# CHAPTER 3

# THE IMPACT OF GENE PATENTS

## INTRODUCTION

3.1 This chapter addresses terms of reference (a)(i) to (iv), which direct the Committee to consider the impact that the granting of patent monopolies over genes and genetic materials has had, is having, and may have had on:

- the provision and costs of healthcare;
- the provision of training and accreditation for healthcare professionals;
- the progress in medical research; and
- the health and wellbeing of the Australian people.

### *Patents granted over genes and genetic material*

*Classes and numbers of patents relating to human genes*

3.2 One of the difficulties in assessing the impact of gene patents concerned the number and character of patents being granted in Australia relating to genes and genetic materials. At filing all patent applications are classified according to the technical matter which they concern using the International Patent Classification (IPC) system.[1]

3.3 IP Australia noted that there are a number of IPC marks which cover biotechnology; however, IPC subclasses C12N and C12Q are relevant to gene patents as they cover most inventions relating to genes and genetic engineering.[2] Of the two subclasses C12N is most likely to contain applications that claim a human gene sequence per se, derivatives of the sequence such as probes and primers, and their use in diagnostic or therapeutic methods. C12Q is more likely to contain applications directed to processes and methods that use gene sequences, rather than claiming the gene sequence per se. In particular IPC subgroups C12N15/12 to C12N15/28 are 'a good but not absolute indicator of patents that claim a human gene sequence'.[3]

3.4 There was particular concern expressed during the inquiry that patents which grant exclusive rights to genetic testing are negatively impacting on the areas covered

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1 Department of Innovation, Industry, Science and Research and IP Australia, *Submission 19*, p. 37.

2 Department of Innovation, Industry, Science and Research and IP Australia, *Submission 19*, p. 37.

3 Department of Innovation, Industry, Science and Research and IP Australia, *Submission 19*, pp 26-27.

in the terms of reference. IP Australia noted that gene patent claims generally fall into two categories: product claims (such as isolated gene sequences per se) and method claims (such as the use of a gene sequence to diagnose diseases or disorders associated with the gene).[4] Similarly, the United States Secretary's Advisory Committee on Genetics, Health, and Society (SACGHS) final report on gene patents and access to genetic tests identified several categories of patent claims which can serve as the basis for exclusive rights to a genetic test. These included patents claims on isolated nucleic acid molecules as well as patent claims on 'processes for the detection of particular nucleic acid sequences or mutations' and 'processes involving simply associating a genotype with a phenotype' (for example associating a particular genetic sequence with the predisposition to a disease).[5]

3.5 A patent claim on an isolated gene sequence can give the patent holder exclusive rights to a genetic test because typical methods of testing the gene in question require the production of the patented sequences. The patent holder's capacity to exclude others from using the sequence gives them exclusive rights to testing. A similar situation occurs where there is a patent on the process or method involving testing for a particular genetic sequence and then associating that sequence with a disease or condition. The SACGHS report states:

> A significant distinction between composition of matter/manufacture claims to isolated nucleic acid molecules and method claims is that claims to molecules cover all uses of the molecule, including uses outside of diagnostics, while a claim to a method of using a molecule would not prohibit one from using that molecule for another method.[6]

3.6 IP Australia estimated there are 202 patents claiming an isolated human nucleic acid molecule which remain current, most of which have a priority date before the completion of the Human Genome Project in 2003.[7] There is no discrete IPC mark for human gene sequences, so the data provided by IP Australia was inclusive of animal genes. However, IP Australia commented that in their experience the majority of patents on gene sequences relate to human genes. The Department of Innovation, Industry, Science and Research and IP Australia joint submission stated that 'the

4 Department of Innovation, Industry, Science and Research and IP Australia, *Submission 19*, p. 7.

5 Secretary's Advisory Committee on Genetics, Health and Society, *Gene Patents and Licensing Practices and Their Impact on Patient Access to Genetic Tests*, April 2010, pp 13-14.

6 Secretary's Advisory Committee on Genetics, Health and Society, *Gene Patents and Licensing Practices and Their Impact on Patient Access to Genetic Tests*, April 2010, p. 14.

7 Ms Lexie Press, IP Australia, *Committee Hansard*, 20 August 2009, p. 34; IP Australia, clarification of evidence, 7 September 2009, p. 1. The 'priority date' is the date on which a patent application was first filed.

inability to separate applications covering human DNA instead of animal DNA is not unique to IP Australia'.[8]

3.7 IP Australia also made the point that, since the first publication of the Human Genome Project in 2001, the filing numbers for methods or processes (sometimes referred to as 'downstream applications') have surged compared to filings for patents for gene sequences per se. IP Australia argued that this situation is unsurprising because, as knowledge of the human genome increases, patentability requirements (for example, the requirements that an invention is 'novel' and involves an inventive step) become more difficult to satisfy.[9] IP Australia submitted that the number of patents on gene sequences—and thus any adverse impacts that may have flowed from these patents—is diminishing. Mrs Fatima Beattie, Deputy Director General of IP Australia, stated:

> Concerns about the breadth of patents granted to the first inventor is common in any new area of technology. As the technology develops the scope of patent rights afforded get narrower and narrower and it becomes harder to satisfy the threshold patentability requirements of novelty and inventive step. This is due to the cumulative growth of prior art and skill of persons working in the technology area…IP Australia's data shows the number of patents claiming isolated human nucleic acid molecules steadily declining since the publication of the Human Genome Project. We expect only a small probability of additional such patents. [10]

3.8 However, Dr Luigi Palombi submitted that IP Australia's assessment of the number and character of gene patents did not fully encompass the scope of the inquiry's terms of reference. He provided an alternative analysis of the number of gene patents in Australia:

> …when I examined IP Australia's database in February this year I found that there were over 15,000 patents and patent applications that concerned both human and microbial genes and non-coding sequences, proteins, and their derivatives. This is not an insignificant number.[11]

3.9 In discussing the number of gene patents, Dr Hazel Moir focused on IPC class C12N15, noting it was not the only class in which gene and related patents may be found, but was the largest. Her submission outlined that there had been 42,326 patent applications in subclass C12N15, with 14,306 patents granted and a cumulative total of 8,352 patents being current as at 12 February 2009.[12]

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8 Department of Innovation, Industry, Science and Research and IP Australia, *Submission 19*, pp 25-26.

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

10 Mrs Fatima Beattie, IP Australia, *Committee Hansard*, 20 August 2009, p. 28.

11 Dr Luigi Palombi, *Committee Hansard*, 14 September 2009, p. 2.

12 Dr Hazel Moir, *Submission 20*, p. 37.

3.10 IP Australia noted that Dr Moir's assessment examined the whole C12N subclass which includes biotechnological inventions that:

> …although related to genetic engineering technology, are unlikely to include claims to isolated gene sequences per se or diagnostic methods based on the use of isolated gene sequences.[13]

3.11 IP Australia argued that a more accurate way of estimating the number of gene patents likely to claim an isolated sequence per se is by analysing the CN15/12 subgroup. Patents claiming methods of using an isolated gene sequence per se are likely to be given a class mark of C12Q 1/68.[14]

3.12 The table of data Dr Moir provided was broadly consistent with the argument by IP Australia that patent applications relating to gene sequences peaked around the time the Human Genome Project was published and completed. However, Dr Moir also noted that reasons for the fall in applications 'could include a genuine fall in the volume of 'inventions' being produced, or applicants [may] now be trying to avoid this class'.[15]

### *Difficulties assessing the impact of gene patents*

3.13 Considerable time was devoted during the inquiry to discussing the actual and potential impacts of granting patents on genes and genetic material. While arguments were made for both the positive and negative impact of patents over genes and genetic material, others argued that there is insufficient evidence or research available to determine the issue. The lack of evidence regarding the impact of gene patents was also a feature of the Australian Law Reform Commission's (ALRC) inquiry in 2004. The ALRC noted that concerns about the impact of gene patents 'were anecdotal or hypothetical, and evidence of problems in practice—outside that small number of well-known examples—was more difficult to verify'.[16]

3.14 The Intellectual Property Research Institute of Australia (IPRIA) argued that:

> …[there is] as yet no empirical work available that carefully examines the relationship between gene patenting and the costs of providing healthcare, the training and accreditation of healthcare professionals, and progress in medical research.[17]

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13 IP Australia, *IP Australia response to Senator the Hon Heffernan's submission*, p. 5 (and see IP Australia, *Correction to IP Australia response to Senator the Hon Heffernan's submission*, p. 1).

14 IP Australia, *IP Australia response to Senator the Hon Heffernan's submission*, p. 5 (and see IP Australia, *Correction to IP Australia response to Senator the Hon Heffernan's submission*, p. 1).

15 Dr Hazel Moir, *Submission 20*, p. 37.

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

17 Intellectual Property Research Institute of Australia, *Submission 36*, p. 6.

3.15 Dr Kwanghui Lim, Associate Director of IPRIA, stated:

> We are not saying that the policy should not be changed; what we are saying is that, if you are going to base your arguments on fact and prior work, there is not enough of it. It is too new a technology…There are a lot of logical arguments that have been put in place, and they are valid ones, but there is not enough actual data…[18]

3.16 Dr Moir also considered that there is a lack of systematic evidence relating to the impact of gene patents. She suggested that there are empirical difficulties in assessing the impact of gene patents, including identifying all the relevant patent monopolies granted; assessing each patent and the benefit of innovation provided by the grant; and identifying whether there are competing products available which provide effectively the same result.[19] Dr Moir also argued that the issue of gene patents is essentially one of competition policy, as patent protection is a regulatory intervention into the innovation market.[20] Dr Moir observed that the Competition Principles Agreement between the Commonwealth, states and territories requires justification for any interference in a market with the effect of reducing competition. However:

> No such data…has been put in front of this committee in regard to patenting genes. There has been a claim that there is no evidence of any harm, but that is a completely different thing from demonstrating that there is any good.[21]

*Improving the collection of data on the patent system and its impacts*

3.17 Dr Moir argued that 'the lack of information on the ways in which granted monopolies are used in Australia is a major problem for the development of sound policy'. She suggested that 'the government might now consider heeding the advice of the Industrial Property Advisory Committee in 1984 relating to the regular collection of information on how the monopolies it grants are used'.[22] This recommendation stated:

> …that the Patent Office introduce procedures to collect more data from applicants and patentees, particularly concerning the use of patents, in a form which facilitates analysis for statistical and general policy assessment purposes, the information so collected being treated as received and held in confidence and subject to privilege.[23]

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18 Dr Kwanghui Lim, Intellectual Property Research Institute of Australia, *Committee Hansard*, 3 August 2009, p. 4.

