical research is yet to be tested by the courts. The development of case law in this area would provide more clarity to researchers on the legitimacy of providing personal health information to individuals that is derived from gene patents. Where an individual is concerned about accessing personal information in accordance with their rights under the Privacy Act, they can make a complaint to the Office of the Australian Information Commissioner, which has responsibility for investigating complaints about privacy issues covered under the Act.

## Public-health specific compulsory licensing arrangements

In addition to generic compulsory licensing provisions, France, Belgium and Switzerland have introduced specially tailored compulsory licensing regimes to remedy patent licensing practices which are considered detrimental to public health. These were introduced following public debates about BRCA gene patents granted by the European Patent Office and concerns over restrictive licensing practices of the patent holder, Myriad. The intention was to overcome perceived deficiencies of generic compulsory licensing regimes, particularly the lack of a quick and effective remedy against unreasonable licensing behaviour with detrimental effects on public health.

In France, existing compulsory licensing provisions were amended to extend the application of *ex-officio* licences for public health to genetic diagnostics (box 9.2). In Belgium, public health was added as a new separate ground for granting a compulsory licence. This provision is intended to apply to the entire medical sector in a non‑discriminatory way. The Swiss mechanism differs somewhat from the Belgian and French systems in the sense that it only deals with inventions regarding diagnostic products or processes. The Swiss patent legislation was amended in 2008 to include a separate compulsory licence to apply in cases of anticompetitive practices contrary to the Swiss *Cartel Act 1995* that relate to such inventions. The concept of ‘public health’ applied to specific compulsory licence regimes varies across these countries, as do the inventions subject to this form of compulsory licensing.

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| Box 2 French public health licensing regime |
| In France, an *ex-officio* licensing regime has been established with respect to patents issued for medicines, medical devices, *in vitro* diagnostic medical devices, related therapeutic products, and processes for obtaining such products, products necessary in obtaining these products, processes for manufacturing such products and *ex vivo* diagnostic methods.  The Minister responsible for industrial property and an advisory committee consider all the circumstances of the case, including the reasons for a patent holder’s refusal to license. This occurs in two instances: prior to establishment of an *ex-officio* regime; and when individual applications for licences to work the patented invention are filed. Once the French Minister responsible for intellectual property has ordered the establishment of an *ex-officio* license regime, any qualified individual can apply for a licence to work the patent. The person has to be qualified from a legal, technical, industrial and financial point of view. A non‑voluntary licence will only be granted if prior attempts to seek access on reasonable terms and conditions have been made.  Under the French Intellectual Property Code (FIPC) there are four different circumstances that may justify an *ex-officio* licence. An *ex-officio* licence regime is legitimate if one of the following applies:   1. The quantity or the quality of the medicines or methods available to the public is insufficient. 2. The medicines or methods are only available at abnormally high prices. 3. The patent is exploited in a manner contrary to public health interests. 4. The patent is worked in a manner resulting in anti-competitive practices, qualified as such in a final administrative or court decision. |
| *Sources*: Van Zimmeren and Van Overwalle (2011); (Article L.613-16 FIPC). |
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According to Van Zimmeren and Van Overwalle (2011), the specially tailored compulsory licensing regimes have never been used in practice. However, they argued that the regimes have several advantages over conventional compulsory licences issued on the grounds of failure to work, including:

* a shortening of the waiting period for applying for a compulsory licence (there is no requirement to wait three years from the grant of the patent, or four years from the filing of the patent application, before applying for a compulsory licence)
* increased incentives for patent holders to provide the patented product or services on reasonable terms, or to license to third parties on reasonable terms (there is some anecdotal evidence from licensing experts that suggest the mechanisms may have an indirect, preventative effect on possibly unduly restrictive licensing behaviour by patent owners).

There are also potential disadvantages of health-specific compulsory licensing regimes.

* The effectiveness of the mechanism may be uncertain if its use is dependent on the willingness of private companies to apply for compulsory licences (although in France and Switzerland, the relevant Minister has the right to initiate proceedings).
* Despite reduced waiting periods compared to a conventional compulsory licence regime, there may be potentially long delays between application for, and granting of, a health-specific compulsory licence, which limit the effectiveness of the mechanism in situations of a potentially urgent nature.
* It may increase incentives, relative to conventional compulsory licence regimes, for firms to relocate their research activities to other countries.

The introduction of a similar health-specific compulsory licensing regime in Australia would need to be compliant with the TRIPS agreement. According to Van Zimmeren and Van Overwalle (2011), a compulsory licence for public health can be justified on the basis of Articles 8 and 30. However, it would be a move away from a technology-neutral patents system, as mandated by Article 27 of the TRIPS agreement.

The Commission considers that determining the grounds for the granting of a health-specific compulsory licensing regime is likely to be problematic. The objective of any new health-specific regime would need to be clarified. That is, whether the primary motivation for such an intervention in Australia is to address concerns about the potential for gene patents to inhibit patient access to diagnostic testing, or concerns that patents inhibit access to medical and health-related innovations more broadly. The National Coalition of Public Pathology submitted:

Under an Ex Officio arrangement, the Health Minister could be granted the power to grant a licence where there are important public health reasons (which should be explicitly defined). Clear legislation should be developed about what an important public health reason is … To avoid every State and Territory Health Minister from having to grant a licence for every applicable patent on public health grounds, their powers may have to be referred to the Federal Health Minister on this matter. (sub. 25, p. 4)

The introduction of a health-specific compulsory licensing regime specifically tailored for gene patents could also be seen as a costly mechanism in reaction to the BRCA gene case, where there are other more efficient and timely non-voluntary access mechanisms such as the Crown use provisions.

