CHAPTER 2

BACKGROUND TO THE INQUIRY

INTRODUCTION

2.1 This chapter provides a brief description of the broader context in which the inquiry occurred, including:

- the events surrounding the attempted enforcement of rights relating to patents for the so called 'breast cancer genes', BRCA1 and BRCA2, by Genetic Technologies Ltd (Genetic Technologies) in Australia; and
- previous and current inquiries into issues relevant to gene patents.

2.2 To frame the analysis and discussion in following chapters, this chapter also provides an outline of:

- the definition of and rationale for the patent system;
- the nature of patent rights;
- the criteria for the grant of a patent; and
- processes for challenging the validity of patents.[1]

The BRCA1 and BRCA2 gene patents

2.3 The gene patents inquiry was instigated largely in response to concerns arising from attempts by Genetic Technologies in 2002-03 and 2008 to enforce its patent rights over the BRCA1 and BRCA2 genes (the BRCA genes) in Australia.

2.4 The BRCA gene patents relate to methods and materials used to isolate and detect mutations in two genes that may indicate a predisposition to certain cancers, notably breast cancer and ovarian cancer. The patent holder is an American company, Myriad Genetics Ltd (Myriad), which has granted Genetic Technologies the exclusive rights to BRCA1 and BRCA2 testing in Australia. Associate Professor Judy Kirk, Director, Familial Cancer Service, Westmead Hospital, explained the significance of the BRCA genes:

> …[Some] families have an inherited fault in a gene which puts them at an incredibly high risk of developing breast and ovarian cancer, and prostate cancer in the men. The two genes that we test in these families are known as BRCA1, the breast cancer 1 gene, and BRCA2…These are genes that we all have and these sequences are in every human being. They are normally involved in cell growth…We will not all have an identical BRCA1 gene.

---

1 The discussion of the patent system in this chapter is not intended to provide an exhaustive description of the patent system, but focuses on those aspects that are most relevant to the issues raised in evidence to the inquiry.

> But some of us…will have a fault or a mutation that is big enough to cause a problem with the protein that that gene makes. Those are the people who are at very high risk of cancer. If we can identify those high-risk individuals we have a great deal to offer them in terms of cancer screening and cancer prevention and even targeted therapies.[2]

Attempted enforcement of rights over BRCA genes by Genetic Technologies

2.5 In 2002-03 and 2008, Genetic Technologies sought to enforce its rights in relation to the BRCA genes in Australia. As is discussed below, the grant of a patent gives a patentee exclusive rights to exploit their patented invention, which means that they can prevent other parties from using or exploiting that invention. In the case of the BRCA genes, Genetic Technologies wrote to research bodies and other entities seeking to prevent these entities from engaging in any further testing for the BRCA genes. For example, representatives of the Peter MacCallum Cancer Centre (PMCC) advised that in both 2002-03 and 2008 the Centre had received 'cease and desist' letters from Genetic Technologies. The letters instructed PMCC to stop conducting BRCA testing and refer all future samples to Genetic Technologies for testing.[3]

2.6 Ultimately, however, Genetic Technologies dropped its legal demands in relation to testing for the BRCA genes. In a report to shareholders on 9 July 2003, Genetic Technologies noted that it was not seeking to enforce its rights over the genes and stated that the BRCA genes 'are our gift to the Australian people'.[4] Similarly, in relation to the attempt in 2008, Genetic Technologies announced that it had reviewed its decision to assert its rights over the testing, and had 'resolved to immediately revert to its original decision to allow other laboratories in Australia to freely perform BRCA testing'.[5]

2.7 In relation to the 2008 demands, the Committee understands that state health departments negotiated with Genetic Technologies following the issuing of the 'cease and desist' letters. While the inquiry did not receive any definitive account of Genetic Technologies' reasons for withdrawing its demands, a number of reasons were suggested. These included that:

---

2 Associate Professor Judy Kirk, *Committee Hansard*, 5 August 2009, p. 50.

3 Professor Stephen Fox, Peter MacCallum Cancer Centre, *Committee Hansard*, 4 August 2009, pp 119-120.

4 Genetic Technologies Limited website, 'A report to shareholders', 9 July 2003, http://www.gtg.com.au/index.asp?menuid=060.070.130.010&artid=98 (accessed 7 October 2009).

5 Genetic Technologies Limited website, 'New position re BRCA testing', 2 December 2008, http://www.gtg.com.au/index.asp?menuid=060.070.130&artid=10748&function=NewsArticle (accessed 7 October 2009).

- there was widespread public and professional criticism of Genetic Technologies for seeking to enforce its rights, and the company wished to avoid further negative publicity;
- Genetic Technologies' purported gifting of the test to the Australian people in 2002-03 may have rendered the enforcement of its rights problematic;
- negotiations with health departments may have indicated that the demands and/or the patents would be legally contested on certain grounds;[6] and/or
- the Australian Competition and Consumer Commission (ACCC) was considering, or had instituted,[7] an investigation into whether the matter raised issues of anti-competitive behaviour.