19 Dr Hazel Moir, *Submission 20*, p.35.

20 Dr Hazel Moir, *Submission 20*, p.45.

21 Dr Hazel Moir, *Committee Hansard*, 20 August 2009, p. 2.

22 Dr Hazel Moir, *Submission 20*, p. 39.

23 Industrial Property Advisory Committee, *Patents, Innovations and Competition in Australia*, 1984, Recommendation 46.

3.18 Professor Peter Drahos noted that, while information about patents is publicly available, it is not available in useful ways. He has suggested that patent offices need to proactively promote the transparency and diffusion of patented invention information, and should 'track and publish the patent portfolios of patent owners, especially those with large patent holdings.'[24]

3.19 Professor Drahos suggested that one way to deal with the complexity and uncertainty generated by 'gaming behaviour' within the patent system would be for regulatory agencies to establish 'patent transparency registers in areas of technology where there were serious risk management issues'. Registers could target specific areas, and companies would be required to use the registers to make a full disclosure of the patents and patent applications surrounding the targeted technology, if they wished to enforce their patent right. Registers could also include disclosure of information relating to ownership and licensing of patents, which is difficult to track. Other users of the patent systems would be able to rely on the information in the register to make informed decisions as to use of technology, innovation and research.[25]

3.20 Senator the Hon. Bill Heffernan's submission to the inquiry also recommended the establishment of a patent transparency register that would track and publish patent portfolios and:

> …develop databases in co-operation with user groups or other interested government agencies so that the degree of concentration of ownership of crucial technologies associated with that portfolio, and information about the licensing and assignment of those technologies are easily and publicly available.[26]

## Provision and costs of healthcare

3.21 During the inquiry there was general agreement that patients, health professionals, researchers and governments are increasingly reliant on medical knowledge concerning the human genome to make decisions about healthcare, and that this reliance is likely to increase in the future. The main issues raised in relation to gene patents and the provision and costs of healthcare were:

- restrictive patent licensing and access to genetic testing services;
- innovation and healthcare;
- the importance of genetic counselling services; and
- the future of genetic testing.

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24 Professor Peter Drahos, *Submission 60*, p. 448.

25 Professor Peter Drahos, *Submission 60*, pp 451-456.

26 Senator the Hon. Bill Heffernan, *Submission 76*, p. 72.

### *Genetic testing services*

3.22 As with the Australian Law Reform Commission's 2004 inquiry, the evidence received by the Committee concerning the impact of gene patents on healthcare focussed predominantly on genetic testing. However, it should be remembered that patents on genes and genetic material may also impact on the provision and costs of other types of healthcare, including gene therapy and the use of stem cells.[27]

3.23 Genetic tests are commonly used in a number of ways in healthcare. These include:

- preventative testing or screening of a patient for genetic variations that may increase the likelihood they will develop a disorder or illness;
- diagnostic testing performed to identify the cause of a patient's symptoms; and
- testing to target specific treatment to a patient.[28]

3.24 While the Medicare Benefits Scheme funds a limited number of genetic tests, state and territory governments fund and provide the bulk of genetic testing and related clinical services in Australia. Many genetic tests are arranged by clinical genetic services and carried out in public laboratories attached to public hospitals. The Commonwealth Government contributes to the funding of these genetic tests and services indirectly through the National Healthcare Agreements. The Department of Health and Ageing also noted that the Pharmaceutical Benefits Scheme funds pharmaceuticals, vaccines and other treatments developed from genes, proteins and other related biological materials, 'assessed to be both effective and value for money.'[29]

3.25 The results of the *Australian Genetic Testing Survey 2006* were highlighted by a number of submissions. The survey found that 437 different genetic tests were available across Australia in 2006. Of these, more than half (55 per cent) were offered by only one laboratory and only five per cent of genetic tests were provided by more than five laboratories. A total of 41,497 molecular genetic tests were rebated by Medicare in 2006. Genetic tests were only a small part of the approximately 60 million pathology tests funded by Medicare that year. A further 119,354 molecular genetic tests were provided by laboratories using non-Medicare funding, presumably through state governments and privately-paying patients.[30]

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27 Australian Law Reform Commission, *Genes and ingenuity: gene patenting and human health*, 2004, pp 465 and 489.

28 Royal Society of Pathologists of Australasia, *Submission 49*, p. 3.

29 Department of Health and Ageing, *Submission 62*, p. 2.

30 Royal College of Pathologists of Australasia, *Submission 49, Report of the Australian Genetic Testing Survey 2006*, pp 15 -17; Medical Technology Association of Australia, *Submission 43*, p. 1.

3.26 The Peter MacCallum Cancer Centre (PMCC) noted comments by the President of the Royal College of Pathologists of Australasia (RCPA), Dr Bev Rowbotham, describing genetic testing in Australia as 'uncoordinated, inequitable and inefficient', predominantly due to the current funding mechanism. Dr Rowbotham commented that most genetic services see their role as the 'rationer' of access to genetic testing, mainly because of the expense of the tests and funding limitations.[31]

3.27 Cancer Council Australia (CCA) highlighted the potential cost burden of genetic testing on patients. They noted that state health departments and family cancer centres provide limited funds for genetic testing from their budget allocations for non-Medicare items. Where this funding is not available, patients may be required to pay for their own tests.

3.28 The Committee heard that the costs for testing can vary considerably depending on the type of test—from just over $100 to more than $2500 per test. Specialised genetic testing is a characteristically complex process with low throughput, and can take up to six months or longer. In some cases, samples are sent overseas for analysis at additional cost.

3.29 CCA noted that, under the current arrangements, there is no adequate legal protection to ensure that genetic testing for cancer risk remains freely accessible at reasonable cost to the health system and consumers.[32] Many submitters and witnesses were concerned that the burden of increased costs due to gene patents will be borne by patients, making access to genetic testing less equitable.

3.30 A number of other groups commented on affordability and accessibility. The NSW Government noted that the number of patients requiring or benefiting from genetic testing is rising, and observed that 'there is a significant concern that access to clinically appropriate testing may be reduced if prices exceed the currently available budgets'.[33]

3.31 The Medical Technology Association of Australia argued that access to genetic testing in Australia 'may be impeded where there is no payment for the test through Medicare' and highlighted that only a small number of tests are covered by the Medicare Benefits Schedule.[34]

3.32 However, Mrs Fatima Beattie, Deputy Director-General of IP Australia, suggested the issue was more '[an issue of] the health funding arrangements for those sorts of tests rather than an issue of the gene patent'. She stated:

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31 Peter MacCallum Cancer Centre, *Submission 28,* p. 5.

32 Cancer Council Australia, *Submission 50*, pp 5-6.

33 NSW Government, *Submission 54*, p. 5.

34 Medical Technology Association of Australia, *Submission 43,* p. 4.

> …the price of the BRCA test, in particular, provided by the exclusive Australian licensee, is on par with the cost of the test performed by the publicly funded clinics. The only difference is about who pays that price, whether it is the Australian government, through the health budget, or whether it is the actual patient.[35]

### *Patent licensing and access to genetic testing*

3.33 The relationship between gene patents and the costs and provision of healthcare was disputed during the inquiry. There were concerns expressed that patent licensing over genetic testing could lead to restrictions on the number of laboratories conducting genetic tests. This could potentially restrict access to testing, delay results, influence the quality of test results and cause costs to rise for patients and the community. For example Dr Palombi commented:

> A patent monopoly over an isolated gene and its genetic information means that anyone that does anything that comes within the scope of that patent monopoly has infringed the patent and is liable to the patentee for damages or an account of profits and can be enjoined from continuing to infringe by the grant of an injunction.
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> That kind of power, which a patentee possesses exclusively, is significant legally, economically and ethically. Legally because it provides the patentee with the right to sue with respect to the unauthorised use for damages, an account of profits and to seek an injunction. Economically because it enables the patentee to control access, use and price, in the exercise of their legal rights as a monopolist. Ethically because how the patentee exercises those rights can impact upon how society functions.[36]

3.34 The RCPA argued that the impact on the provision and costs of healthcare of a gene patent largely depends on the licensing approach taken by the patent owner. A number of models of licensing access were identified, including:

- the open access model, where no fee is charged by the patent owner for testing the relevant gene but royalties can be earned through producing and selling commercial test kits;
- the restricted access model, where the patent holder offers one of two options. The first option is that laboratories are licensed to perform their own in-house tests. This license consists of an up-front fee and ongoing royalties for each test performed. The second option is that laboratories must use a kit supplied (and method specified) by the patent holder (or sole licensee). This allows the patent holder to limit the number of tests that can be performed with each kit, and means the cost of the commercial kit may be significantly greater than an in-house test developed by the laboratory; and

35 Mrs Fatima Beattie, IP Australia, *Committee Hansard*, 15 June 2010, p. 37.

36 Dr Luigi Palombi, *Submission 4*; answer to question on notice, 2 April 2009, p. 5.

- the closed access model, where the patent holder does not offer licensing and mandates that all testing be completed at a nominated laboratory.[37]

3.35 The RCPA discussed the differences between these approaches and noted examples where the use of a restricted or closed model by a patent holder had influenced the provision and cost of genetic testing. In particular, where a laboratory is allowed to develop or refine its own in-house test, it is able, if required, to better meet the requirements of the local population, as variations in the frequency of genetic errors mean that a genetic test may not be accurate for all ethnic groups.

3.36 An example of the restricted model was IgH and TCR gene rearrangement tests performed on cancer tissue from patients with lymphoproliferative disorders or acute myeloid leukaemia. The United States based patent-holder, InVivoScribe Technologies, approached all Australian laboratories currently performing such tests and insisted they switch to the exclusive use of the company's kit and method or obtain a sub-license to use their own tests. The RCPA noted that the cost of the in-house test for laboratories was $28 per patient (excluding labour and other costs) while the cost of the provided kit was $292 per patient (excluding labour).[38]

3.37 The South Australian Government also outlined an example where a restricted approach by a patent holder has had an impact on health provision. In 2005, a company which claimed to be the exclusive licensee for genetic tests for cytochrome P450 mutations wrote to the Institute of Medical and Veterinary Science (now SA Pathology) and advised they would be exercising their exclusive right on the licence. The company sought a one-off fee of £20,000 and five per cent of any fees for tests performed. These additional costs were described as 'untenable' and the Institute ceased performing the test. The South Australian government noted that similar situations had occurred for other tests.[39]

3.38 The RCPA described Genetic Technologies's actions in seeking to enforce its licence rights against public laboratories in Australia performing BRCA1 and BRCA2 genetic tests as an example of the closed model of gene patent licensing. They considered this situation highlighted a number of problems with the closed approach to licensing. These included that having only a single provider of a genetic testing:

- limits opportunities for laboratory quality assurance;
- gives absolute control over the price of the test;
- allows the patent holder to develop an exclusive and private database of the genetic variation for that gene in the population; and
- exposes the delivery of health services to the risk of instability.[40]

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37 Royal College of Pathologists of Australasia, *Submission 49*, pp 8-11.