Moreover, public reaction to perceived restrictive licensing behaviour appears to have been effective in many countries in putting pressure on patent holders to license gene patents, as noted by the OECD (2002):

Industry representatives recognised that governmental and public pressure (particularly from patient groups and the medical establishment) have a powerful influence on their licensing strategies. Public reaction against ill-conceived licensing and enforcement practices carries weight in corporate decision making. (p. 73)

Furthermore, the Commission considers that a health-specific compulsory licence regime may have a number of unintended effects on investment and the allocation of resources in innovative effort. If a new regime has the effect of broadening the circumstances in which compulsory licences can be invoked (relative to conventional compulsory licences), a consequence of this is a reduction in the rights of the patent holder to exploit health-related patents. In turn, this could reduce the returns to health-related innovation, relative to areas not subject to specific compulsory licensing provisions, and may result in reallocation of investment funds into those areas at the expense of health-related innovation. In other words, the regime may introduce a distortion into the innovation market.

A key issue is whether such an approach might be more appropriate than current non-voluntary access mechanisms to address systemic or potentially unanticipated problems in the future, that may arise as a result of restrictive licensing practices.

The Commission’s view is that, given uncertainty about future developments in healthcare technology, and potential unintended effects on the development and use of this technology, it is not clear that health-specific compulsory licensing would improve the overall effectiveness and efficiency of the Australian patents system.

## Use of government purchasing power in health

A number of participants to this inquiry (for example, AusBiotech sub. 21; WEHI sub. 9) and previous reviews into gene patents (ACIP 2010c; ALRC 2004; SCARC 2010) supported an arrangement for genetic testing similar to the Pharmaceutical Benefits Scheme (PBS). The Australian Government (2011a) rejected a recommendation from the ARLC (2004) that the Australian Health Ministers’ Advisory Committee should examine options for using government funding and purchasing power to control the cost of goods and services that are subject to gene patents and used in the provision of healthcare. This was on the basis that it did not see a need for an additional mechanism to address the cost of medical goods and services beyond the existing funding mechanisms under the Medicare Benefits Schedule (MBS) and the PBS. This section examines whether the current arrangements provide a suitable alternative to compulsory licensing.

### Current arrangements

The Australian Government controls and contributes to the cost of medical procedures and pharmaceuticals using funding mechanisms under the MBS and the PBS. The Government also contributes to the funding of public hospitals, including outpatient clinic services, which are generally provided by state and territory governments.

#### Pathology services and genetic testing

The Medical Services Advisory Committee (MSAC) provides advice to the Commonwealth Minister for Health and Ageing on the safety, clinical effectiveness and cost-effectiveness of new medical technologies and procedures, including pathology services which cover some genetic testing. This advice informs Australian Government decisions about public funding (including listing on the MBS) for new, and in some cases existing, medical procedures. This can be a slow process, and there is no mechanism for determining which genetic tests should be prioritised for Medicare funding (DOHA 2011a).

In Australia, genetic testing is provided by:

* specialist genetic testing laboratories in the public hospital system (this is the usual route for complex testing and typically provided free of charge to public patients who are residents of that state, while interstate and private clinic patients may be charged)
* laboratories accredited to provide the genetic tests listed on the MBS and thus eligible for a Medicare rebate
* research laboratories, either as part of research activities or on a fee-for-service basis
* small private laboratories on a fee-for-service basis (RCPA 2008).

Some genetic tests are only available if the patient pays directly. Other genetic tests may only be available through overseas laboratories. The most recent data on genetic tests provided across all of Australia (including both MBS and non-MBS listed tests) are available from the *Australian Survey of Genetic Testing 2006*.

The majority of genetic tests are funded by state and territory health departments using a range of mechanisms including cost-recovery. Only a small proportion of genetic tests are listed on the MBS. According to the survey data, only 5 (less than 2 per cent) of the 437 different types of tests that were provided by Australian molecular genetic laboratories in 2006 were funded by the Commonwealth through Medicare.[[2]](#footnote-3) However, this accounted for 26 per cent of tests conducted in 2006, and 40 per cent in 2007 (table 9.1). Between 2006 and 2007, the number of types of Medicare and non‑Medicare rebated tests did not change, however the volume of Medicare-rebated tests increased by 90 per cent. This reflected the uptake of new tests, rather than an expansion of existing tests.

Table 9.1 Molecular genetic tests, Australia, 2006-2007**a**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| *Laboratory funding* | *2006* | |  | *2007* | |
|  | *Number* | *%* |  | *Number* | *%* |
| Medicare rebated | 41 497 | 26 |  | 78 806 | 40 |
| Non-Medicare rebated | 119 354 | 74 |  | 117 342 | 60 |
| Total | 160 851 | 100 |  | 196 148 | 100 |

a Number of molecular genetic assays.

*Source*: RCPA (sub. 16).

In addition to MBS-listed tests, there are approximately 450 types of tests available in Australia (DOHA 2011a). Of these, approximately 55 per cent were offered by only one laboratory and 21 per cent were offered by only two laboratories in 2006. The majority of tests were provided by laboratories in only one state or territory. The Royal College of Pathologists of Australasia (RCPA 2008) noted that there is wide disparity in the availability of genetic tests between states and variability of access is most acute for relatively uncommon genetic disorders. The RCPA (sub. 16) also noted that many of the tests that were only provided by one or two laboratories (around 75 per cent of all types of genetic tests nationally) were low‑volume tests (less than 100 samples assayed each year). It suggested there are benefits in terms of quality assurance and economic efficiency from centralising these tests in one or two ‘reference laboratories’.

Screening represented the largest share of tests performed by patient group in 2006‑07, followed by diagnostic testing (table 9.2). The increase in the proportion of tests provided to the ‘unknown group’ between 2006 and 2007 was attributed to an almost doubling of the volume of Medicare‑rebated HFE tests during this period.[[3]](#footnote-4)