2.8 In correspondence to the Committee, the ACCC advised that, in response to Genetic Technologies' attempt to enforce its rights over the BRCA testing in 2008, the Commission had begun to consider concerns that the attempt by Genetic Technologies to withdraw access to its intellectual property rights raised issues under section 46 of the *Trade Practices Act 1974* (TPA), which relates to misuse of market power. In determining this question, the ACCC was considering:

- whether Genetic Technologies had market power in a market concerning the provision of testing services for susceptibility to breast cancer by way of its exclusive licence over the patents;
- whether Genetic Technologies took advantage of any market power or had taken advantage of its exclusive licenses; and
- if Genetic Technologies had taken advantage of its market power, whether it was for the purpose of eliminating, or substantially damaging, its competitors.

2.9 However, following advice that Genetic Technologies had decided not to seek to enforce its rights over the BRCA patents, the ACCC advised that it was not ultimately required to form a view as to whether Genetic Technologies had breached section 46 or any other provision of the TPA.[8]

2.10 The attempts by Genetic Technologies to enforce its rights over the BRCA genes in Australia highlighted significant concerns about the potential impacts of gene patents on the healthcare industry, particularly in terms of medical research and the delivery of healthcare (as reflected by this inquiry's terms of reference). Despite the withdrawal of Genetic Technologies' demands, there has been much public discussion and debate about the potential for the BRCA or other gene patents to adversely impact

6 Dr Gerard Cudmore, Office for Science and Medical Research, Department of Industry and Investment, New South Wales, *Committee Hansard*, 5 August 2009, p. 91.

7 Mr Chris Reid, Department of Health and Ageing, *Committee Hansard*, 20 August 2009, p. 45.

8 Australian Competition and Consumer Commission, correspondence dated 16 October 2009, p. 2.

on these areas both now and in the future. These issues are fully considered in Chapter 3.

AUSTRALIA'S PATENT SYSTEM

2.11 An understanding of the operation of Australia's patent system is fundamental to any consideration of the issues around gene patents and their effect on the matters described by the inquiry's terms of reference: healthcare, medical research and the health and wellbeing of Australians.

2.12 The legislation which governs the patent system in Australia is the *Patents Act 1990*.

Definition of a patent

2.13 A patent is a private property right granted by the Crown to the inventor of a product, method or process in a field of technology.[9] A patent allows the patent holder to prevent others from exploiting the invention, and so to maximise the commercial potential of the invention for the duration of the patent. In simple terms, a patent grants a monopoly to the patent holder.

Purpose of the patent system

2.14 Unlike many Acts, the *Patents Act 1990* (the Act) does not specifically set out any objects (objectives). However, as noted in the 2004 Australian Law Reform Commission report, *Genes and ingenuity: gene patenting and human health* (the ALRC report), the goal of the patent system is 'fundamentally economic'.[10] The patent system seeks to encourage the availability of new and useful technologies to society through the incentive of a monopoly to commercially exploit an invention for a given period, usually 20 years.[11]

2.15 The patent system further promotes innovation through encouraging the diffusion of knowledge, as it is a condition of the grant of a patent that the inventor is required to publicly disclose their invention. This ensures that others can utilise and build on an innovation to further develop new and useful technologies.

2.16 Mrs Fatima Beattie, Deputy Director-General, IP Australia, summarised the rationale of the patent system in the following way:

> The objective of Australia's patent system is to benefit Australia by stimulating industrial innovation and encouraging technology access and

9 Mark J Davison, Anne L Monotti and Leanne Wiseman, *Australian intellectual property law*, Cambridge University Press, Melbourne, 2008, p. 377.

10 Australian Law Reform Commission, *Genes and ingenuity: gene patenting and human health*, June 2004, p. 53, available at http://www.alrc.gov.au/inquiries/title/alrc99/index.html.

11 *Patents Act 1990*, section 67.

> transfer. The system rewards inventors with a period of exclusivity to prevent others from exploiting their invention in return for disclosing their invention to the public. Diffusion of knowledge in the public domain helps to facilitate research in emerging fields of the patented invention.[12]

Nature of patent rights

Scope of patent rights

2.17 As noted above, the grant of a patent gives the patent holder a monopoly, or exclusive rights, over an invented product or process. In relation to a product, the Act defines the term 'exploit' as:

- the making, hiring, selling or otherwise disposing of the product;
- offering to make, sell, hire or otherwise dispose of the product;
- the use or import of the product; and
- the keeping of the product for any of the above purposes.

2.18 In relation to a process, the term 'exploit' is defined as using the process or method to do any of the acts outlined above in respect of a product resulting from such use.[13]

2.19 A patent holder might seek to exercise their patent rights in any number of the ways described above in seeking to maximise the profit potential of their patent. It is also common for patent holders to enter into a licence agreement with a third party to allow that party to exploit an invention in certain ways. Such agreements may be entered into exclusively or concurrently with a number of parties. As noted above, the patent holder for the BRCA gene patents is an American company, Myriad, which has granted exclusive rights to Genetic Technologies for the exploitation of those patents in Australia.

Limits on patent rights

2.20 Despite the theoretical breadth of patent rights, in practice a patent does not grant an absolute right to exploit an invention in any way the inventor may choose. The ALRC report explains:

> A patent holder may have to satisfy regulatory requirements in order to exploit the patented product or process; for example, a patented pharmaceutical compound may need approval under the *Therapeutic Goods Act 1989* (Cth) before it can be marketed lawfully and sold as a treatment

---

12 Mrs Fatima Beattie, IP Australia, *Committee Hansard*, 19 March 2009, p. 3. For a brief overview of the historical development of the patent system see Mark J Davison, Anne L Monotti and Leanne Wiseman, *Australian intellectual property law*, Cambridge University Press, Melbourne, 2008, pp 378-381.