38 Royal College of Pathologists of Australasia, *Submission 49*, p. 9.

39 South Australian Government, *Submission 16*, p. 8.

40 Royal College of Pathologists of Australasia, *Submission 49*, p 11.

3.39 The RCPA also noted that there is a risk that patent monopolies on genetic testing may result in inappropriate standards of care, where they have the effect of blocking access to appropriate testing or promoting use of certain tests inappropriately.[41]

3.40 Other witnesses and submissions argued that gene patents negatively impact on equitable access to healthcare. For example, Dr Jennifer Leary argued that patents inevitably lead to a 'demand for profit', and licensing fees or lack of competition in the market will lead to increased testing costs. She also noted that a monopoly on service provision leading to increased costs means that those who cannot pay privately may not have access to genetic testing.[42] The Human Genetics Society of Australasia also stated that 'monopoly testing removes competition, which may result in excessive pricing and restricted access, particularly within the public health system which provides the majority of genetic testing'.[43]

3.41 The Society argued that such monopolies would create healthcare inequities between those who rely on public services and those who can afford to pay for tests privately.[44]

3.42 The Victorian, South Australian and New South Wales governments used the example of genetic testing for BRCA1 and BRCA2 to illustrate the negative impact a closed approach to licensing could have on healthcare, funding and access to genetic testing. The Victorian Government estimated that redirecting predictive gene testing for breast cancer to an exclusive provider would cost an additional $0.5 million per annum initially, an increase of 50 per cent on current funding for testing. Increased costs would require governments to either allocate additional funding to maintain service levels or reduce the number of funded tests, resulting in increased waiting times for public patients and reduced service equity as those able to pay would gain preferential access to private services. They noted that these cost implications would increase if this scenario were to occur across multiple genes and testing patents.[45]

3.43 Similarly the South Australian Government stated that, if Genetic Technologies had been successful in imposing a monopoly on testing for the BRCA genes, the cost of testing would have risen significantly, 'meaning additional cost to individuals, families and the South Australian Government'.[46] The New South Wales Government stated there is evidence the patent rights are 'adversely affecting medical care' and that healthcare providers feel that gene patents will decrease the integrity of gene tests and increase the cost of conducting genetic analyses. They noted 'there is a

41 Royal College of Pathologists of Australasia, *Submission 49*, p 14.

42 Dr Jennifer Leary, *Submission 39*, p. 4.

43 Human Genetics Society of Australasia, *Submission 33*, pp 1-2.

44 Human Genetics Society of Australasia, *Submission 33*, pp 1-2.

45 Victorian Government, *Submission 61*, p. 2.

46 South Australian Government, *Submission 16*, p. 8.

significant concern that access to clinically appropriate testing may be reduced if prices exceed the currently available budgets'.[47]

3.44 Some witnesses and submitters were concerned that patenting genes and genetic material could lead to commercial monopolies for gene testing associated with cancer and therefore increased costs for patients. The key concerns of the Cancer Council Australia related to the potential for monopolisation of genetic material through gene patents to reduce public access to predictive, diagnostic and therapeutic genetic technology in cancer control, and to increase their cost to both government and the community.[48] This view was shared by Breast Cancer Network Australia:

> In particular we are concerned that a private company holding a gene patent could limit access to genetic testing for women by insisting that tests are only conducted through specified laboratories, or that the cost of the test could be increased in order to increase the profitability of the testing process for the company.[49]

3.45 PMCC argued that restricted and closed approaches to licensing genetic tests could reduce the ability of public laboratories to offer genetic testing for other genes. PMCC stated that 'common gene tests provide a critical mass for laboratories, allowing them to undertake occasional testing for rarer mutations' that are not commercially attractive to large companies. These rarer mutations could become 'orphan diseases' with no genetic test available. PMCC also argued that losing 'core screening work' could result in some public laboratories closing, and that this would adversely affect clinical activity. PMCC noted that genetic tests are often not clear cut and require close consultation between the clinicians who manage the patients and the molecular pathology team performing the tests and interpreting results.[50] This type of close consultation could be inhibited where a restricted or closed approach to patent licensing is adopted.

3.46 There were also concerns raised about the misallocation of healthcare resources. Some feared that if genetic testing is not accessible, affordable and targeted to patients with high clinical need (because of the impact of gene patents) then healthcare costs will increase as a result of illnesses which may have been preventable.[51] For example, Dr Jennifer Leary considered that the health budget could be burdened 'through the development of disease that may have remained undetected without access to testing or through undergoing unnecessary surveillance and treatment procedures'.[52] Similarly, Associate Professor Judy Kirk advised:

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47 New South Wales Government, *Submission 54*, p. 5.

48 Cancer Council Australia, *Submission 50*, p. 6.

49 Breast Cancer Network Australia, *Submission 47*, p. 3.

50 Peter MacCallum Cancer Centre, *Submission 28*, p. 5; See also Dr Jennifer Leary, *Submission 39*, p. 4.

51 Breast Cancer Action Group NSW, *Submission 30*, p. 1.

52 Dr Jennifer Leary, *Submission 39*, p. 4.

> If genetic testing is not available to all appropriate families, it is likely that preventable cancers will occur in (unidentified) high risk individuals, leading to increased costs that could be avoided. In addition, if genetic testing is not available to all appropriate families, it is likely that (unidentified) low risk individuals will have inappropriately high levels of cancer surveillance, also increasing costs to the system.[53]

3.47 Ms Heather Drum, a member of Breast Cancer Network Australia, also highlighted the cost benefits for patients, the community and government of genetic testing which may facilitate preventative healthcare measures. She stated:

> Bypassing a diagnosis of cancer means bypassing the expensive costs of treatments such as chemotherapy and radiotherapy. My chemotherapy was somewhere in the vicinity of $2,000-plus per cycle, then include doctors appointments, hospital admissions, pathology tests, further drugs test treating side-effects and the time out of work. I spent nearly 18 months in treatment, working only sporadically—all unplanned.[54]

3.48 However, many other submissions rejected concerns about the impact of gene patents on access to genetic testing services. The Department of Health and Ageing (the Department) noted that the 2004 ALRC inquiry found little evidence that gene patents and licensing practices with respect to genetic testing have had any significant impact on the cost and provision of healthcare in Australia. The Department also highlighted that, since that report, neither the Australian Health Ministers' Advisory Group on Human Gene Patents and Genetic Testing nor the National Health and Medical Research Council's (NHMRC) Human Genetics Advisory Committee had been advised of any systemic concerns about the impact of gene patents on the cost of healthcare.[55]

3.49 IP Australia also noted the lack of empirical evidence identifying adverse impacts caused by gene patents. In particular, it observed that 'there has been no evidence that patents have resulted in any person being denied access to molecular genetic testing'. IP Australia suggested concerns about gene patents generally 'related to anecdotal evidence and what hypothetically could happen in future in terms of patentee licensing behaviour, costs and availability of genetic tests'.[56]

3.50 In response to particular concerns about the monopolisation of genetic testing by patent holders, IP Australia observed:

> On the issue of 'monopolisation' or single provider of tests, we note that over 55 [per cent] of the 437 genetic tests performed in 2006/07 in Australia were offered by one laboratory. Our understanding is that the

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53 Associate Professor Judy Kirk, *Submission 9*, p. 2.

54 Ms Heather Drum, Breast Cancer Network Australia, *Committee Hansard*, 3 August 2009, p. 89.

55 Department of Health and Ageing, *Submission 62*, p. 2.

56 IP Australia, *Submission 19*; and supplementary submission, 30 September 2009, p. 2.

> provision of a single provider for these tests did not seem to be subject to a patent in Australia…This statistic indicates that many market forces other than patents and exclusive licensing arrangement determine whether tests are provided by one laboratory and the prices charged for the tests. These factors include demand and market size.[57]

3.51 Genetic Technologies defended its role in providing BRCA genetic testing services, describing the company as a 'positive contributor to improving the health and well being of the Australian people'.[58] Genetic Technologies argued that, prior to its entry into the market, BRCA testing was 'performed [using] all manner of different test protocols among the state laboratories and many of these were slow and suboptimal in their specificity and accuracy'. Genetic Technologies stated that it had improved the accuracy, timeliness and efficiencies of the test process, and provided a benchmark against which many of the public laboratory services can be measured. Further, Genetic Technologies noted that it had never been requested to participate in an open and transparent tender for the provision of genetic testing services. According to the Genetic Technologies submission:[59]

> …we contend that our service has met a previously unfulfilled demand in the Australian health care sector. We do not force any customer to use our service and we charge a publicly published price. [Genetic Technologies] contends that it operates the most cost effective BRCA testing laboratory in the country and would welcome any subjective review of efficiencies and costs-charges incurred for such testing across all laboratories...[60]

3.52 Genetic Technologies also highlighted the United States SACGHS public consultation draft report on *Gene patents and licensing practices and their impact on patient access to genetic tests*. They noted that the draft report findings, which discussed gene patents and genetic testing in the context of the United States healthcare system, indicated that patents covering genetic tests and related licensing practices do not appear to be impeding patient or clinical access to tests.[61] The SACGHS draft report found that the evidence from the case studies examined during the inquiry:

> …did not reveal widespread overpricing for genetic diagnostic tests that were patented and exclusively licensed relative to tests that were either unpatented or non-exclusively licensed.[62]

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57 IP Australia, supplementary submission, 30 September 2009, p. 2.

58 Genetic Technologies Ltd, *Submission 24*, p. 6.

59 Genetic Technologies Ltd, *Submission 24*, p. 6.

60 Genetic Technologies Ltd, *Submission 24*, p. 6.

61 Genetic Technologies Ltd, *Submission 24*, p. 5.

62 Secretary's Advisory Committee on Genetics, Health, and Society, *Public consultation draft report on gene patents and licensing practices and their impact on patient access to genetic tests*, March 2009, p. 98.

3.53 The draft report concluded:

> Based on its review of the literature, case studies, and review of international policies regarding gene patents, SACGHS found little in the way of broad or consistent evidence that indicates either positive or negative effects of gene patents on patient access to diagnostic tests.[63]

3.54 The SACGHS draft report also stated that instances in which patient access to genetic tests may have been impeded were often caused not by the patent itself but by the way it was licensed or used.[64] However, the SACGHS final report, released in April 2010, noted that, where patents and licensing practices have created a sole provider of a genetic test, patient access to testing had suffered in cases where:

- the sole provider did not accept the patient's health insurance and the patient could not otherwise afford the test;
- patients wished to have a second-opinion from an independent laboratory; and/or
- patent enforcement disputes delay or prevent testings.[65]

3.55 The Johnson & Johnson Family of Companies (JJFC) noted that, while many thousands of gene patents have been granted in Australia, only a small few have raised concerns about the ability of public institutions to provide testing. Furthermore, where there have been concerns, such as with the BRCA2 test, the parties 'have reached an amicable resolution that has not hindered the effective screening of the gene'. JJFC argued:

> …costs pressures can be more effectively regulated by the market than by legislation governing the inventions themselves. Once again the BRCA-2 case can be used as an example. The pricing for tests utilising the BRCA-2 patent are varied in different countries, reflecting each environment's individual market dynamics. Additionally, the recent announcement in Australia that the tests could be conducted in public hospitals was brought about by general market forces.[66]

3.56 The Institute of Patent and Trade Mark Attorneys of Australia suggested that some of the opposition to patents on genes and genetic materials was due to a philosophical objection to gene patents. They also stated that:

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63 Secretary's Advisory Committee on Genetics, Health, and Society, *Public consultation draft report on gene patents and licensing practices and their impact on patient access to genetic tests*, March 2009, p. 98.

64 Secretary's Advisory Committee on Genetics, Health, and Society, *Public consultation draft report on gene patents and licensing practices and their impact on patient access to genetic tests*, March 2009, p. 108.

65 Secretary's Advisory Committee on Genetics, Health, and Society, G*ene patents and licensing practices and their impact on patient access to genetic tests*, April 2010, pp 3-4.

66 Johnson & Johnson Family of Companies Australia, *Submission 44*, p. 11.

> Other groups opposed to gene patenting may be self serving in that they wish to provide commercial services in the area of gene testing and healthcare without having to pay royalties or legitimate fees to patent owners and innovators.[67]

3.57 The Committee received evidence from Professor Dianne Nicol and Dr Jane Nielsen regarding their research in 2002-03 involving surveys and interviews with Australian researchers, biomedical companies and genetic testing laboratories. The research found that, while there was a great deal of concern about gene and related patents, there was little evidence that such patents were actively being enforced against genetic testing laboratories in Australia at that time.[68]

### *Innovation and healthcare*

3.58 Submitters and witnesses also discussed the impact of gene patents on the provision and costs of healthcare more broadly, with many focusing on the extent to which gene patents promote or discourage research and innovation in medicine.