Table 9.2 Genetic tests by patient group, Australia, 2006-07

Number and per cent of assays

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Patient Groupa | 2006 | | 2007 | | % change |
|  | No. | % | No. | % |  |
| Screening | 64 547 | 40.1 | 60 960 | 31.1 | -6 |
| Diagnostic | 45 437 | 28.5 | 55 902 | 28.5 | 23 |
| Somatic (acquired) | 13 092 | 8.1 | 16 094 | 8.2 | 23 |
| Family (germline) | 7 614 | 4.7 | 7 775 | 4.0 | 2 |
| Pharmacogenetic | 470 | 0.3 | 944 | 0.5 | 101 |
| Supplementary | 281 | 0.1 | 362 | 0.2 | 29 |
| Unknown | 29 411 | 18.3 | 54 110 | 27.6 | 84 |
| Total | 160 852 | 100 | 196 147 | 100 | 22 |

a Screening refers to testing an unaffected person who is not recognised as being at increased risk of carrying a mutation. This includes neonatal screening for cystic fibrosis or screening a patient for pharmacogenetic variants prior to commencing drug therapy. Somatic refers to testing for non-heritable variants, typically in cancer tissue. Diagnostic refers to testing of an affected patient (of any age, including prenatal) to determine the genetic basis of the disease. Family refers to testing of an unaffected person (of any age, including prenatal) who is at increased risk of carrying a genetic mutation on the basis of family history. This will usually refer to testing for a mutation already identified in the family, and includes predictive/pre-symptomatic testing and carrier testing. Pharmacogenetic refers to testing of an affected person for heritable genetic variants to guide choice and dose of drug treatment. Supplementary refers to additional testing (in any patient group) to clarify an initial result. Unknown refers to testing for unknown purposes. This includes HFE and FMR1 tests which according to the descriptions in the MBS schedule encompass both diagnostic and family testing.

*Source*: RCPA (sub. 16).

The volume of medicare-rebated genetic tests increased fourfold between 2002 and 2012 (figure 9.1).[[4]](#footnote-5) However, genetic tests accounted for less than 0.5 per cent of all Medicare-rebated pathology tests in every year during this period. This proportion may increase significantly in future years. Over one-third of applications currently being considered by MSAC for listing on the MBS relate to genetic tests and/or associated services. In some cases, this includes a review of existing MBS items (DOHA, pers. comm., 5 November 2012).

Figure 9.1 MBS (Medicare-rebated) pathology services

Average services per capita (per 100 000 population)a

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| --- |
| *Panel A: Cytogenetic servicesb*  *Panel B: All pathology services (including cytogenetic services)c* |

a Services are calculated by dividing the number of services provided by a Medicare registered provider and processed by Medicare Australia in a month by the number of people enrolled in Medicare at the end of each month for the financial year ending 30 June. b Cytogenetic services include MBS-listed items 73287-73294 under category 6 (Pathology services). These relate to analysis of abnormalities of whole chromosomes (each chromosome contains many different genes) and molecular genetic testing (analysis of gene mutations linked to specific diseases). c Haematology includes testing related to many aspects of diseases which affect the blood such as anaemia, leukaemia, lymphoma and clotting or bleeding disorders. Chemical involves testing to detect changes in substances in blood and body fluids (electrolytes, enzymes, and proteins) in association with many diseases and also includes detecting and measuring tumour (cancer) markers, hormones, poisons, therapeutic and illicit drugs. Microbiology includes testing to detect diseases caused by infectious agents such as bacteria, viruses, fungi and parasites. Other pathology services include cytogenetics, immunology, tissue pathology, cytopathology, infertility and pregnancy tests and simple basic tests.

*Source*: Medicare Australia (2012).

In 2011-12, genetic services and benefits accounted for over $29 million or 0.2 per cent of total Medicare item expenditure (table 9.3). State and territory governments spend an estimated $34 million annually on genetic testing in excess of the money paid through the MBS (DOHA 2011a).

Table 9.3 Medicare services and benefits, 2011-12

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Type of service | Services | | Benefits | |
|  | No. | % | $ million | % |
| All genetic services | 184 036 | 0.1 | 29.2 | 0.2 |
| All pathology services | 114 694 266 | 34.5 | 2 236.7 | 12.7 |
| All medical services | 332 609 731 | 100.0 | 17 697.2 | 100.0 |

*Source*: Medicare Australia (2012).

The funding arrangements for pathology services funded through the MBS have recently been reviewed by the Department of Health and Ageing (box 9.3).

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| Box 3 Funding Agreement for MBS pathology services |
| In March 2011, the Department of Health and Ageing released its final discussion paper on the *Review of Funding Arrangements for Pathology Services*. This review, undertaken by the Medical Benefits Reviews Task Group, informed a five-year funding agreement between the Australian Government and the Australian Association of Pathology Practices, the Royal College of Pathologists of Australasia, and the National Coalition of Public Pathology. The Agreement, which was signed in April 2011, sets the maximum and minimum government outlays relating to services in the Pathology Services Table (PST) of the MBS. Among a number of objectives, the agreement is intended to promote:   * development of a more transparent mechanism for setting and reviewing schedule fees for PST items, based on better cost information * competition in the pathology sector * development of a National Pathology Framework * improvement of data collection through MBS payment arrangements * implementation of electronic requesting and reporting of pathology across the sector * development of appropriate policy and funding mechanisms for genetic testing.   The development of a national approach to genetic services, including financing, is currently being considered by a working party that will provide advice to the Australian Government on possible reforms by the end of 2012. The PST expenditure implications of any reforms may affect government outlays under the agreement. |
| *Source*: DOHA (2011a; 2012a). |
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Data are not available on the proportion of genetic tests provided in Australia that are patented. However, the RCPA (sub. 16) noted that one major public sector laboratory estimated that at least 50 per cent of the genetic tests it offers could be covered by one or more Australian patents. A US study in 2005 found that 20 per cent of approximately 23 700 genes identified had been patented, with up to 20 patents and 12 patent holders for any one gene.

The Centre for Law and Genetics (sub. 3) noted it is currently undertaking a survey of the Australian human genetic diagnostics industry to create empirical data on the impediments caused by patents in the provision of genetic diagnostic tests.

#### Pharmaceuticals

The primary role of the PBS is to achieve the objective of the National Medicines Policy, endorsed by Australian Government in 1999, to ensure the provision of timely access to the medicines that Australians need, at a cost that individuals and the community can afford.