13 *Patents Act 1990*, Schedule 1, Dictionary, p. 160.

> for a particular condition. Similarly, the use of a patented invention is subject to the general law; for example, the components required to manufacture a car may be the subject of many patents, but the car must still be used in accordance with motor traffic laws.[14]

2.21 Further, and of particular significance to the inquiry, a patent holder's rights might also be limited or constrained by operation of certain provisions of the Act, pertaining to compulsory licences and Crown use.[15] These are discussed in more detail in Chapter 5.

2.22 In Australia, it is uncertain as to whether a research exemption exists in relation to the patent system. This issue is discussed in more detail in Chapter 5.

Requirements for grant of a patent

2.23 The Act contains a number of criteria or requirements for patentability of an invention under Australian law. Together, these criteria establish a threshold for the patentability of an invention. The Act provides that an invention will be patentable if, inter alia, it:

- is a 'manner of manufacture';
- is novel;
- involves an inventive step;
- is useful; and
- the details of the invention are sufficiently well disclosed or described.[16]

Manner of manufacture

2.24 The Act requires that an invention be a 'manner of manufacture'.[17] This relates to the question of what can be the subject matter of a patent. Put simply, it means that a patent must relate to 'an artificial state of affairs':[18] a product, process or method that

---

14 Australian Law Reform Commission, *Genes and ingenuity: gene patenting and human health*, June 2004, p. 55, available at http://www.alrc.gov.au/inquiries/title/alrc99/index.html.

15 *Patents Act 1990*, sections 133 and 163. The Act also contains provisions under which the Governor-General may direct that a patent or invention that is the subject of a patent application be acquired by the Commonwealth (for payment of compensation). These provisions were not addressed in the submissions and evidence to the inquiry and are not discussed further in this report.

16 The requirements discussed here are not exhaustive but focus on those aspects of patent law that are most relevant to the issues raised by the inquiry.

17 *Patents Act 1990*, section (18)(1)(a).

18 Department of Innovation, Industry, Science and Research and IP Australia, *Submission 19*, p. 3.

arises through some form of 'human intervention with nature to bring about some physical change'.[19]

2.25 The Act does not define 'manner of manufacture' but merely states that an invention must be a 'manner of manufacture within the meaning of section 6 of the *Statute of Monopolies*', a law from 1623 pertaining to monopolies.[20] The decision not to specifically define the term in the Act reflects a view at the time of its creation that it would be 'difficult to draft a definition that would adequately reflect the body of law that had progressively fleshed out the concept of a manner of manufacture'.[21]

2.26 Moreover, a number of reviews of Australia's patent system preceding the passage of the Act had concluded that the 'manner of manufacture' test should be retained because its flexibility allows it to respond to or encompass new developments in technology or human ingenuity.[22] Prior to 1959, judicial interpretations had driven a significant evolution of the term 'manner of manufacture' in respect of the scope of patentable subject matter. Along with the extension of the term to include processes as well as products, a number of general and specific classes of unpatentable inventions had been identified, including:

- a general prohibition on the patenting of intellectual information and conceptions, such as business schemes, instructions, mathematical formulae, discoveries and principles of nature; and
- specific prohibitions on the patenting of certain subject matter, such as methods for medical treatment of humans and living matter.

2.27 However, in 1959, the basis of the current legal conception of the term 'manner of manufacture' was established by the High Court case *National Research Development Corporation v The Commissioner of Patents* (the NRDC case).[23] In simple terms, the court endorsed a more expansive definition of 'manner of manufacture', whereby patentability is determined by reference to the policy intent of the (then) Act rather than by application of a strict definition.[24] The ALRC report provides the following summary of the present approach to interpreting 'manner of manufacture':

---

19 Mark J Davison, Anne L Monotti and Leanne Wiseman, *Australian intellectual property law*, Cambridge University Press, Melbourne, 2008, p. 377.

20 The *Statute of Monopolies* may be understood as the originator of modern patent law statutes.

21 Mark J Davison, Anne L Monotti and Leanne Wiseman, *Australian intellectual property law*, Cambridge University Press, Melbourne, 2008, p. 409.

22 Australian Law Reform Commission, *Genes and ingenuity: gene patenting and human health*, June 2004, p. 118, available at http://www.alrc.gov.au/inquiries/title/alrc99/index.html.

23 (1959) 102 CLR 252.

24 Mark J Davison, Anne L Monotti and Leanne Wiseman, *Australian intellectual property law*, Cambridge University Press, Melbourne, 2008, pp 408-9.