3.59 IP Australia commented that the access and cost issues related to gene patents are not limited to the prices incurred by individual patients. For example, it argued that the patent system promotes innovation in healthcare and, without this strong incentive to companies and researchers, 'there may be no or much slower access to newer and better tests'.[69] IP Australia also noted that innovations in human genetic research had benefited society through the availability of new and better healthcare products and services, such as the Gardasil vaccine against cervical cancer.[70]

3.60 This line of reasoning was supported by a number of other submissions, which emphasised the positive impacts of gene patents on the costs and provision of healthcare. The Institute of Patent and Trade Mark Attorneys of Australia, for example, stated that significant innovation in biotechnology had resulted 'in numerous new treatments, prevention, diagnostics and health guidance'.[71] The Victorian Government acknowledged that, while genetic tests are a cost pressure for governments, 'gene technologies may ultimately reduce healthcare costs through earlier and more accurate diagnoses and the ability to determine the suitability of individuals to therapeutic interventions'.[72] Similarly, the Law Council of Australia suggested:

> While patent protection can be expected to result in increased cost to the consumer during the period of exclusivity, this perceived disadvantage is to

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67 Institute of Patent and Trade Mark Attorneys of Australia, *Submission 31*, p. 5.

68 Professor Dianne Nicol and Dr Jane Nielsen, *Submission 23*, p. 7.

69 Mrs Fatima Beattie, IP Australia, *Committee Hansard*, 20 August 2009, p. 29.

70 IP Australia, *Submission 19*, p. 8.

71 Institute of Patent and Trade Mark Attorneys of Australia, *Submission 31*, p. 12.

72 Victorian Government, *Submission 61*, p. 2.

> be compared with the alternative option, which, in practice, may be that the product is not available to the consumer at all.[73]

3.61 However, others argued the impact of gene patents was likely to be negative on healthcare innovation. This was particularly the case because 'once the gene sequence for a particular disease related gene has been identified and isolated, the development of a diagnostic test is not particularly onerous'.[74]

3.62 Senator the Hon. Bill Heffernan's submission to the inquiry outlined the adverse impacts of four patents on the cost and access to healthcare in Australia and overseas. In relation to the polypeptides of erythropoietin patent he stated the 'most immediate and significant impact of this patent monopoly was on the cost of provision of healthcare in Australia'. The patent had other impacts including that 'Australian scientists and researchers were directly inhibited for research purposes'.[75]

3.63 CCA commented that the monopolisation of genetic testing eliminates competition and carries the risk of sole providers having no incentive to find more efficient and affordable ways to undertake tests and make other use of the genetic information they control.[76]

3.64 The RCPA stated that patent holders can block further development of a genetic test, either by restricting analysis to one laboratory or by requiring laboratories to use a commercial kit. The RCPA described a situation where patent rights over a genetic test effectively blocked the delivery of supplementary testing which would have increased the accuracy and usefulness of the test for patients. While the supplementary method had been described by research scientists, other laboratories could not offer the test because they were not licensed to analyse the relevant genes.[77]

3.65 PMCC recognised that patents have played an important role in protecting and facilitating 'the transfer of novel intellectual property for the benefit of the community at large and the creators of that property', but considered genes to be a special case which should not be subject to patents. They argued that permitting gene patenting meant that there is no incentive for the gene patent holder to continue to improve their commercially available genetic test and particularly not to reduce the cost or improve the efficiency of the test. They highlighted variable pricing of the BRCA1 and BRCA2 genetic tests in different countries and noted that the cost of this test has not reduced appreciably in the United States despite the continuing reduction in the cost of genetic sequencing over time.[78]

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73 Law Council of Australia, *Submission 57*, p. 1.

74 Professor Dianne Nicol and Dr Jane Nielsen, *Submission 23*, p. 5.

75 Senator the Hon. Bill Heffernan, *Submission 76*, p. 8

76 Cancer Council Australia, *Submission 50*, p. 7.

77 Royal College of Pathologists of Australasia, *Submission 49*, p. 13.

78 Peter MacCallum Cancer Centre, *Submission 28*, pp 2-3.

### *Genetic counselling and family cancer centres*

3.66 There was considerable support expressed for the current approach to genetic testing in the public sector where 'patients receive their results and advice through a structured and considered clinical service with a holistic view to their healthcare'.[79] In particular there was support for family cancer centres, especially from patient groups associated with this disease.[80] In general, family (or familial) cancer centres provide genetic testing, medical advice, genetic counselling and psychological support to patients and their families who have health issues associated with cancer. Some feared that this comprehensive and supportive approach to genetic testing for cancer and other conditions could be at risk if patents restrict genetic testing to a limited number of laboratories.

3.67 The NSW Government noted that the impact of genetic test results on patients can be challenging and complex. Test results can indicate risk but do not indicate if and when symptoms will develop. Certain results can impact on a person's ability to obtain life insurance or employment and can have implications for health decisions. The NSW Government argued that it was therefore 'vital that supportive clinical processes, including provision of information and counselling, are provided to assist individuals with informed decision-making'.[81] The Victorian Government also commented on the benefits of an integrated approach to genetic testing:

> For human genetics services, there are risks in separating diagnostic testing from expert interpretation, counselling and support. All of these functions are critical in ensuring that individuals are accurately and fully informed of the implications of their test results.[82]

3.68 Genetic counselling was also seen as important because of the wide implications of genetic testing for family members.[83] Associate Professor Judy Kirk commented on some of the challenges facing those undertaking genetic testing:

> …before a family goes ahead with testing, they need to understand what the implications would be for the men and the women of the family. They need to understand the health implications, what it might mean for their children and what it might mean in terms of accessing insurance. They need to think about what sort of screening and prevention measures we would have in the event of a positive genetic test which shows a high risk and how they would communicate that to the rest of the family, and notify at-risk family members.[84]

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79 Dr Jennifer Leary, *Submission 39*, p. 7.

80 For example Cancer Voice NSW, *Submission 47*, p. 2.

81 NSW Government, *Submission 54*, p. 5.

82 Victorian Government, *Submission 61*, p. 3.

83 Professor Ian Olver, Cancer Council Australia, *Committee Hansard*, 5 August 2009, p. 29.

84 Associate Professor Judy Kirk, *Committee Hansard*, 5 August 2009, p. 79.

3.69 The importance of genetic counselling was highlighted by witnesses from Breast Cancer Network Australia (BCNA), who described their experiences of obtaining genetic test results and the impact it had on their subsequent healthcare decisions. These decisions could include preventative surgery such as prophylactic mastectomies intended to reduce the risk of cancer.[85] The BCNA representatives noted that, without adequate communication, information and support, the results of a genetic test can be highly distressing and confronting for patients. They were concerned that, if gene patent rights were used restrictively, the genetic counselling component of current genetic testing processes could be lost and replaced by a commercially cheaper approach, where, for example, relevant samples are sent to external laboratories for testing and test results are then sent directly to the patient.[86]

3.70 Similarly, the Country Women's Association of NSW was concerned that gene patent monopolies may threaten the ability of healthcare authorities in Australia to deliver high-quality genetic testing services. In particular, the Association was concerned that:

> …one-on-one friendly counselling would be lost if public hospitals lost their right to do testing on a privately patented gene and the entire nation's testing done through one commercial centre'.[87]

3.71 Misgivings about the potential for gene patents to alter the current public sector approach to genetic testing were also expressed by the Human Genetics Society of Australasia (HGSA). Under the current model, access to testing in the public sector is targeted to individuals assessed as being at high risk. Testing is conducted through specialist genetics and associated medical services in conjunction with appropriate genetic counselling. The HGSA noted that this approach limits unnecessary testing and ensures patient consent to testing is well informed and valid. The HGSA was concerned that:

> Exclusive intellectual property rights may encourage commercialisation and direct marketing [of genetic tests] to the wider, generally low risk, community, and thus may exploit anxiety, have questionable clinical utility and be costly to individuals.
>
> Genetic tests with health implications should not be available in direct to consumer form but through request by a qualified health care professional in an appropriate clinical setting, in order to provide the person with the relevant information and counselling so that consent to testing is well informed and valid. This is especially the case with patented tests, where

85 Mrs Kristi Smith, Breast Cancer Network Australia, *Committee Hansard*, 3 August 2009, pp 84-85; Ms Heather Drum, Breast Cancer Network Australia, *Committee Hansard*, 3 August 2009, pp 85-89.

86 Breast Cancer Network Australia, *Submission 48*, p. 5.

87 Country Women's Association of NSW, *Submission 35*, p. 4.

> lay individuals may have unrealistic expectations of the potential of such tests. Patenting does not guarantee efficacy or clinical utility in all cases.[88]

3.72 Dr Jennifer Leary also warned that patent monopolies 'have the potential to result in an increase in 'direct to market' advertising of genetic tests'. Dr Leary stated:

> The U.S and Canadian experience of 'direct to market' advertising has resulted in the exploitation of breast cancer anxiety and increased private testing of those for whom the clinical utility of the test is questionable. Market driven access to testing also has the potential to reduce the spectrum of tests available.[89]

### *The future of genetic testing and treatment*

3.73 While the Committee's terms of reference were directed at the impact that the granting of gene patents 'has had, is having and may have had', many submissions and witnesses were more concerned about future impacts, particularly on the cost and provision of healthcare. There was a general consensus that the trend in genetic testing and treatment would move toward testing multiple genes or whole patient genomes as testing techniques improve and the cost of testing decreases. The results of these tests would then be used to personalise treatment for each patient and effectively target treatments.[90]

3.74 Professor Ron Trent argued that the focus should be on genomics rather than genetics, noting the possibility that in five to ten years whole genome sequence tests may be completed for $1000. He highlighted that tests involving multiple genes were more likely to encounter problems with gene patents. Professor Trent stated:

> We are now in the genomics era…We have had a discussion today about single genes, yet we know that there are tests that will test 20, 30 or 40 genes at once. Goodness knows what sorts of patent issues are involved in 30 or 40 genes in one test.[91]

3.75 The United States Secretary's Advisory Committee on Genetics, Health and Society final report on gene patents also dealt with this issue. It noted that developing whole-genome sequencing will likely depend on acquiring multiple rights. Negotiating licences to all the relevant patents could be expensive and the cumulative cost of these licenses could make these products unmarketable. It stated:

> These concerns are more than hypothetical. Patents are already hindering the development of multiplex tests [which test multiple genes]. Laboratories

88 Human Genetics Society of Australasia, *Submission 33*, p. 3.

89 Dr Jennifer Leary, *Submission 39*, p. 7.

90 For example, Dr Gillian Mitchell, *Committee Hansard*, 4 August 2009, p. 104.

91 Professor Ron Trent, *Committee Hansard*, 5 August 2009, p. 76.

> utilizing multiplex tests are already choosing not to report medically significant results that pertain to patented genes for fear of liability.[92]

## Training and accreditation for healthcare professionals

3.76 While the use of genetic testing was described as increasingly common in a broad range of healthcare areas, the health professionals most closely involved in genetic testing and services were identified as being:

- clinical geneticists (specialist medical practitioners);
- genetic pathologists;
- geneticists (specialist medical laboratory scientists); and
- genetic counsellors.