Once a prescription drug is approved for marketing, the producer or sponsor usually applies to have the drug listed on the PBS. Similar to the MBS process, the Pharmaceutical Benefits Advisory Committee (PBAC) makes recommendations to the Australian Government on the suitability of drugs and medicinal preparations for subsidy under the PBS and the vaccines for listing under the National Immunisation Program. The recommendations are based on comparative clinical effectiveness and cost effectiveness. Following this, the Pharmaceutical Benefits Pricing Authority (PBPA) negotiates prices paid with the sponsor and makes recommendations to the Minister on pricing determinations for drugs recommended for listing on the PBS.

The Australian Government considers the advice of both the PBAC and the PBPA and makes a decision on whether the drug will be listed on the PBS.[[5]](#footnote-6) The PBPA may also recommend revised prices where the use of a drug is extended or changed. In addition, the PBPA reviews prices of all brands of pharmaceutical items listed on the PBS at least once each year.

The PBPA’s approach to pricing determinations under the PBS is based on cost‑effectiveness criteria and comparative price referencing (box 9.4). It does not take into account the patent status of a drug or include a price premium to provide compensation for patent rights (ALRC 2004). Where there are two or more brands of the same drug on the PBS schedule, the Government subsidises each brand to the same amount, up to the cost of the lowest-price brand (DOHA, sub. 22). If a drug manufacturer cannot agree with the Government on a price, it may sell the drug on the private prescription market. However, this is generally an unattractive option, given the provision of a subsidy through the PBS and the fact that doctors generally confine their prescribing to the PBS list.

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| Box 4 Pricing of drugs under the PBS |
| In making recommendations to the Australian Government on the prices that should be paid for items recommended for listing on the PBS (and in reviewing the price of items already listed on the PBS), the Pharmaceutical Benefits Pricing Authority (PBPA) is required to take account of:   * the advice of the Pharmaceutical Benefits Advisory Committee (PBAC) on clinical and cost-effectiveness * prices of alternative brands * comparative prices of drugs in the same therapeutic group * cost data information * prescription volumes, economies of scale and product stability * prices of items containing the drug in reasonably comparable overseas countries * other factors the applicant may wish the PBPA to consider * any directions of the Minister.   The PBPA uses a number of pricing methods in making its recommendations. Most commonly used are the Cost-Plus method, Reference Pricing and Weighted Average Monthly Treatment Cost. It may recommend either a ceiling price or price range for an item that has been approved by the PBAC following negotiation. Under the PBS, patient contributions towards medication costs at pharmacies are capped. |
| *Sources*: DOHA (2009a); PBPA (2009). |
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The ALRC (2004) found there was evidence that the PBS allows relatively low prices for drugs to be maintained because the Government acts as a monopsony — a single buyer in a market with a number of sellers. However, while the Government is the only purchaser of many drugs in the Australian market, this monopsony does not extend to international markets, and its buying power is weakened by pharmaceutical companies that use their global market power to influence prices. The impact of the PBS on suppressing the price of different categories of drugs depends on the extent to which there are competing or substitute drugs in the market. Producers of unique or breakthrough drugs that are the only form of treatment or cure for a particular disease (and are often patented) have a monopoly position in the market, at least for a period of time. In such cases, the Government is in a relatively weaker bargaining position (IC 1996).

There are a number of cases where utilisation of a drug, medicinal preparation or vaccine listed on the PBS is likely to be targeted to a small population with a particular disease. DOHA (2011) noted that of the total number of applications submitted, approximately one-third of sponsors predicted an estimated use of less than 2000 prescriptions in the first 12 months of listing. A number of products are excluded from the PBS because they are designated as an orphan drug or considered for the Life Saving Drugs Program. However, the costs to the Government of subsidising patient access to these products can be significant because of high unit costs.

The Australian Government has announced a review of the system of patents for pharmaceuticals (IP Australia 2012i). This will consider a number of issues, including whether the current arrangements are being used to extend pharmaceutical monopolies at the expense of generic pharmaceuticals entering the market. The review, which is expected to be completed in April 2013, will look at the pharmaceutical extension of term provisions (introduced to the Patents Act in 1998) and the current approach to granting patents for new formulations and new methods of manufacturing.

### Is government purchasing power a suitable alternative?

The ALRC (2004) and others have previously recommended that governments use their purchasing power in health to address concerns about equitable and affordable healthcare. The ALRC considered that in some cases intervention in the patent process by government health departments is warranted:

In some circumstances, health departments should be willing to challenge patents, or their exploitation, in the public interest. Patent holders will have an incentive to ensure that the exploitation of their patent rights does not prejudice public healthcare or medical research if they face the realistic prospect that their patents will face detailed scrutiny by government authorities. (p. 480)

As noted, the Australian Government rejected proposals for the introduction of new arrangements as there are already mechanisms in place under the MBS and the PBS. It accepted a recommendation by the ALRC that, where gene patents have an adverse impact on medical research or the cost‑effective provision of healthcare, governments should consider exercising existing legal options to seek access, including:

* challenging a patent, requesting re-examination, or applying for revocation of a patent under the Patents Act
* making a complaint to the ACCC of a potential breach of Part IV of the *Competition and Consumer Act 2010* (Cwlth)
* exploiting or acquiring a patent under the Crown use and acquisition provisions
* seeking the grant of a compulsory licence under the Patents Act.

The Commission’s view is that, as discussed in chapter 5, gene patent owners are not typically placing unreasonable restrictions on access to their technologies. From the evidence available to the Commission, the BRCA gene case is not representative of industry behaviour. Moreover, gene patenting may have already peaked as an issue raising public concern. As noted by Pfizer (sub. 5, p. 2), the majority of the earlier broad patents, which include the BRCA patents, are nearing the end of their patent life and patent offices have been increasing the novelty and inventiveness threshold in issuing patents. Nevertheless, the Peter McCallum Cancer Centre observed:

There remains … a public perception, and indeed a possibility, that there may be isolated occasions where patent holders may … attempt to enforce their rights unreasonably and either not supply patented materials in the Australian market or apply unreasonable licensing provisions to their use. (sub. 14. p. 1)