> For an invention to be a 'manner of manufacture', as interpreted in NRDC, it must belong to the 'useful arts' rather than the 'fine arts'; it must provide a material advantage; and its value to the country must be in the field of economic endeavour. However, judicial interpretation has also recognised a number of categories of subject matter that will fail to satisfy the test. These include mere discoveries, ideas, scientific theories and laws of nature.[25]

2.28 IP Australia identified the following principles from the NRDC case:

- the distinction between discovery (which is unpatentable) and invention is very fine;
- it is the practical application of information to a useful end that takes a discovery into the realm of 'manufacture';
- 'manner of manufacture' should not be rigidly defined: its purpose is to encourage national development in 'excitingly unpredictable fields'; and
- an invention is patentable if it gives rise to an 'artificially created state of affairs' in the 'field of economic endeavour'.[26]

2.29 A second significant element in the approach of Australian courts in determining whether an invention is a 'manner of manufacture' is that the Act contains few specific limitations on patentable subject matter. These are:

- human beings and the biological processes for their generation; and
- plants and animals, and the biological processes for the generation of plants and animals.[27]

2.30 A number of judicial comments have indicated that the absence of express statutory exclusions has been influential in the willingness of courts to accept broader subject matter as a manner of manufacture.[28] Together, the NRDC case and the lack of express prohibitions on patentability in the Act have had an expansive effect on the limits of patentable subject matter in Australia:

> The lack of express statutory exceptions combined with the breadth of the *NRDC* judgment has enabled courts to remove the fetters that may otherwise prevent new developments from being patentable. The result has been a piecemeal erosion of formerly perceived classes of excluded subject

---

25 Australian Law Reform Commission, *Genes and ingenuity: gene patenting and human health*, June 2004, p. 118, available at http://www.alrc.gov.au/inquiries/title/alrc99/index.html.

26 Department of Innovation, Industry, Science and Research and IP Australia, *Submission 19*, p. 13.

27 Section 18(2) and (3). The second limitation applies in respect of innovation patents, a form of patent not further discussed in this report. For further information on innovation patents see IP Australia website, http://www.ipaustralia.gov.au/patents/what_innovation.shtml (accessed 10 September 2009).

28 See for example *Rescare Ltd v Anaesthetic supplies Pty Ltd* (1992) 25 IPR 119, 151 (Gummow J); and *Bristol-Myers Squibb Co v F H Faulding & Company Ltd* (2000) 97 FCR 524.

> matter. *NRDC* itself rejected the former exclusion of patents for horticultural and agricultural methods. Subsequent decisions declared patents valid for computer programs and methods of medical treatment for humans with the result that a number of formerly excluded classes of subject matter are now regarded as patentable. Patents are granted for computer programs, computer implemented systems used in business, living plants, animals, genetic materials and recombinant DNA techniques.[29]

2.31 In relation to gene patents in particular, the IP Australia submission advises:

> Despite the long judicial history, to date no court decision in Australia has considered specifically whether isolated and purified gene sequences are proper subject-matter for patents. In the absence of Australian precedents, IP Australia has turned for guidance to decisions and practice relating to chemical compounds.[30]

Discovery v invention

2.32 In the context of genes and genetic materials, the requirement that an invention be a manner of manufacture assumes particular importance in relation to a longstanding distinction between inventions and discoveries under the law, and this issue was raised in numerous submissions to the inquiry.

2.33 Patent law recognises only 'inventions' as being patentable; 'discoveries' are not patentable. Evidence to the inquiry revealed strong differences of opinion over IP Australia's current practice of accepting isolated or purified genetic sequences as 'inventions'. This issue is discussed in detail in Chapter 4.

'Contrary to law' and 'generally inconvenient' exclusions

2.34 The Statute of Monopolies provides that a patent may not be granted on the grounds that a new manner of manufacture is 'contrary to law' or otherwise 'generally inconvenient'. The Advisory Council on Intellectual Property (ACIP) options paper on patentable subject matter explains:

> Section 6 of the Statute of Monopolies provides that patents are only available for manners of new manufacture that are 'not contrary to law nor mischievous to the state by raising prices of commodities at home or hurt of trade or generally inconvenient'. This results in a definition of invention that

29 Mark J Davison, Anne L Monotti and Leanne Wiseman, *Australian intellectual property law*, Cambridge University Press, Melbourne, 2008, p. 410. For further discussion of the development of exclusions in the *Patents Act 1990* see Dr Hazel Moir, *Submission 20*, p. 25.

30 Department of Innovation, Industry, Science and Research and IP Australia, *Submission 19*, p. 13.

> goes beyond technological development and includes social and economic factors.[31]

2.35 However, the ACIP paper notes that under Australian law it is currently unclear whether inventions can be excluded from patenting on public policy grounds, such as for being 'generally inconvenient':

> Arguably, patents may also be refused on public policy grounds where the grant of a patent would be 'generally inconvenient'. This arises from the reference to section 6 of the *Statute of Monopolies* in the definition of invention. Unlike the other exclusions, general inconvenience forms part of the definition of invention rather than a category of inventions to be excluded from patentability. However, its meaning and its ongoing application is unclear.[32]

2.36 The availability of general exclusions such as on the grounds that an invention is 'generally inconvenient' is the subject of an inquiry by ACIP into patentable subject matter. The issue of general and specific exclusions to patentable subject matter and the ACIP review are discussed in Chapter 5.

Novelty

2.37 A claimed invention must be novel or not previously known. This question relates to the issue of whether there has been previous publication or use of an invention.

2.38 The requirement for 'novelty' is simply understood as ensuring that a patent is only granted for an invention that is truly new, in the sense of being not previously known in a given field of knowledge. This means that, at the time of application for a patent, the details of the invention must not have been 'published or made publicly available through use anywhere in the world'.[33]

2.39 Whether an invention is novel is judged by a comparison with the state of knowledge in the field relevant to the invention, which is referred to as the 'prior art base'.

Inventive step

2.40 A claimed invention must involve an 'inventive step'. This question relates to the level of ingenuity required for an invention to be granted a patent.