3.77 The Department of Health and Ageing noted that the training and accreditation of healthcare professions is a responsibility shared between the university sector and a range of professional bodies, such as the Australian Medical Council, specialist medical colleges, nursing registration boards, and the Australian Psychology Accreditation Council. Specialist medical education is delivered by specialist colleges, faculties and chapters. A National Registration and Accreditation Scheme for a number of professions including medical practitioners, nurses and psychologists commenced on 1 July 2010. The Division of Paediatrics and Child Health in the Royal Australasian College of Physicians and the Royal College of Pathologists of Australasia are particularly involved in genetic testing and services.[93]

3.78 The Medical Technology Association of Australia highlighted that tests not covered by Medicare—which represent the majority of genetic tests conducted—have not been subject to significant regulatory oversight in Australia, and laboratories performing these tests have not necessarily been accredited by the National Association of Testing Authorities. However, it noted that this lack of certainty about genetic testing quality will change with the arrival of regulatory oversight of genetic testing through the in vitro diagnostic regulatory framework to be administered by the Therapeutic Goods Administration.[94]

3.79 The Department of Health and Ageing commented that the new framework would 'ensure the quality of all therapeutic devices, including in vitro diagnostic kits used for genetic testing, and reduce the risk of test kits producing unreliable results'.[95] The new framework commenced on 1 July 2010. The Department's submission stated:

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92 Secretary's Advisory Committee on Genetics, Health, and Society, *Gene patents and licensing practices and their impact on patient access to genetic tests*, April 2010, p. 3.

93 Department of Health and Ageing, *Submission 62*, p. 3.

94 Medical Technology Association of Australia, *Submission 43*, p. 4; Department of Health and Ageing, *Submission 62*, p. 4.

95 Department of Health and Ageing, *Submission 62*, p. 4.

> The framework is being introduced to address concerns that many of these technologies are available on the Australian market with no regulatory oversight and no certainty that they perform as intended. Of key concern is genetic self-testing whereby people may order tests via the internet or direct from a provider, without essential information, counselling and support needed to deal with the results.[96]

3.80 Several submitters to the inquiry did not consider that the granting of patents for genetic materials could have an adverse impact on the provision of training and accreditation of healthcare professionals.[97] The Walter and Eliza Hall Institute of Medical Research (WEHI) noted there was a current shortage of molecular pathologists in Australia. However they considered this was due to a lack of funding and career attraction, and the rapid growth in molecular diagnostics, rather than gene patents. The WEHI did not believe that expressly prohibiting gene patents would have a positive impact on Australia's skill base, and pointed out that the most skilled countries in this area are those that allow the patenting of human genes.[98]

3.81 Others considered that, if gene patents caused genetic testing to be limited to private laboratories, or led to samples being sent overseas for testing, this could negatively impact the training and accreditation of healthcare professionals in Australia. For example, the Human Genetics Society of Australasia stated:

> Enforcement of patents may take testing off-shore or to a sole licenser resulting in the loss or lack of development of local expertise and opportunities for training…
>
> Monopoly rights may create disenfranchisement of other laboratories, usually public hospital/research laboratories, through loss of expertise and trained staff, which may further negatively impact on skill and scientific developments transferable across the range of laboratory tests.[99]

3.82 The Victorian Government stated that the current genetics workforce is predicted to be insufficient to meet future demand. It was concerned that a concentration of genetic testing in private laboratories could reduce the opportunities for student training and professional accreditation. It also noted that higher licensing costs on public laboratories could translate into fewer enrolments and increased course fees for genetics courses.[100] CCA also noted the importance of academic institutions maintaining internationally competitive standards, 'particularly at a time of medical

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96 Department of Health and Ageing, *Submission 62*, p. 4.

97 Davies Collison Cave, *Submission 27*, p.7; Institute of Patent and Trade Mark Attorneys of Australia, *Submission 31*, p. 9.

98 Walter and Eliza Hall Institute of Medical Research, *Submission 26*, p. 13.

99 Human Genetics Society of Australasia, *Submission 33*, p. 3.

100 Victorian Government, *Submission 61*, p. 3.

workforce pressure and when the scope of genetic medicine is on the threshold of significantly widening'.[101]

3.83 A number of submissions commented on the potential risks for training and accreditation in the event that restrictive licensing approaches by patent owners cause public laboratories to reduce the number and variety of genetic testing services offered. The National Coalition of Public Pathology argued that patenting a process that provides exclusive access to a gene will hinder 'the transfer of knowledge and expertise among health professionals in new areas of knowledge and professional development'.[102] Similarly, the RCPA argued:

> By restricting testing to one laboratory, the training of the next generation of pathologists and laboratory scientists in the area covered by the patent will be impaired. Further it will limit the number of knowledgeable and trained individuals who can assist in the diagnosis and management of at-risk patients.[103]

3.84 The importance of laboratories sharing testing results and expertise to improve professional development was emphasised in several submissions.[104] Associate Professor Judy Kirk described data exchange amongst professional peers, benchmarking and continuous improvement as 'fundamental to the optimal training and accreditation of healthcare professionals'.[105] Dr Jennifer Leary observed:

> Training and subsequent accreditation of scientists in the molecular genetic discipline depends on access to the experience of others, availability of DNA and clinical resources to expand knowledge and the sharing of scientific information. The granting of patents will have a negative impact on the ability to train molecular genetic scientists and clinical trainees specialising in molecular pathology…
>
> …[if] DNA resources for testing become concentrated in laboratories with the monopoly rights to test, scientific skills will degrade through a lack of opportunity to undertake such training across the broad range of tests required.[106]

3.85 The RCPA noted that long complex genetic testing, such as for the BRCA1 and BRCA2 genes, allows professionals performing this work to gain skills that are applicable in other areas of genetic testing. The RCPA submitted that, if such testing were done in a single laboratory 'the loss of volume, complexity and training

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101 Cancer Council Australia, *Submission 50,* p. 7.

102 National Coalition of Public Pathology, *Submission 40,* pp 2-3.

103 Royal College of Pathologists of Australasia, *Submission 49,* p. 12.

104 For example, NSW Government, *Submission 54,* p. 5.

105 Associate Professor Judy Kirk, *Submission 9,* p. 2.

106 Dr Jennifer Leary, *Submission 39,* p. 5.

opportunities would significantly compromise the operation and sustainability of the public sector laboratories'.[107]

3.86 Further, the RCPA felt that testing in multiple laboratories assists the assessment of diagnostic tests by benchmarking performance against peers and having independent assessment of external quality assurance.[108]

## Progress in medical research

3.87 As outlined in Chapter 2, the main policy rationale for the patent system is to provide incentives for individuals and organisations to invest in research, development and innovation.[109] In order to receive protection, patent applicants must publicly release details of their inventions, allowing other researchers to utilise and build on the knowledge which has been disclosed. However, patents can also act as a brake on innovation where patent monopoly rights are used to impede the research of later innovators.[110] During the inquiry the Committee heard arguments highlighting these conflicting perspectives on the impacts of gene patents on medical research.

### *Incentives for medical research*

*Patent system driving innovation and research*

3.88 A number of submissions noted that Australia's intellectual property system has supported innovation and research in medicine, and claimed that patents act as an incentive for investment, development and innovation in medical research.[111] This was seen as being true in the particular case of patents relating to genes and genetic material.[112]

3.89 The close relationship between intellectual property protection and funding for medical research was outlined by a number of companies and publicly funded research institutions. The Association of Australian Medical Research Institutes noted:

> For medical research institutes, a significant proportion of the income derived from the licensing of these innovations flows directly back to the institutes which fostered them, thus perpetuating a cycle of research and innovation.[113]

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107 Royal College of Pathologists of Australasia, *Submission 49,* p. 12.

108 Royal College of Pathologists of Australasia, *Submission 49,* p. 12.

109 Department of Innovation, Industry, Science and Research and IP Australia, *Submission 19,* p. 7.

110 Professor Andrew Christie, *Submission 38,* p. 6.

111 FB Rice & Co., *Submission 34,* p. 1.

112 For example, Genetic Technologies, *Submission 24,* p. 4.

113 Association of Australian Medical Research Institutes, *Submission 72,* p. 2.

3.90 WEHI outlined the importance of intellectual property to its ongoing research and commercialisation program. Three of approximately 300 patents held by WEHI generate significant revenue. WEHI receives around $2.6 million in royalty income from patents annually, with $1.3 million of this being derived from patents on human gene sequences. This income supplements the substantial public funding provided by the Australian Government (approximately $48.1 million per annum) and overseas funding.[114]

3.91 WEHI advised that it had filed 30 patent applications in Australia claiming gene sequences, with 21 of these being commercialised through licensing. WEHI highlighted a number of inventions derived from their genetic research which would not have 'been progressed to their current stage within the pipeline leading to clinical adoption' without patent protection.[115]

3.92 The role of patent protection in offsetting the large investment costs of medical research for investors was seen as particularly important by some submitters.[116] Medicines Australia argued that guaranteeing a period of market exclusivity through the patent system was necessary to mitigate the extraordinary risks for companies in investing in research and development and bringing new therapies to market.[117] It was noted that many start-up companies relied on patent protection as a means of attracting capital, including direct foreign investment.[118] The Johnson & Johnson Family of Companies emphasised the high costs associated with developing genetic medical research:

> Patent protection provides investors with a high level of assurance that they will be able to recover the cost of development. This is particularly crucial in the biotechnology sector…[In order to] ensure return on investment a high level of importance is placed on eliminating unpredictability.[119]

3.93 Genetic Technologies also emphasised the positive impact of patents in the biotechnology area. They noted that products in this area generally take about ten years of research and development to bring to market. They argued that patents provided certainty for innovators and investors over these timeframes:

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114 Dr Julian Clark, Walter and Eliza Hall Medical Research Institute, *Committee Hansard*, 3 August 2009, p. 56; Walter and Eliza Hall Medical Research Institute, answer to question on notice, received 3 August *2009*, p. 1.

115 Walter and Eliza Hall Institute of Medical Research, *Submission 26*, pp 3-5.

116 See, for example, Biotechnology Industry Organisation, *Submission 28*, pp 1-2.

117 Ms Deborah Monk, Medicines Australia, *Committee Hansard*, 5 August 2009, p. 32.

118 Department of Innovation, Industry, Science and Research and IP Australia, *Submission 19*, p. 8.

119 Johnson & Johnson Family of Companies Australia, *Submission 45*, p. 10.

> Inventors and investors need an appropriate system under which they have faith that the product that they plan to market will justify the cost of the research and development they are required to commit to in advance…[120]

3.94 The importance of the patent system in providing a stable framework which protects the intellectual property of innovators and facilitates technology transfers was also emphasised.[121] For example, IPRIA highlighted research showing how intellectual property protection assists 'upstream' biotechnology firms to sell or licence technology to 'downstream' pharmaceutical companies, who are then able to develop these technologies through the commercialisation process.[122]

*Patent system hindering innovation and research*

3.95 However, some stakeholders did not consider that the relationship between patents and incentives for progress in medical research in genetics was clear-cut.