As noted in chapter 5, concerns regarding the effect of patents on the affordability of medical treatment are broader than the BRCA case, and rapid development in medical science and biotechnology could present future challenges for the patents system. Inquiry participants (for example, NHMRC, sub. 33) noted that increasingly many diseases and conditions require analysis of multiple genes and whole-genome sequencing will be important to provide more personalised medicine. There is uncertainty as to whether patents over specific isolated genes will be infringed by whole‑genome sequencing. Concerns have been raised that this presents a potential barrier to the future development of technology, as noted in a report by the US Secretary’s Advisory Committee on Genetics, Health, and Society:

As multiplex testing and whole-genome sequencing become commonplace in medicine, challenges to innovators in obtaining access to licensing information may discourage the development of advanced tests and their application to medicine. (SACGHS 2010, p. 62)

The Commission considers that wholesale changes to existing arrangements to ensure equitable and affordable healthcare are unlikely to be warranted purely on the basis of concerns related to the BRCA case. Moreover, it is evident that gene‑related diagnostic and therapeutic services are being funded more extensively under the MBS and PBS. There has been an increase in the number and complexity of applications to MSAC for genetic diagnostic tests (DOHA 2012). This seems inevitable as healthcare becomes increasingly reliant on gene-related technologies, and new treatments are often hybrid and co-dependent. For example, diagnostic treatments are often intended to determine the use of a medicine and this may require assessments by both the MSAC and the PBAC. The existing MBS and PBS processes provide mechanisms for negotiating the supply and price of new medical technologies with producers, regardless of whether they are patented. The Commission, therefore, does not see a compelling case for changing the important checks and balances built into the Australian Government's funding arrangements for healthcare.

There have been concerns that the current evaluation processes for listing on the MBS and PBS may not be capable of responding quickly enough to some rapidly developing fields of medical technology (SCARC 2010; DOHA 2011). The Commission notes that the Australian Government has recently reviewed health technology assessment (HTA) processes involving a number of Commonwealth agencies including the Therapeutic Goods Administration, MSAC and PBAC. Following this, measures have been introduced to improve the efficiency of HTA processes, such as the establishment of a single entry point to receive applications for subsidy under the MBS, PBS and Prostheses List (DOHA 2009b). Further, a number of changes have been proposed to improve the timeliness of MSAC processes for public funding applications for diagnostic tests (DOHA 2012).

In situations where existing mechanisms associated with the government's use of purchasing power are considered too slow or are not effective to facilitate access to important health-related technologies, governments could resort to Crown use provisions (particularly in emergencies), and also consider changes to the approval and funding arrangements if necessary.

## Non-voluntary licensing by a collecting society

As discussed in chapter 4, there are several cooperative mechanisms used by firms to facilitate licensing of multiple patents and enable greater access to technology such as cross licensing, patent pools and clearing houses.

Collecting societies, such as copyright collectives, are a type of licensing clearinghouse. Copyright Agency Limited (CAL) has been established as a collecting society with the authority to licence copyrighted works, collect royalties from users (as part of compulsory licensing arrangements or individual licences negotiated on behalf of its members) and distribute the proceeds to copyright owners (box 9.5). Where a collecting society, representing one or a number of copyright holders, is unable to negotiate a licence agreement with a potential licensee, the Copyright Tribunal has the power to make orders on the charges and conditions it considers to be ‘reasonable in the circumstances’.

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| Box 5 Copyright Agency Limited and the Copyright Tribunal |
| Copyright Agency Limited (CAL) is a non-profit rights-management organisation that collects and distributes copyright fees for text and images to holders of copyrights. CAL was appointed by the Commonwealth Attorney-General in 1990 to manage the statutory licence in the *Copyright Act 1968* (Cwlth) (Copyright Act) for educational use of text and images (educational statutory licence), and by the Copyright Tribunal in 1998 to manage the statutory licence for government use of text and images (government statutory licence). These statutory licences allow use of content without a copyright clearance, provided fair payment is made to rights holders. CAL was also appointed by the Australian Government in May 2010 to manage the [artists' resale royalty scheme](http://www.resaleroyalty.org.au/). It also distributes payments to Australian copyright holders for works used overseas where licence fees have been collected by a collecting society in that country.  The basis of licence fees negotiated by CAL varies depending on the type of licence. However, they generally comprise a fee for the volume and type of use, rather than the use of specific works.  Unlike the Patents Act, there are no explicit compulsory licensing provisions in the Copyright Act. However, s. 183 of the Copyright Act allows the Crown to use copyright material for the services of the Commonwealth or a state after paying compensation to the owner, making this a type of compulsory licence. The licence terms are agreed between the parties, or set by the Copyright Tribunal if parties do not reach an agreement.  The Copyright Tribunal has jurisdiction with respect to both:   * statutory licences when specified conditions are satisfied (essentially statutory exclusions from infringement of copyright for the reproduction of certain materials by educational institutions or institutions assisting persons with disabilities) * voluntary licences negotiated between a copyright holder or its representative, such as a collecting society, and the licensee. Licences granted under licence schemes are often referred to as blanket licences and cover all works in the particular collecting society’s repertoire.   The Copyright Tribunal has jurisdiction to confirm, or vary, a licence scheme or proposed licence scheme. It may also substitute a new scheme for the one referred to it (ss. 154-156 of the Copyright Act). Section 157 provides for various kinds of applications to the Tribunal by licensors and prospective licensees where there has been a failure to agree on the grant of a licence. This may include cases where a licence scheme applies. The Tribunal has the power to make orders as to the charges and conditions it considers ‘reasonable in the circumstances’. |
| *Sources*: CAL (2012); Copyright Tribunal of Australia (2009). |
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The Commission has considered the option of a establishing a collecting society, under the Patents Act, to compel a patent holder to grant licences for a specific purpose, such as access to specific gene patents for diagnostic testing. The collecting society’s role could be to administer licences and negotiate some of the terms on behalf of patent holders, including licence fees. It could also be responsible for collecting royalties and distributing these to patent holders. Patent holders (or the collecting society acting on their behalf) and potential licensees could have the option of making an application to a court or tribunal for independent price adjudication if the parties fail to reach agreement on a licence.