---

31 Advisory Council on Intellectual Property, 'Patentable subject matter: options paper', September 2009, p. 34.

32 Advisory Council on Intellectual Property, 'Patentable subject matter: options paper', September 2009, p. 16.

33 Mark J Davison, Anne L Monotti and Leanne Wiseman, *Australian intellectual property law*, Cambridge University Press, Melbourne, 2008, p. 377.

2.41 The requirement that an invention involve an inventive step is fundamental to the patent system, as it ensures that a monopoly is not awarded for knowledge that was obvious or that would have been available at the time of the patent application.

2.42 Whether an invention involves an inventive step is judged by a comparison with the state of knowledge in the field relevant to the invention, which is referred to as the 'prior art base'. The prior art base includes information in a document, or information made publicly available by doing an act, anywhere in the world; and 'common general knowledge' in the relevant art in Australia.[34]

2.43 The element of inventive step was relevant to a number of issues raised by submitters and witnesses in relation to gene patents.

Challenging patents

2.44 IP Australia submitted that there are in total four opportunities for the validity of a patent to be tested under the Act:

- each application is examined by IP Australia before it may be accepted or refused (examination);
- each accepted application may be opposed before grant by any party, including the Minister (opposition);
- applications may be re-examined before grant at the discretion of the Commissioner of Patents, and the patent must be re-examined after grant on request from any person in an approved form, including the Minister (re-examination); and
- post-grant, the validity of a granted patent can be challenged in the courts by any party, including the Minister (revocation).

2.45 The evidence to the inquiry concerning the testing of the validity of patents mainly concerned the examination stage of the patent process. The main requirements of patent examination were described above.

Revocation of granted patents

2.46 Evidence concerning post-grant challenges to patents (revocation) highlighted that this is a time-consuming and costly process that is usually only pursued by commercial interests.

2.47 The Committee heard claims that there is a significant number of patents of questionable quality currently in force, and there was therefore some consideration of the possibility of challenging granted patents through post-grant opposition in the courts—that is, by seeking their revocation.

---

34 IP Australia, 'Getting the balance right: towards a stronger and more efficient IP rights system', March 2009, p. 10.

2.48 It is important to understand that, under the Act, a grant of a patent by the Commissioner of Patents (the Commissioner) does not guarantee or necessarily imply that a patent is legally valid.[35] This means that the revocation of a patent may always be sought, and in fact the patent system is premised on the idea that patents may or will be tested through legal proceedings. Once a patent is granted, a person may apply to the Commissioner to have the patent revoked. The grounds for any such application are set out in section 59 of the Act, with the most relevant for the purposes of the inquiry being that the 'invention is not a patentable invention' (section 59(b)). This ground encompasses all the aspects of validity set out in sections 18(1) and (2), including that the invention:

- is not a manner of manufacture;
- lacks novelty; and
- is obvious (that is, does not meet the inventive step requirement).

2.49 The Commissioner must determine an application in accordance with the Patents Regulations 1991. Decisions of the Commissioner may be appealed to the Federal Court by any party.[36]

Obstacles to seeking revocation of patents through the courts

2.50 The evidence of many submitters and witnesses pointed to the expense of opposing patents through the courts, given the complex technical and legal aspects of the patent system. As noted above, the grant of a patent does not guarantee that all the requirements of patentability are satisfied, so in fact the patent system is premised on the idea that questionable patents may or will be tested in the courts. Dr Hazel Moir explained that '[no] application which the patent office accepts can be assumed to be valid until it has been tested [in the courts]'.[37]

2.51 However, the Committee heard that there are relatively few court challenges to granted patents, except in cases where there are sufficient commercial motives and resources involved. Dr Luigi Palombi explained:

> …the real problem is that we have no efficient way of testing the validity of these patents. It costs millions of dollars, it costs a lot of time, and you need to be a very sophisticated litigant to actually test the validity of these patents…It is also very difficult for non-profit, charitable organisations, such as the Cancer Council, to run the risk of litigation. Under the rules in Australia, if you sue and you lose you have to pay the costs, even if lawyers were to do that case for free.[38]

35 See *Patents Act 1990*, sections 20 and 21.

36 *Patents Act 1990*, sections 59 and 60.

37 Dr Hazel Moir, *Committee Hansard*, 20 August 2009, p. 6.

38 Dr Luigi Palombi, *Committee Hansard*, 14 September 2009, p. 17.

2.52 Dr Palombi noted that a *pro bono* offer to test the validity of the BRCA patents in Australia had been refused by the Cancer Council Australia due to concerns about the potential cost-exposure of the legal proceedings. Dr Palombi observed that 'the whole system is stacked against anyone other than the patentee'. [39]

2.53 The submission of the South Australian Government also pointed to the apparent under-use of the legal system to challenge patents, even in cases where patents are of questionable quality. This is probably attributable to the complexity and high cost of the system. The submission also pointed to other factors, noting in particular that patent insurance is available to patent holders to cover the costs of defending a challenge to a patent's validity. In relation to revocation proceedings, the patent system therefore contains significant disincentives to potential challengers of patents.[40]

2.54 Mr Richard Hamer, Member, Business Law Section, Law Council of Australia (LCA), observed that legal challenges to patents are more common where large commercial interests are at stake. In the case of pharmaceutical patents, for example, generic-drug companies are proactive in challenging patents thought to contain any weaknesses. While smaller companies are unlikely to mount challenges, industry associations or other concerned groups have funded patent challenges. However, the LCA was not aware of any specific challenges to gene patents.[41] Mr Hamer noted that in many cases it is uneconomic, given the potential costs and risks of litigation, for patent holders to undertake legal action, even where they are aware of certain patent infringements.[42]

2.55 Some evidence suggested that, in many cases, threat of legal action is secondary to intentions to enter into licence agreements—that is, the threat of legal action is used strategically to persuade another party to negotiate a licence agreement in order to avoid expensive and time-consuming legal battles.[43] However, this raises the prospect that such threats could lead to such agreements being entered into even when based on unmeritorious claims, simply because a party cannot risk the expense of court proceedings.