3.96 Cancer Voices NSW (CVNSW) argued that there is no evidence 'that offering patents is necessary to encourage the identification or isolation of human genes', given the potential outcomes of other models for promoting innovation. As an example it pointed to Australia's funding contribution to the International Cancer Genome Consortium (ICGC), a voluntary scientific organisation which aims to create a catalogue of genomic abnormalities in tumours of different cancer types. Countries in the ICGC share information, allowing the comparison of different cancers. The NHMRC, which has contributed to the ICGC, describes it as one of the most ambitious biomedical research efforts since the Human Genome Project.[123] CVNSW was concerned that such approaches could in fact be undermined by the patenting of genes and genetic material:

> We are concerned that if genes and genetic material can be patented and if those patents are enforced this vital area of medical research will be more costly, slower and less translatable to the end beneficiaries: us.[124]

3.97 The SACGHS final report on gene patents found that the prospect of patent protection does not play a significant role in motivating scientists to conduct genetic research. While the report found that patent protection does stimulate some private investment in genetic research, it also found that patents could harm genetic research. It states:

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120 Genetic Technologies Ltd, *Submission 24*, p. 4.

121 Department of Innovation, Industry, Science and Research and IP Australia, *Submission 19*, p. 9.

122 Intellectual Property Research Institute of Australia, *Submission 36*, p. 5; Joshua Gans and Scott Stern, 'The Product Market and the Market for "Ideas": Commercialization Strategies for Technology Entrepreneurs', 2003, vol. 32, *Research Policy*, p. 333.

123 National Health and Medical Research Council, *Report on the operations of the NHNRC: Strategic Plan 2007-2009*, p. 77.

124 Ms Sally Crossing, Cancer Voice NSW, *Committee Hansard*, 5 August 2009, pp 2-3.

> Although the patent law requirement of disclosure and description of a claimed invention is meant to expand the public storehouse of knowledge and stimulate follow-on research, there is evidence to suggest that patents on genes discourage follow-on research[125]

3.98 Senator the Hon. Bill Heffernan using the example of a patent on associated with the hepatitis C virus (HCV) stated that evidence received proved that 'Chiron's patent monopoly over the HCV biological materials impeded the development of diagnostic tests that were necessary for the continued health and wellbeing of the Australian people'. He argued that 'gene patents can so easily overreach, with unintended consequences on medical and scientific research'.[126]

3.99 The significant role of public and charitable funding of medical research was highlighted in relation to this issue. Dr Lim of IPRIA noted that one of the arguments made against gene patents was that much of the research in the area is publicly funded through government grants or completed at universities. Where this is the case, the granting of gene patents could be perceived as privatising a public good.[127]

3.100 Dr Hazel Moir also noted that a large part of the funding for the basic medical research on which patented products are based is often provided by governments or non-profit foundations. Dr Moir pointed to the apparent inequity of granting patents derived from research funded in this way, commenting that '[it seems harsh that] health departments should then have to pay monopoly prices for products whose development was largely funded by taxpayers or philanthropists'.[128]

3.101 Furthermore, Dr Moir observed that the patent system pre-dates the widespread use of publicly funded incentives for medical research—such as public financing of research and taxpayer subsidies for private investment in research. However, the scope of the monopolies rights granted by the patent system has not been reassessed to take these forms of public funding into account.[129]

3.102 Professor Ian Olver argued that competition is in fact the driving force for commercial medical research, and that allowing patent monopolies on genetic products or sequences actually hinders this competition. Professor Olver also noted that 'a lot of the great discoveries in the past have not relied on commercial interests', citing the achievements of the Human Genome Project as an example.[130] Similarly, Dr Anne Ronan stated that medical research is 'not always driven by profit', and that

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125 Secretary's Advisory Committee on Genetics, Health, and Society, G*ene patents and licensing practices and their impact on patient access to genetic tests,* April 2010, p. 3.

126 Senator the Hon. Bill Heffernan, *Submission 76*, p. 16.

127 Dr Kwanghui Lim, Intellectual Property Research Institute of Australia, *Committee Hansard*, 3 August 2009, p. 3.

128 Dr Hazel Moir, *Submission 20*, pp 43-44.

129 Dr Hazel Moir, *Submission 20*, pp 43-44.

130 Professor Ian Olver, *Committee Hansard*, 5 August 2009, p. 8.

the research breakthroughs in medical knowledge can provide other benefits to companies 'in terms of status, staff development and publicity'.[131] Dr Ronan observed that:

> The absence of patents in other areas of medical research has not hampered medical research development. Most medical research is carried out because people have started off caring for patients and they desperately want to find answers.[132]

### *The anti-commons*

3.103 The Committee also heard many concerns that patents on genes and related materials are detrimental to innovation and medical research. In particular, submissions referred to the 'tragedy of the anti-commons', which describes situations where the existence of numerous rights holders prevents socially desirable outcomes. In the case of gene patents, this can occur where the number and scope of patent rights inhibits research and innovation because of concerns about infringing patents or the difficulties of obtaining licences to use patented materials.[133]

3.104 Professor Nicol and Dr Nielsen commented that gene patents may have a greater impact on medical research because genes and related inventions are 'particularly powerful tools in biomedical research and product development'. Professor Nicol and Dr Nielsen argued that, where access to basic research is restricted, there is likely to be a detrimental effect on subsequent downstream research and development.[134] Despite the continuing advances in biomedical research and development, there remains potential for the scope and number of gene patents to adversely impact on this area:

> Owners of patents claiming broadly applicable foundational technology could refuse to license or license on a restrictive basis, blocking off whole areas of downstream innovation. And if the patent landscape is too cluttered, necessitating entry into licence negotiations over multiple patents, innovation could be further impeded or delayed, creating what has become known as a tragedy of the anticommons. Such negative impacts on innovation would be likely to have flow on effects in terms of consumer access, and could extend to basic upstream research as well...[135]

3.105 A number of submitters pointed to concerns about the fragmentation of ownership of patent rights in genes, and the potential for this to frustrate medical research. In particular, this could create uncertainty and impose additional transaction

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131 Dr Anne Ronan, *Submission 3*, p. 2.

132 Dr Anne Ronan, *Committee Hansard*, 5 August 2009, p. 64.

133 Michael Heller, 'Can patents deter innovation? The anticommons in biomedical research', 1998, vol. 280, *Science*, p. 698.

134 Professor Dianne Nicol and Dr Jane Nielsen, *Submission 23*, p. 8.

135 Professor Dianne Nicol and Dr Jane Nielsen, *Submission 23*, p. 10.

costs on researchers attempting to negotiate access to patented genetic inventions. Dr Graeme Suthers of the RCPA commented:

> …many genes that are patented currently have multiple patents on the one gene. If you track the ownership of each individual patent applying to this gene, you end up with a dense thicket of arrows [patents].[136]

3.106 The fragmentation of patent rights over genes and genetic material could lead to situations where a researcher, for example, will need to secure the consent of multiple rights holders in order to undertake research on a number of genes. In such cases, the refusal of any single one of those rights holders can effectively prevent the entire research project. Associate Professor Webster of IPRIA commented that there is 'little evidence that the anti-commons exists in Australia'. However, she noted that the state of empirical knowledge on this issue is poor, and the law may well need to account for the potential for the anti-commons to arise.[137]

3.107 WEHI did not consider that the available data supports the view that there is an anti-commons effect relating to gene patents in Australia. WEHI pointed to research in the US in which only one per cent of biomedical researchers reported having had to delay, and none had to abandon, a project as a result of patents. Conversely, the research found that 25 per cent of pathology laboratories had abandoned a genetic test as a result of patents. WEHI suggested that this was probably due to a lack of willingness to accept the market price and access terms. WEHI concluded:

> These observations suggest neither the anti-commons nor restrictions on access are seriously limiting academic research – despite the fact that biomedical researchers operate in a patent-dense environment, without the benefit of a clear research exemption. Fears of widespread anti-commons effects blocking the use of upstream discoveries have largely not materialised.[138]

3.108 IP Australia also commented that available data shows 'a rise in patents claiming downstream uses of isolated human nucleic acid molecules'. Mrs Fatima Beattie stated:

> This indicates to us that basic research and innovation are not being stifled by patents. The evidence so far is that licensing issues are often resolved in the market through commercial negotiations, except for isolated instances like BRCA.[139]

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136 Dr Graeme Suthers, Royal College of Pathologists of Australasia, *Committee Hansard*, 4 August 2009, p. 40.

137 Associate Professor Beth Webster, Intellectual Property Research Institute of Australia, *Committee Hansard*, 3 August 2009, pp 9-10.

138 Walter and Eliza Hall Institute of Medical Research, *Submission 26*, pp 8-9.

139 Mrs Fatima Beattie, IP Australia, *Committee Hansard*, 20 August 2009, p. 28.

3.109 Professor Peter Drahos argued that the patent system has 'increasingly generated tremendous amounts of uncertainty' for medical researchers because of the volume of patent applications and new patents being granted. This uncertainty about breaching patent rights could cause medical researchers to become 'risk adverse'.[140] Professor Drahos's research found:

> Companies are often not sure that they have found all the patents relevant to a product on which they are working. They frequently have doubts about the scope of the patents they have found. Patents, unlike blocks of land, do not come with settled boundaries. These kinds of uncertainty are especially dangerous from the point of view of the public management of risk…[141]

3.110 However, Mr Hamer of the Law Council of Australia observed that, in his experience, research scientists are generally well informed about the patent system. Mr Hamer noted it was standard practice for researchers to '[conduct] searches before they engage in their research to ensure that they are not reinventing the wheel and to ensure that there is freedom to operate'. [142]

3.111 The Committee heard that patent attorneys regarded freedom-to-operate searches as a common practice to identify what patents may exist in relation to a given field. Such searches are commonly undertaken in the early stages of a research program.[143] Davies Collison Cave suggested that apprehensions about the adverse impacts of patent protection on genetic research 'to large extent [arise] from a lack of understanding by researchers of the patenting process as well as a lack of experience and expertise to commercial exploit research'.[144]

3.112 In contrast, the Committee also received a submission from Ms Naomi Hawkins, a UK researcher with an interest in patent issues, who described the main legal challenge of gene patents as being the difficulties of effectively conducting due diligence and the associated problem of a potentially crowded patent landscape. Despite this, Ms Hawkins suggested that patents in fact have a minimal impact on researchers. This is not because patents are being appropriately managed but because 'patents are essentially ignored by those who develop genetic tests in the public sector, and patent holders do not tend to take any enforcement action'.[145]

3.113 Dr Luigi Palombi commented that, in his experience, restrictions caused by gene patents can interfere with the ability of scientists to undertake research. While

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140 Professor Peter Drahos, *Committee Hansard*, 20 August 2009, p. 18.

141 Professor Peter Drahos, *Submission 60*, p. 450.

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

143 Mr John Slattery, Davies Collison Cave, *Committee Hansard*, 4 August 2009, p. 10; Mr Richard Jarvis, Law Council of Australia, *Committee Hansard*, 4 August 2009, p. 88.