The objective of a collecting society would be to provide a means to access specific patents and facilitate the licensing of multiple patents by a single body. In doing so, it may overcome some of the difficulties parties face when developing their innovation requires access to many other patents. DOHA stated that:

… such a mechanism could allow much quicker, cheaper and less cumbersome access to patents which need to be utilised in a health or broader context. However, there may be insufficient demand to justify the establishment and maintenance of such a body by Government. (sub. 22, p. 9)

The Centre for Law and Genetics (sub. 3) noted that it had previously supported the creation of a statutory licensing scheme for some types of patents, particularly in the field of genetic technology. It considered that these would be most appropriate for technologies that are newly emerging, or where patent thickets have the capacity to interfere with incremental innovation. It suggested that non-voluntary schemes should be restricted to specific sectors, for example, the public research and public health sectors.

However, there are important differences between copyright works and patents that potentially limit the effectiveness of using collecting societies as a mechanism to facilitate access to patents. These relate to differences in their use and the characteristics of licensing agreements. Spence (2009) outlined a number of differences in the purpose and features of copyright collecting societies and patent royalty clearinghouses in the context of gene patents.

* It is easier to determine the scope and use of copyright works relative to patents. Copyright collecting societies control the use of particular types of work in specific contexts (mostly musical and literary works in relation to public performance and reproduction). The determination of licence conditions is therefore more straightforward for copyright than gene patents that may be used for a variety of different purposes.
* Gene patents are most frequently used for upstream inventions, while copyright usually protects works that are finished products. Therefore, there may be an available substitute if the collecting society sets unreasonable prices for a copyright work. In contrast, there may be no substitute for a gene patent where it is an upstream patent for a research tool, and consequently this may hinder downstream development of technology.

Patent licences are heterogeneous and technology-specific compared to copyright, where there is more scope for standard terms of use. Therefore, patents are less amenable to standard licensing by a central body.

Most inquiry participants did not support non-voluntary licensing of patents by a collecting society, primarily because of the inherent differences between copyright and patents. For example, IPTA submitted that:

A collecting society may have a place in administering the rights of copyright owners where the rights are limited to reproduction of a copyright work. However, such societies have no place in administering granted rights such as patents, where the value of each granted right and the potential for exploitation under the Patents Act must be individually determined according to a unique combination of factors intrinsic and extrinsic to the patented technology. (sub. 18, p. 6)

Similarly, the Law Council of Australia observed:

While there are examples of industries (including aspects of computer technology) where widespread non-exclusive licensing, including bulk pricing of patents, is known, we are not aware of any examples of a successful collecting scheme for patents anywhere in the world. It is likely that the reason for that is quite fundamental. In particular, the variable nature and value of patent rights would mean that the determination of price to users and the distribution of royalties to patentees would frequently need to be assessed on a case by case basis. The ability to determine a standard general charging mechanism and a fair general method of splitting the revenue among IP owners, which are the key to collecting schemes, are not present. Administrative costs and disputes at both levels are likely to consume any return. (sub. 32, p. 11)

In summary, copyright and patents are sufficiently different to mean that collecting societies are not an appropriate vehicle for administering non-voluntary access to patents. Moreover, it could be costly to establish and maintain a collecting society for patents. Furthermore, introducing a legislative requirement to grant compulsory licences for patents in a specific area, like other mechanisms considered in this chapter, would also create a technology‑specific mechanism in the patents system. This may have unintended adverse impacts on investment and the allocation of resources. In light of the above, the Commission does not support non-voluntary licensing of patents by a collecting society.

## Licences of right

The ALRC (2004) identified a voluntary ‘licence-of-right’ (LOR) system used in the United Kingdom as a useful model to facilitate access to patented genetic inventions, should the need for a statutory licensing scheme arise in the future. Such a LOR system would be applicable to all patents.

A LOR is a legally enforceable mechanism by which a patent holder voluntarily chooses to provide access to a patented invention to anyone who is willing to accept the conditions. This can include payment of an ‘appropriate return’ determined by a public undertaking (for example, a court) (Schovsbo 2009). This means the patent holder effectively loses the ability to enter into exclusive licences. LORs normally entitle a patent holder to pay a reduced level of patent fees.

The main benefit of a LOR mechanism is to facilitate access to patented inventions by reducing the cost of identifying licensees and negotiating licence agreements. By registering a LOR, patent holders flag their willingness to license. To assist prospective licensees, some intellectual property offices maintain a publicly available list or database of granted patents that are endorsed LOR. Thus, a LOR can benefit inventors who are uncertain of the potential users of their invention or ways to promote it. A LOR might also be attractive to small businesses which do not have the financial resources required to defend their IP rights, or organisations such as universities which rely on non‑exclusive licensing (STOA 2007).

### Licence-of-right provisions in other countries

In addition to the United Kingdom, LOR provisions exist in national patents legislation in Switzerland, Germany, New Zealand, Singapore and a number of developing countries. There has also been a proposal to establish a LOR system as part of a Community Patent across the European Union (EU) (Schovsbo 2009). Text related to this proposal is included in draft regulations for the Community Patent:

The proprietor of a European patent with unitary effect may file a statement with the European Patent Office that he-she is prepared to allow any person to use the invention as a licensee in return for appropriate compensation. (Council of the European Union 2011)

Under the *Patents Act 1977* (UK), once a patent is granted, the patent holder may apply to the Comptroller of Patents for an entry in the patent register that its patented invention is available as a LOR. The Comptroller will check if the patent holder is precluded by a contract from offering their patent as a LOR. Once entered into the register, the invention is available for licensing to any party. The parties must agree on the licence terms or, failing agreement, the Comptroller of Patents can set them. Renewal fees are halved for patents made available as a LOR. At any time during the life of a patent, the patent holder may apply to have a LOR removed, provided there is no existing licence under that patent. If a LOR is removed, the patent holder must repay the fee discounts they received.

Similarly, in New Zealand and Singapore, the terms of a LOR are negotiated between the patent holder and the licensee or, in the event that the parties fail to reach agreement, the Commissioner of Patents (for New Zealand) and the Registrar of Patents (for Singapore) may be asked to settle the terms. In both countries, renewal fees are halved for patents registered as a LOR (NZ Ministry of Business Innovation and Employment, pers. comm., 21 November 2012; IPOS 2012a).