2.56 Professor Peter Drahos advised that in practice very few patents are challenged in the courts:

> …it is important to remember that very few patents are ever litigated. The litigation rates in the United States are less than two per cent; that is the most active litigation system in the world. In most other countries, it is less

39 Dr Luigi Palombi, *Committee Hansard*, 14 September 2009, p. 17.

40 South Australian Government, *Submission 16*, p. 5.

41 Mr Richard Hamer, Law Council of Australia, *Committee Hansard*, 4 August 2009, pp 83-84.

42 Mr Richard Hamer, Law Council of Australia, *Committee Hansard*, 4 August 2009, p. 87.

43 Mr Richard Hamer, Law Council of Australia, *Committee Hansard*, 4 August 2009, p. 87.

> than one per cent. So relying on courts to reform the patent system is fairly futile, actually.[44]

2.57 Given the expense of challenging patents through the courts, some submitters and witnesses suggested that the Government should consider funding a public interest litigation to challenge the validity of gene patents, particularly in relation to the question of whether human genes and genetic material should be regarded as patentable subject matter. Dr Palombi advised:

> If a test case were to be brought I think that it would be completely appropriate for the Commonwealth to fund the litigation to resolve what is going to happen to the patents that have already been granted. We are probably going to need a court decision to make it clear as to whether or not these patents are valid or whether the claims over isolated biological materials are valid.[45]

2.58 The Committee notes that, on 8 June 2010, Maurice Blackburn Lawyers representing Cancer Voices Australia and Ms Yvonne D'Arcy commenced proceedings in the Federal Court of Australia, seeking to invalidate the BRCA patents in Australia.[46] This is discussed further in Chapter 4.

Re-examination of patents

2.59 The Act provides a discretion to the Commissioner to re-examine an application and a granted patent on an own-motion basis.[47] A third party may not initiate any such re-examination until a patent has been granted. However, once granted, re-examination of a patent must be conducted if a request is received from the patentee or a member of the public (unless there are other proceedings pending);[48] or by a court (section 97(3)).

2.60 On re-examination of a patent specification, the Commissioner must report on whether the claim, when compared with the prior art base:

- is not novel; and
- does not involve an inventive step.[49]

---

44 Professor Peter Drahos, *Committee Hansard*, 20 August 2009, p. 16.

45 Dr Luigi Palombi, *Committee Hansard*, 14 September 2009, p. 13.

46 Cancer Voices Australia & Anor v Myriad Genetics Inc & Ors, Federal Court of Australia, NSD643/2010, available at https://www.comcourts.gov.au/file/Federal/P/NSD643/2010/actions.

47 Mark J Davison, Anne L Monotti and Leanne Wiseman, *Australian intellectual property law*, Cambridge University Press, Melbourne, 2008, p. 399.

48 See *Patents Act 1990*, sections 97, 97(2) and 97(4).

49 *Patents Act 1990*, sections 98(1) and (2). This effectively means that the only grounds available for refusing to grant or revoking the grant of a patent on re-examination are lack of novelty and/or inventive step.

2.61 Following requirements for informing an applicant of any adverse decision, the Commissioner may refuse to grant or revoke a patent. Any such decision by the Commissioner may be appealed to the Federal Court.[50]

2.62 Dr Matthew Rimmer suggested that the re-examination process could provide a more affordable and thus accessible means of challenging the validity of patents:

> Once the patent is granted, it then becomes very difficult to challenge the validity of the patent in terms of the costs and expenses associated with that. The United States regime has been making much greater use of re-examination of patents once they are granted. The Public Patent Foundation, which is a civil society organisation, has been particularly good of late in bringing re-examination requests against critically important patents such as, for instance, the BRCA1 and BRCA2 patents and some of the Wisconsin Alumni Research Foundation's stem cell patents. So some are keen on re-examination as a less expensive means of assessing the validity of patents. Some are interested in postgrant opposition proceedings in relation to the validity of patents. It is a big problem at the moment, because the current environment really allows patent trolls to flourish, because parties in most instances will be willing to pay a licence fee rather than necessarily take legal action.[51]

International patent system

2.63 The Committee heard that the patent system is relatively uniform across a number of countries, following many years of efforts to harmonise intellectual property systems. This has occurred as an aspect of international cooperation in the areas of economic and trade development.

2.64 A number of submissions to the inquiry raised issues related to the international system of patent law. In particular, a number of stakeholders contended that certain reforms to Australia's patent system could place Australia in breach of its international obligations. The potential for reform of Australia's domestic patent system to create breaches of its international obligations was identified in the ALRC report, which observed:

> …[Proposed reforms to the patent system] may have implications for Australia's obligations under multilateral agreements dealing with patents and other intellectual property laws, and under bilateral free trade agreements with other states, including the free trade agreement recently concluded with the United States.[52]

---

50 *Patents Act 1990*, sections 100(3) and 101(4).