144 Davies Collison Cave, *Submission 27*, p. 7.

145 Ms Naomi Hawkins, *Submission 22*, p. 3.

most scientists ignore these restrictions, Dr Palombi noted that '[when] someone does decide to enforce those patents, all hell breaks loose'.[146]

3.114 CCA observed that there is significant investment in cancer research in Australia, and was concerned that gene patents might in fact be acting as a disincentive to cancer researchers. This is because:

> …[patents] give a patentee the ability to impose conditions on the use of these materials in the conduct of that research, including a requirement to share ownership of intellectual property that may result from that research.[147]

3.115 The 2004 ALRC report discussed such far-reaching or 'reach-through' license conditions, in which patent holders retain rights over future discoveries made by licensed researchers. The report noted that, while reach-through licence agreements may offer some advantages—for example, by permitting researchers to defer payment until research yields valuable results—they are perceived by researchers as benefiting patent holders disproportionately.[148]

3.116 The ALRC report stated that there is 'little evidence' that gene patents have had any significant adverse impact on the conduct of genetic research in Australia. It cited international studies which suggested that patent holders and researchers are capable of developing working solutions for dealing with problems. These solutions 'sometimes take time to work out, and may not be optimal, but research generally moves forward'. However, the report also noted that 'the current position may change, particularly if patent holders become more active in enforcing patent rights'.[149]

3.117 An example of a situation where restrictive licensing approaches have had significant impacts on medical research was described by PMCC. PMCC had planned to conduct tests on a large cohort of women to determine the frequency of BRCA1 and BRCA2 mutations. The study was being conducted in collaboration with a commercial partner, Myriad Genetics, who was to conduct the testing. However, it became apparent that Myriad Genetics would be in breach of a licensing agreement with Genetic Technologies if it did in fact conduct the tests. Professor Bowtell explained:

> We went to [Genetic Technologies] and told them this was a research study and it had implications for understanding the frequency of these mutations in the population and could actually be good for their business in the end. We asked whether we could go ahead and do this [BRCA testing] with

146 Dr Luigi Palombi, *Committee Hansard*, 14 September 2009, pp 15-16.

147 Cancer Council Australia, *Submission 50*, p. 7.

148 Australian Law Reform Commission, *Genes and ingenuity: gene patenting and human health*, Report 99, 2004, pp 305 & 309.

149 Australian Law Reform Commission, *Genes and ingenuity: gene patenting and human health*, Report 99, 2004, p. 307.

> Myriad. It was an extraordinarily hostile reaction and…[Genetic Technologies] shut it down. Myriad was unable to move and that avenue completely collapsed.[150]

3.118 IP Australia noted that many comparable industries, such as 'software, electronics, organic chemistry and pharmaceuticals', have managed to deal with cross-licensing issues; there was no reason the biotechnology industry would not be able to deal with these issues in a similar way.[151] Professor Nicol noted that research results suggested that practical strategies to work around patents are being found in biomedical research and other areas that are impacted by gene patents. These strategies included:

- licensing and other collaborative arrangements;
- ignoring patents;
- working around patents; and
- challenging the validity of patents.

3.119 Professor Nicol stated that there 'are many reasons' driving the type and nature of the strategies being employed, including the difficulty for patent holders in pursuing infringers, the practical benefits of cooperative strategies and the uncertain validity of certain patents.[152]

3.120 The view that 'working solutions' had been developed to mitigate the negative impacts of patents on genetic medical research appeared to be supported by Pfizer Australia. Pfizer Australia advised that it licensed use of gene patents in the development of new medicines, and regarded licensing fees as part of normal business costs. These costs had not been a barrier to the development of new medicines.[153] Pfizer Australia stated that their own policy was explicit that gene patents must not impede research. The quoted policy stated:

> …gene inventions and, in particular, research tools should be readily available for non-commercial purposes consistent with the advancement of biomedical research. This may be achieved through scientific publications or patent licensing. In the latter case, patents should be available for licensing on a voluntary basis for non-commercial purposes. Such licenses should be available on a non-exclusive and non-discriminatory basis and under fair terms consistent with the advancement of biomedical research.[154]

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150 Professor David Bowtell, Peter MacCallum Cancer Centre, *Committee Hansard*, 4 August 2009, pp 114-115.

151 Mrs Fatima Beattie, IP Australia, *Committee Hansard*, 20 August 2009, p. 29.

152 Professor Dianne Nicol, *Committee Hansard*, 3 August 2009, p. 28.

153 Pfizer Australia, *Submission 51*, p. 10.

154 Pfizer Australia, *Submission 51*, p. 10.

***Research tools and databases***

3.121 A number of submitters and witnesses expressed concern that gene patents would restrict the development of genetic medical research by preventing researchers from accessing genetic materials, samples and data held by companies.[155] For example, the BCNA saw a risk that:

> …gene patent holders may choose to charge a fee for access to data and samples, which could be prohibitive for publicly funded researchers, or which could place considerable additional burdens on their research budgets.[156]

3.122 There were also concerns that monopoly testing may create restricted knowledge bases and remove opportunities for shared knowledge in research and improved result interpretation.[157] Dr Jennifer Leary warned that the monopolisation of testing due to gene patents could result in information on genetic variants being 'locked up' by companies, which would treat such data as a valuable commercial asset. Dr Leary also highlighted the importance of information sharing for genetic research and clinical care:

> Sharing knowledge of mutations is essential to understanding the clinical significance of the rare variants that can be observed in genes. Access to unpublished experimental data, knowledge of the frequency of observations, knowledge of instances of co-occurrence with other variants in addition to robust exchange of ideas amongst a variety of scientists can all help to unravel the complexity faced in the interpretation of the variants.[158]

3.123 With particular reference to the BRCA genes, Dr Luigi Palombi argued that the cost of allowing gene patents to be enforced includes 'the opportunity cost for Australian laboratories to gather important scientific data'. Dr Palombi described this data as vitally important to improve the reliability of BRCA gene testing. This is because the genes are complex and lack universally applicable genetic markers, which means there is a need for the data to be shared among laboratories.[159] The importance of accessible databases of genetic testing was also raised by the RCPA, who argued patents on genetic materials could create exclusive databases of genetic variants. The RCPA submission explained:

> If genetic testing is provided by multiple laboratories, they will often pool their records of genetic variants in public databases. As more data accumulate about the frequency of variants and their association with

155 Ms Janet Green, Breast Cancer Action Group, *Committee Hansard*, 5 August 2009, p. 3.

156 Breast Cancer Network Australia, *Submission 48*, p. 4.

157 Human Genetics Society of Australasia, *Submission 33*, p. 2; NSW Government, *Submission 54*, p. 5.

158 Dr Jennifer Leary, *Submission 39*, p. 4.

159 Dr Luigi Palombi, *Submission 4, Part 2*, p. 42.

> disease, this information will help laboratories to interpret variants and provide useful information to requesting clinicians and patients. These databases are in the public domain and are a resource for other laboratories, researchers, companies, and policy makers.
>
> If testing of a gene is provided by a single laboratory, there is no incentive to create a public database of variants. In effect, the information about genetic variants becomes the property of the patent-holder, with no opportunity for this information to be reviewed by independent researchers, or made available for public analysis.[160]

3.124 Other stakeholders were concerned that gene patents could jeopardise successful relationships established between clinical care and medical research entities. HGSA argued that gene patents may limit the further investigation that currently occurs in public hospital laboratories as new variants are identified, and stressed that 'the line between service and research is not always clear'.[161]

3.125 HGSA also emphasised the importance of the relationships between patients, healthcare professionals and medical researchers. In many cases, samples taken from patients for genetic testing are held by laboratories to enable further research. As new medical data becomes available, laboratories can return to stored samples for further testing. The results of new tests can then assist the healthcare of patients and feed back into ongoing medical research.

3.126 Ms Heather Drum, a member of BCNA, was concerned that there is potential for patent holders to enforce their rights over the BRCA genes and affect the ability of researchers to continue to conduct research on tissues and samples donated by individuals and families.[162] Ms Drum commented:

> We have been confident to donate various tissues from the surgeries, secure in the knowledge that it will be used in research by Peter Mac. We have been assured our tissues will continue to be used in research and even retested for the BRCA1 and 2, should further discoveries be made.
>
> …we are one of those families where the tissue is really important to the researchers. I would feel really devastated if the tissues my sisters and I have donated were used to make money out of patenting thereby excluding other women from being treated appropriately on the basis of future breast cancer research.[163]

3.127 The South Australian Government stated that private sector research is published much less frequently than research done in the public sector. The South

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160 Royal College of Pathologists of Australasia, *Submission 49*, p. 13.

161 Human Genetics Society of Australasia, *Submission 33*, p. 2.

162 Ms Heather Drum, Breast Cancer Network Australia, *Committee Hansard*, 3 August 2009, p. 89.

163 Ms Heather Drum, Breast Cancer Network Australia, *Committee Hansard*, 3 August 2009, p. 89.

Australian Government submission suggested that if genetic testing is concentrated in the private sector 'there is a risk of genetic data residing with this sector, making it difficult for staff with the public health system to access data for population health studies'.[164]

3.128 However, WEHI noted that it had not experienced any restrictive licence requirements that have prevented it from conducting further research. Nor had it experienced any infringement or enforcement challenges. Further, WEHI's patents have not impeded rapid publication in the public domain.[165] The WEHI submission commented that:

> …gene patents have had no negative impact on WEHI's research activities and ability to innovate. Furthermore, we believe that rather than hindering dissemination of research results, patents actually reduce the possibility of information being kept as trade secrets.[166]

### *The general research exemption*

3.129 Patents confer monopoly rights that exclude others from using the invention, including those who wish to use the invention for research (unless they obtain a licence from the patentee). There is no specific exemption for research or experimental use in the *Patents Act 1990*, and it is unclear whether a defence of research or experimental use is available under Australian law (because it has not been tested in the courts).

3.130 However, the committee heard that there is a widespread belief in research institutions that a general research exemption exists in Australia, which allows research to be conducted on patented materials.[167] Many institutions rely on this belief to conduct research or to experiment on patented materials, despite being unsure as to the scope and limits of any such assumed exemption.[168]

3.131 The Committee heard that IP Australia is in the process of public consultation over a proposed statutory experimental use exemption.[169] This issue is discussed further in Chapter 5.

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164 South Australian Government, *Submission 16*, p. 10.

165 Walter and Eliza Hall Institute of Medical Research, *Submission 26*, p. 5.

166 Walter and Eliza Hall Institute of Medical Research, *Submission 26*, p. 8.

167 Intellectual Property Research Institute of Australia, *Submission 36*, p. 7.

168 See, for example, Mr John Slattery, Davies Collison Cave, 4 August 2009, *Committee Hansard*, p. 10.

169 Department of Innovation, Industry, Science and Research and IP Australia, *Submission 19*, p. 31.

## Health and wellbeing of the Australian people

3.132 The broad scope of the term of reference relating to the 'health and wellbeing of the Australian people' invited evidence covering a number of issues. Much of this evidence repeated or elaborated on the matters discussed above relating to the provision and costs of healthcare, training and accreditation of healthcare professionals and the progress of medical research. A number of submitters and witnesses felt that the granting of patent protection in respect of genetic materials has not had any direct impact on the health and wellbeing of the Australian people.[170]

3.133 Several submissions focussed on the economic and employment benefits of the fields of biotechnology and medical research which are supported by patent protection. For example, the Tasmanian Government noted that healthcare issues need to be balanced against the economic benefits of the 'biotechnology and pharmaceutical industry, which can produce highly successful companies'.[171]

3.134 IP Australia commented that, while it is difficult to isolate the contribution of gene patents, the Australian pharmaceutical industry employs 40,000 people and was Australia's second largest exporter of manufactured goods in 2008.[172] IP Australia submitted research which attempted to calculate the 'patent premium' in Australia—the implicit subsidy provided to innovators through the patent system. Although this did not address the specific impact of gene patents, the overall patent premium was estimated to be $12 billion, which is 'much larger than the support to innovators via direct transfers from the government or fiscal incentives'.[173]

3.135 The Institute of Patent and Trade Mark Attorneys of Australia (IPTMAA) highlighted the number of patent applications filed in the area of biotechnology by Australian research institutes. IPTMAA argued that, without the possibility of obtaining patent protection, a number of well-known Australian biotechnology innovations may not have achieved commercial success. IPTMAA also noted that 33 of the 90 companies listed on the Australian Securities Exchange (ASX) in the Pharmaceuticals, Biotechnology and Life Sciences Industry Group had applied for, or obtained, patents in the area of biotechnology.[174]

3.136 Genetic Technologies identified itself as an Australian company 'built on so-called gene patents' that employs 61 people in Australia and generated $16 million revenue in 2008. Genetic Technologies argued that it is a significant contributor to the

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170 Davies Collison Cave, *Submission 27*, p. 8.