It appears that LOR mechanisms are only used for a small proportion of patents. In the United Kingdom, Schovsbo (2009) attributed this to a lack of awareness of the possibility of a LOR, and unattractiveness of negotiating licensing agreements because no model licence was available. The number of UK LOR applications has fluctuated over time (figure 9.2). As of 22 November 2012, 9622 LORs (about 2.5 per cent of patents in force) were registered on the UK patents register (UK IPO pers. comm.,23 November 2012). It would be difficult to measure the impact of LORs in the United Kingdom, as patent holders are not required to register licences.

Figure 9.2 UK licence of right applications, 2002 to 2011

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*Source*: UK IPO (pers. comm., 31 October 2012).

In Singapore, there were almost 200 patents registered as a LOR in 2012 (about 0.5 per cent of patents in force) (IPOS 2012a; IPOS 2012b). In New Zealand, of approximately 37 000 patents in force in 2012, only four were registered as LORs (NZ Ministry of Business Innovation & Employment, pers. comm., 21 November 2012). The limited use of LORs in these countries suggests that they have had a small impact on the number of voluntary licences negotiated.

The term ‘licence of right’ is sometimes used to refer to non-voluntary measures to access patents. For example, under Swiss law, research tools fall outside the scope of the research exemption. A LOR was introduced to safeguard access to essential research tools. If an owner of a patent related to a research tool refuses to grant a licence, a judge will grant a non-exclusive licence and determine the terms and conditions (Van Zimmeren and Van Overwalle 2011).

A number of countries have removed LOR provisions from their patents legislation. Prior to 1992, Canadian law imposed a non-voluntary LOR on all patented pharmaceutical products marketed in Canada. Generic manufacturers could produce and market patented medicines in return for paying a royalty, which the Commissioner of Patents typically set at 4 per cent of revenue (Reichman 2010). According to Reichman, critics argued that, although it helped to establish the generics industry, the Canadian LOR discouraged the establishment of a research-based sector. In the early 1990s, the US Government pressed the Canadian Government to abandon its LOR scheme in exchange for US producers contributing a share of their profits to support medical research in Canada. The Canadian LOR approach was later prohibited by the North American Free Trade Agreement (Reichman 2010).

In France, a special LOR provision was recently removed from the French Intellectual Property Code because it had never been used (Van Zimmeren and Van Overwalle 2011). The LOR provision in the *Indian Patents Act 1970* was removed in 2002 to make the Indian patents regime compliant with the TRIPS agreement (IELRC 2002; Indian Government 2002).

The New Zealand Parliament is currently considering a Bill that, as part of a major revamp of that country’s patents legislation, would repeal its LOR provisions (appendix B). According to the NZ Ministry of Business Innovation & Employment (pers. comm., 21 November 2012), the reason for this is that very few New Zealand patents have been endorsed with a LOR, which suggests they are not fulfilling any useful purpose.

### Is a licence-of-right mechanism warranted in Australia?

Adopting a LOR mechanism in Australia would not address cases where patent holders are unwilling to license widely, but it may be useful in facilitating voluntary licensing when they are willing to do so. It would be desirable for such a mechanism to be technology neutral, as occurs in other countries, rather than being specific to a particular area such as gene patents.

It appears that the cost of introducing a voluntary LOR mechanism would be low, particularly if changes are introduced as part of a package of other legislative changes. There would be some costs involved in maintaining a register of LORs, but they would be relatively small. Maintaining an arbitration mechanism for cases where the parties cannot agree on licence terms would be more problematic. Moreover, the limited use of LOR mechanisms in other countries, and their abolition in some cases, suggests that the benefits are small and may not outweigh the costs.

The Commission has not identified any research on LOR mechanisms in other countries that would be useful in determining whether the adoption of such a mechanism in Australia would deliver a net benefit. Participants are invited to provide further input on this issue.

information request 9.1

The Commission requests further input on the likely costs and benefits of introducing a licence-of-right mechanism in Australia, and whether there would be a net benefit. Feedback is also sought on how such a mechanism should be designed, such as:

* how licence terms and conditions would be determined in cases where the parties fail to reach an agreement
* whether incentives should be provided to patent owners who register a licence of right, such as the reduced patent renewal fees offered in some countries.

## Other measures to encourage voluntary licensing

A perceived benefit of compulsory licensing is its deterrent effect against refusals to licence on reasonable terms. Consideration could also be given to measures that facilitate voluntary licensing, as noted above for a LOR mechanism. This section examines whether voluntary licensing should be encouraged through model licences and discounted patent fees.

### Model licensing agreements and guidelines

The cost and complexity of drafting and negotiating licence agreements is a major obstacle to licensing patents, as found in an OECD survey of European and Japanese firms (Zuniga and Guellec 2009). Patent licensing agreements are generally negotiated on an individual contract basis. Firms often have complex licensing strategies and use the expertise of patent attorneys in negotiating patent licensing agreements. Nonetheless, the development of model agreements and interpretative guidelines for patent licensing, particularly for small business, could facilitate voluntary licensing.

As discussed in chapter 10, a number of industry organisations (for example, AusBiotech Ltd, the Australian Institute for Commercialisation, and the Licensing Executives Society) have programs and activities that provide information, education and training related to licensing of intellectual property and technology commercialisation practices. However, this does not generally include model agreements and guidelines for patent licensing.

Model patent licence agreements such as that published by Creative Commons (2012) serve as potential examples of model agreements. This is a standard model licence to use in a public licence offer that aims to provide a ‘science commons’ to facilitate research. A licensee can use a public offer to publicise its willingness to licence patent rights in a reasonable and non-discriminatory manner. The agreements are intended to attract potential licensees who might otherwise not have been aware that certain patent rights were available for licence or who might be unwilling to approach the licensor because of the expected large transaction costs associated with negotiating a licence.