51 Dr Matthew Rimmer, *Committee Hansard*, 20 August 2009, p. 16.

52 Australian Law Reform Commission, *Genes and ingenuity: gene patenting and human health*, June 2004, p. 87, available at http://www.alrc.gov.au/inquiries/title/alrc99/index.html.

2.65 Australia is a party to a number of international legal instruments relating to intellectual property, which together reflect the ongoing harmonisation of the systems of the signatories. Australian domestic law has given effect to significant provisions of these agreements, including:[53]

Paris Convention

2.66 The Paris Convention for the Protection of Industrial Property 1883 is the principal international agreement on intellectual property. In relation to patents it provides, inter alia, for mutual recognition of the rights of the nationals of signatory states.

Patent Cooperation Treaty

2.67 The Patent Cooperation Treaty 1970 allows a patent to be filed simultaneously in multiple jurisdictions by filing a single international application in one country. Determining the validity of the patent remains the responsibility of each national patent office.

Budapest Treaty

2.68 The Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure 1977 establishes an international system for the deposit of microorganisms relating to patent applications.

TRIPS Agreement

2.69 The Agreement on Trade-Related Aspects of Intellectual Property Rights 1994 (TRIPS Agreement) establishes, inter alia, the minimum standard of patent protection that each member of the World Trade Organization (WTO) must provide under its national laws. Domestic law may augment any such standards as long as this does not affect the operation of other provisions of the TRIPS Agreement.

2.70 The TRIPS Agreement was the main focus of submissions to the inquiry on Australia's international obligations. A number of aspects of the Agreement were highlighted as being relevant to gene patents, and particularly the question of whether human genes and genetic materials should be expressly prohibited under the Act:

- a requirement that member states make patent protection available for any inventions, whether products or processes, in all fields of technology;
- provision for optional exclusions from patentability that may be adopted by member states; and

53 The following discussion of international agreements is largely based on Australian Law Reform Commission, *Genes and ingenuity: gene patenting and human health*, June 2004, pp 88-93, available at http://www.alrc.gov.au/inquiries/title/alrc99/index.html.

- a right for member states to provide limited exceptions to patent rights, including public policy exceptions, so long as such exceptions do not unreasonably conflict with the normal exploitation of a patent, and do not unreasonably prejudice a patent holder's rights.[54]

2.71 There was significant disagreement amongst some submitters and witnesses concerning the extent to which the TRIPS Agreement prevents Australia from expressly prohibiting or otherwise treating gene patents differently under the Act. This issue is discussed in more detail in Chapter 4.

Australia-United States Free Trade Agreement

2.72 In addition to the agreements outlined above, any reform of Australia's patent system may also have to take into account obligations or constraints arising from bilateral trade agreements with other countries. In particular, the Australia-United States Free Trade Agreement (AUSFTA), entered into on 18 May 2004, contained a number of provisions pertaining to aspects of the patent system, including:

- exclusions from patentability;
- revocation of patents;
- Crown use and compulsory licensing; and
- the requirement of 'usefulness' for patentability.[55]

2.73 The ALRC report notes that AUSFTA may be significant for any suggested reform of Australia's patent system: '[in cases where] the AUSFTA reflects existing Australian law or practice, the agreement may act as a constraint on future change'.[56]

Previous and current inquiries relevant to gene patents

Previous inquiries

2.74 The Committee notes that a number of previous inquiries have reported on both particular and general issues relevant to its inquiry into gene patents. The Committee acknowledges these efforts and was able to draw on this work to inform its own considerations. Notable completed inquiries include:

54 Australian Law Reform Commission, *Genes and ingenuity: gene patenting and human health*, June 2004, pp 88-93, available at http://www.alrc.gov.au/inquiries/title/alrc99/index.html.

55 Australian Law Reform Commission, *Genes and ingenuity: gene patenting and human health*, June 2004, p. 94, available at http://www.alrc.gov.au/inquiries/title/alrc99/index.html. These amendments were passed in the *US Free Trade Agreement Implementation Act 2004*.

56 Australian Law Reform Commission, *Genes and ingenuity: gene patenting and human health*, June 2004, p. 94, available at http://www.alrc.gov.au/inquiries/title/alrc99/index.html.

IPAC review of Australia's patent system

2.75 The report *Patents, innovation and competition in Australia* was presented to the Government on 29 August 1984. It was produced by the Industrial Property Advisory Committee (IPAC), chaired by Mr John Stonier. This report was influential in informing the policy underlying the development of the *Patents Act 1990*.[57]

IPCRC report on competition and intellectual property law

2.76 The *Review of intellectual property legislation under the Competition Principles Agreement* (the Ergas Report) was presented to the Government on 30 September 2000. It was produced by the Intellectual Property and Competition Review Committee (IPCRC), chaired by Mr Henry Ergas.