Other examples are the model research collaboration agreements published by the UK Intellectual Property Office in 2005, following the Lambert Review of Business-University Collaboration (box 9.6). These were developed as a mechanism to foster technology transfer between universities and business, and have been used by a number of organisations, including SMEs, to reduce the costs, time and uncertainty of negotiating collaboration agreements (HM Treasury 2006). While there is limited evidence of the use and impact of the agreements, one survey found that around 60 per cent of respondents believed the model agreements simplified the process of constructing contracts and has saved them time (UK IPO, pers. comm., 31 October 2012).

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| Box 6 UK model research collaboration and consortium agreements |
| The UK Intellectual Property Office published the Lambert toolkit for universities and companies that wish to undertake collaborative research projects with each other. The toolkit includes:   * Model Research Collaboration Agreements — these are five different agreements which cover one-to-one projects, with each providing a different approach depending on which party is to own and have the right to exploit the intellectual property. The terms of the five model agreements vary based on whether the sponsor has exclusive rights to use intellectual property or may negotiate further licensing or assignment of some of the university’s IP, or whether the university has the right to use the IP for non-commercial purposes. * Model Consortium Agreements — these are four agreements that are used when more than two parties are collaborating. They use the same terminology and structure as the five research agreements, but contain additional provisions to cover some of the complications that arise as a result of having more than two parties. |
| *Source*: UK IPO (2012). |
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The Australian Government (2011) accepted, in principle, a recommendation made by the ALRC (2004) that Biotechnology Australia, in collaboration with stakeholders, develop model materials transfer agreements for use by research organisations. The Australian Government also agreed to investigate options for developing model agreements and interpretative guidelines for patent licences involving genetic materials and technologies. These were to be non-binding model agreements developed in collaboration with Biotechnology Australia, state and territory governments, and other relevant stakeholders. However, Biotechnology Australia was abolished in 2008, and it appears that the recommended model agreements were not developed.

While model agreements have the potential to reduce the costs of patent licensing, it is questionable whether a one-size-fits-all approach can work in practice. The rapid pace of technological development and diversity of patent licensing arrangements might limit the usefulness of model licensing agreements, even for use within a specific field of technology. Licensing arrangements vary based on a wide range of characteristics such as: the licence type; duration; field of use; remuneration for the licensor; exclusivity of the licence; and obligations and rights of the licensee and licensor (chapter 4). The Centre for Law and Genetics submitted:

While there have been attempts to draft standard licensing agreements for the licensing of genetic inventions, their success has been limited, probably due to the fact that so many different licence terms are used within the industry, and because the technology being licensed is in a constant state of development and modification. (sub. 3, p. 9)

Thus, the Commission does not consider that there is a strong case for requiring governments to develop model licences. However, interpretive licensing guidelines have been developed in some sectors with the aim of fostering more effective and efficient transfer of technology and delivery of new products to market. In response to concerns about how certain genetic inventions have been licensed and exploited, particularly for diagnostic genetic services, OECD member countries agreed to guidelines for the licensing of genetic inventions used for human healthcare purposes. The guidelines outline principles and best practice for business, researchers and health providers that enter into licensing agreements and are intended to stimulate genetic research while maintaining appropriate access to health products and services. While the guidelines outline basic licensing terms and concepts, they are not intended to cover all aspects of licensing, material transfer or technology transfer agreements (OECD 2006).

### Discounted patent fees

Another potential mechanism to encourage voluntary licensing could be to provide financial incentives through discounted patent fees. For example, patent holders could pay a reduced level of patent renewal fees if they enter into licensing agreements.

IP Australia’s patent fees include charges for patent application, examination and renewal. Renewal fees are charged annually by IP Australia, and rise during the term of a standard patent, from $300 on the 4th anniversary of the filing date, to $2300 on the 20th anniversary of the filing date (appendix B). Separate fees are charged for filing and examination processes associated with Patent Cooperation Treaty applications. The costs associated with applying for and maintaining a patent generally include both the official application fees and patent attorney fees. Based on a study of international patenting costs, Australian patent renewal fees accounted for about 60 per cent of total patent costs, and patent attorney fees accounted for about 35 per cent (not including patent litigation costs) (appendix B). Renewal fees accounted for about 95 per cent of total official and maintenance fees.[[6]](#footnote-7)

The extent to which discounted patent fees increase incentives for patent holders to enter into licensing agreements will depend on the magnitude of these fees relative to other costs of patenting as well as the potential economic benefits from licensing a patent. Reducing official patent fees (at least maintenance and renewal fees) is unlikely to encourage voluntary licensing when they are small in proportion to potential licensing revenue.

As discussed in chapter 4, some firms may choose to license out patents for strategic reasons, for example, to prevent others from infringing on a patent or to establish a patented technology as a defacto industry standard. Some firms may decline to licence their patents to avoid disclosure of commercially sensitive information to third parties and create a barrier to imitation by potential competitors to maintain market share. In such cases, reducing patent fees is unlikely to affect firm incentives to license their patents.

Moreover, reducing patent fees would compromise IP Australia’s ability to fund its activities, which is based on a cost-recovery model. Given these considerations, there do not appear to be strong grounds for lowering patent fees.

1. The exception under NPP 6.1(g) covers circumstances where providing access to personal information would be a breach of confidence under the law, for example a breach of professional privilege (OFPC 2001). [↑](#footnote-ref-2)
2. There were five MBS-listed tests: BCR/ABL1, F5, FMR1, HFE and HLA-B. [↑](#footnote-ref-3)
3. Detection of mutation of the human hemochromatosis protein encoded by the HFE gene is used to test for hemochromatosis, a metabolic disorder that causes iron overload in the human body. [↑](#footnote-ref-4)
4. The volume of cytogenetic services doubled between 2006 and 2007 due to the addition of several new genetic tests on the MBS. [↑](#footnote-ref-5)
5. The decision to subsidise an item is considered by Cabinet if the net cost to the PBS is greater than $10 million per year, and then determined by the Minister for Health and Ageing. [↑](#footnote-ref-6)
6. Official and maintenance fees include charges for filing, examination, granting and renewal of patents. Maintenance fees are patent renewal fees or annuities that are estimated as the non‑discounted sum across 20 years of protection (Park 2010). [↑](#footnote-ref-7)