2.77 The Ergas report concluded that intellectual property laws and competition policy are 'largely complementary' on the basis that the former promotes innovation, 'which is a key form of competition'. However, it acknowledged that a tension exists between the two because of the potential for exclusive rights to promote anti-competitive behaviour:

> It must also be recognised that the rights granted by the intellectual property laws can be used for anti-competitive ends. This occurs when the rights are used to claim for the creator not merely a share of the efficiency gains society obtains from the creation, but also super-normal profits that arise from market power unrelated to the creation.[58]

2.78 The Ergas report concluded that the threshold for obtaining a patent should be higher, on the basis that monopolistic rights can excessively affect competition if granted to inventions that are not truly innovative.[59] The recommendations of the Ergas report (and an earlier ACIP Review of the Enforcement of Industrial Property Rights (patent enforcement))[60] were partially implemented in the *Patents Amendment Act 2001*.[61]

---

57 Industrial Property Advisory Committee, *Patents, Innovation and Competition in Australia*, August 1984, available at http://www.acip.gov.au/library/Patents,%20Innovation%20and%20Competition%20in%20Australia.pdf.

58 Intellectual Property and Competition Review Committee, *Review of intellectual property legislation under the Competition Principle Agreement*, September 2000, p. 6.

59 Parliamentary Library, 'Patents Amendment Bill 2001', Bill Digest No. 1 2001-02, available at http://www.aph.gov.au/library/pubs/BD/2001-02/02bd001.htm.

60 Available at http://www.acip.gov.au/reviews_completed.html#enforce.

61 Parliamentary Library, 'Patents Amendment Bill 2001', Bill Digest No. 1 2001-02, available at http://www.aph.gov.au/library/pubs/BD/2001-02/02bd001.htm.

Australian Law Reform Commission report on gene patenting and human health

2.79 The report *Genes and ingenuity: gene patenting and human health* (the ALRC report) was presented to the government on 29 June 2004. As per usual practice, a broad-based expert advisory committee was established to provide the ALRC with general advice and assistance with the report.

2.80 The ALRC report concluded that it was too difficult to expressly prohibit patents on genetic sequences due to the 'hard and inconvenient fact' of the number of patents that had been granted on genetic sequences since the 1980s.[62] Finding that there was no case for 'radical overhaul of the patents system', the ALRC's recommendations were based on the view that 'it was far preferable to focus on reforms that would directly address the existing problems and make the system work better'.[63]

2.81 The report contained 50 recommendations, which focussed on three areas. These were:

- to the extent that gene patents highlighted any deficiencies in the patenting system, correcting systemic weaknesses in the patent system;
- improving the patent system in general, including a suite of reforms directed at the practices of IP Australia; and
- ensuring the appropriate use and exploitation of gene patents, particularly in the three sectors on which the ALRC was instructed to focus: research, biotechnology and healthcare.

2.82 The recommendations of the ALRC report served as an important reference point for much of the evidence received by the present inquiry in submissions and testimony.[64]

ACIP reviews relating to patent law

2.83 ACIP has completed a number of reviews with particular reference to patent law, including:

- review of Crown use provisions for patents and designs (November 2005); and
- review of patents and experimental use (October 2005).[65]

---

62 Australian Law Reform Commission, *Submission 18*, p. 2.

63 Australian Law Reform Commission, *Submission 18*, p. 2.

64 The full list of the ALRC's recommendations can be viewed via the ALRC web site at http://www.alrc.gov.au/inquiries/title/alrc99/index.html.

65 These reports are available from Advisory Council on Intellectual Property web site at http://www.acip.gov.au/reviews_completed.html#crownuse.

Current inquiries

2.84 At the time of writing, there are also relevant inquiries being conducted by ACIP and IP Australia.

ACIP review of patentable subject matter

2.85 ACIP is conducting a review of patentable subject matter. The review website notes that in recent years a variety of concerns have been raised about the sorts of things that can be patented in Australia, and draws attention to the findings of the ALRC report that the 'manner of manufacture' test is ambiguous and obscure. The review will include consideration of:

- the appropriateness and adequacy of the 'manner of manufacture' test as the threshold requirement for patentable subject matter under Australian law; and
- the historical requirement that an invention must not be 'generally inconvenient'.[66]

2.86 The review released an options paper in September 2009, with responses to be provided by 13 November 2009. The Committee understands that the final report will be provided to Government in late 2010.

IP Australia review of the patent system

2.87 IP Australia advised that it is conducting a review of the patent system, which is being undertaken in the context of the innovation review the Government initiated late in 2008.[67] A number of consultation papers identifying areas of proposed reform have been released as part of this process.

2.88 The purpose of the review is to:

- reduce barriers in the innovation landscape for researchers and inventors;
- improve certainty about the validity of granted patents; and
- allow patent claims to be resolved faster.[68]

2.89 Department of Innovation, Industry, Science and Research and IP Australia advised:

---

66 Advisory Council on Intellectual Property web site, http://www.acip.gov.au/reviews.html#subject (accessed 29 September 2009).

67 For information on the innovation review see http://www.innovation.gov.au/innovationreview/Pages/home.aspx.

68 IP Australia, 'Getting the Balance Right', Consultation Paper March 2009, available at http://www.ipaustralia.gov.au/pdfs/news/ip_reforms_balance.pdf; IP Australia, 'Exemptions to Patent Infringement', Consultation Paper, March 2009, available at http://www.ipaustralia.gov.au/pdfs/news/ip_reforms_exemptions.pdf.

IP Australia is progressing a package of reforms to the Australian patent system. The package is comprehensive, covering a range of proposals that would result in increased thresholds for patentability and to bring Australia into alignment with other jurisdictions.[69]

69 Department of Innovation, Industry, Science and Research and IP Australia, *Submission 19*, p. 3.