171 Tasmanian Government, *Submission 53*, p. 1.

172 Department of Innovation, Industry, Science and Research and IP Australia, *Submission 19*, p. 8.

173 Paul Jensen et al, *Estimating the Patent Premium: Evidence from the Australia Inventor Survey*, Intellectual Property Research Institute of Australia, Working Paper 11/09, May 2009, p. 25.

174 Institute of Patent and Trade Mark Attorneys of Australia, *Submission 31*, p. 12.

Australian economy and has made a positive contribution (in the order of $60 million) to Australia's balance of payments.[175]

3.137 The Committee also heard about the emotional and financial stress experienced by patients and their families undergoing genetic testing. For example, Dr Belinda Coyte advised that there was a considerable financial burden in obtaining complicated genetic testing for her son, including tests which were only available overseas and subject to considerable delay.[176] Ms Trish Carey, whose daughter died of a complication of Marfan Syndrome, explained genetic testing for her granddaughter in relation to this condition could cost approximately $3000. The point was made that restrictive enforcement of patent rights in relation to genetic testing could add to the stress and the costs incurred by patients and their families.[177]

3.138 Others noted that the impacts of gene patents are potentially very broad, and extend beyond the realm of healthcare to other industries, including agriculture and conservation. For example, Dr Rimmer noted the potential of current gene research in the field of energy and global warming:

> J Craig Venter, who did shotgun sequencing of the human genome, is now applying that same technology to shot gun sequencing the world's micro-organisms in the oceans under the Sorcerer II Expedition. His synthetic genomics project is very much focused on developing novel minimal genomes to address certain concerns about biofuels, partly funded by the department of energy.[178]

3.139 The privacy of genetic test results and the potential for discrimination based on those results, particularly in the area of healthcare and life insurance, were also issues raised with the Committee. Reference was made to decisions made by the European Patent Office, which upheld the rights of Myriad Genetics over particular mutations in BRCA2 associated with a predisposition to breast cancer among the Ashkenazi Jewish community. Consequently, in certain overseas jurisdictions patients with this ethnic background were likely to pay more for this type of genetic testing.[179]

3.140 The BCNA argued that strict rules need to be put in place to ensure that genetic data is not treated as a commodity and that the privacy of patients using genetic testing services is ensured. The BCNA observed:

> …the granting of gene patents could increase the risk of discrimination against women and men who test positive to a genetic mutation such as the

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175 Genetic Technologies Ltd, *Submission 24*, p. 6.

176 Dr Belinda Coyte, *Submission 55*, p. 2; Dr Belinda Coyte, *Committee Hansard*, 4 August 2009, pp 93-96.

177 Ms Trish Carey, *Submission 56*, p. 1.

178 Dr Matthew Rimmer, *Committee Hansard*, 20 August 2009, p. 23.

179 Dr Graeme Suthers, Royal College of Pathologists of Australasia, *Committee Hansard*, 4 August 2009, p. 47.

> BRCA 1 or BRCA 2 gene mutation. We are concerned that a company that holds the sole right to test for the presence of a gene or gene mutation would also hold a significant amount of personal genetic information.[180]

3.141 The Department of Health and Ageing noted that the management of privacy issues in healthcare has been challenged by the implications arising from genetic technologies. It commented that insurers are currently not able to ask, or indirectly coerce, applicants for insurance to undertake genetic testing. However, the Department also noted:

> Currently, the position is that an insured person's duty of disclosure to his or her insurer includes an obligation to disclose knowledge which that person has acquired through genetic testing Moreover, insurers are not prevented from requesting family history and genetic testing results, from which they can make decisions about whether to insure individuals or not, and if so, upon what terms.[181]

## CONCLUSION

3.142 While scientific understanding of genetics has progressed over the years since the report by the ALRC into gene patents, the indications concerning the impacts of gene patents in Australia appear to have remained largely the same. The actions of Genetic Technologies in relation to BRCA1 and BRCA2 have renewed many of the concerns about gene patents held by government officials, healthcare professionals, researchers and patient groups. However, the evidence the Committee received concerned only isolated examples of impacts from gene patents on healthcare, training and accreditation of healthcare professionals, medical research and the health and wellbeing of the Australian people.

3.143 Although evidence of negative impacts caused by gene patents was relatively sparse, significant potential impacts were highlighted during the inquiry. The Committee was concerned that there do not appear to be strong mechanisms in place to effectively monitor the impacts of gene patents. Without this information it is difficult for policy makers and regulators to respond to the potential impacts of gene patents, should they occur.

3.144 Despite such concerns, the Committee could not therefore conclude that gene patents have caused significant impacts on the provision and costs of healthcare in Australia to date. The Committee also acknowledges that it is possible that patent protection has, at least in some cases, encouraged innovation and thus had positive impacts on the delivery of health services through the development of better testing and treatments. This may have led to lower healthcare costs, for example, by introducing genetic testing to target expensive treatments.

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180 Breast Cancer Network Australia, *Submission 48*, p. 6.

181 Department of Health and Ageing, *Submission 62*, p. 4.

3.145 The granting of patent monopolies has been associated with some accessibility and affordability issues for patients. However, it is difficult to determine the contribution gene patents have made to these issues, which are also subject to other factors such as the rapid development of, and increased demand for, genetic testing and treatment, and the level and structure of public funding.

3.146 The evidence received clearly identified the use of closed, restrictive or exclusive licensing models by gene patent holders as a key potential risk to the accessibility, affordability, accuracy and timeliness of genetic testing services. While there is theoretically no limit to what a patent holder might seek to charge for a licence, commercial realities mean that the more usual outcome is that negotiated licence agreements will result in a level of charge that reflects what potential licence holders can afford and are willing to pay.[182] However, the Committee notes that patent regulators and regulation should be robust enough to ensure that they can respond to instances where commercial influences fail to ensure broad licensing of patents which are important to the health and wellbeing of Australians. These licensing issues are considered further in Chapter 5.

3.147 The potential impact of gene patents on the current integrated public sector approach to genetic testing was highlighted by a number of submissions and witnesses. It was clear to the Committee that this poses risks in several areas which will need to be closely monitored by IP Australia and health departments around Australia. The possible affected areas include the number and capacity of public laboratories conducting genetic testing, the relationship between genetic testing and standards of clinical care, and the provision of medical advice and genetic counselling to patients using genetic testing services.

3.148 The Committee received little evidence concerning the impacts of gene patents on the training and accreditation of healthcare professionals. However, restrictive approaches to licensing by gene patent owners were again identified as a key potential risk. Genetic testing being conducted in a restricted number of laboratories, or samples required to be sent overseas for testing as a consequence of patent rights, would clearly reduce opportunities for training and limit the development of expertise for Australian healthcare professionals.

3.149 The evidence presented to the inquiry revealed that there are few instances in Australia where enforcement of a patent has restricted medical research. However, examples where gene patent licensing has impeded research, including the incident described by the Peter MacCallum Cancer Centre, indicated this could be a problem area in the future. The lack of impacts on medical research may be due to researchers ignoring patent rights or assuming that an exemption exists for medical research and experimental use. Patent protection was seen by many as an important incentive for the encouragement of research and to offset the large investments required to undertake research and development. Again, restrictive licensing approaches by patent

182 Mr John Slattery, Davies Collison Cave, *Committee Hansard*, 4 August 2009, p. 29.

owners were perceived as a key potential risk through reducing access to research tools and databases, contributing to anti-commons scenarios which restricted research, and by creating uncertainty for medical researchers.

3.150 Evidence to the inquiry indicated that there is a lack of accessible data in relation to gene patents. The Committee notes that many witnesses and submitters argued that policy in relation to gene patents should be based on evidence and research rather than apprehensions regarding circumstances which may occur in the future. Others highlighted the lack of research and empirical evidence available concerning the impacts of gene patents.

3.151 The *Australian Genetic Testing Survey 2006* was undertaken in response to the lack of available data on the level of demand and supply of genetic testing. The RCPA undertook the survey in consultation with the Human Genetics Society of Australia and with funding from the Department of Health and Ageing. This collaborative approach to data collection and analysis in relation to genetic testing and healthcare should be encouraged, expanded and regularly updated. The debate over gene patents would benefit from increased empirical evidence and research concerning the costs and provision of genetic testing and treatment.

3.152 The ALRC's report considered that the impact of genetic technologies needed to be closely monitored by health policy makers in Australia. The ALRC recommended that the Australian Health Ministers' Advisory Council should establish processes for (a) economic evaluation of medical genetic testing and other new genetic medical technologies and (b) examination of the financial impact of gene patents on the delivery of healthcare services in Australia.[183] The Committee agrees that better information in relation to the use of gene patents in Australia is needed.

3.153 Professor Drahos and others have also suggested the establishment of a patent transparency register, whereby companies would be required to disclose patent holdings in designated subject matter areas. The system would be intended to promote transparency and to overcome some of the issues relating to accessibility of information regarding gene patents, which may act as barriers to research and innovation. A proposal was also made by Dr Moir to include a requirement in the patent renewal process to regularly require patent owners to disclose the use of their monopoly rights.[184] This would be an additional administrative burden on patent owners but would allow policy makers to track the use and enforcement of patents. While the Committee considers these suggestions to have merit, it notes that other submissions, particularly those from research institutes and relevant companies, have not highlighted this as an area of reform.

3.154 Given the lack of comprehensive, systematic and accessible data and information on the impact of patents generally, and of the impacts of gene patents on

183 Australian Law Reform Commission, *Genes and Ingenuity*, 2004, pp 470-472.

184 Dr Hazel Moir, *Submission 20*, p. 39.

healthcare and medical research in particular, the Committee considers that the Government should support the development and maintenance of better systems to collect patent data and information as per Recommendation 19-1 of the 2004 ALRC report, which states:

> **Recommendation 19–1**
>
> The Australian Health Ministers' Advisory Council (AHMAC) should establish processes for:
>
> (a) economic evaluation of medical genetic testing and other new genetic medical technologies; and
>
> (b) examination of the financial impact of gene patents on the delivery of healthcare services in Australia.[185]

This information will facilitate assessments regarding the costs and benefits of gene patents in relation to healthcare and medical research in Australia.

3.155 The Committee also endorses the need to establish a patent transparency register. The Committee considers that these initiatives will also support the activities of an external oversight body for the patent system in Australia (see Recommendation 15 and related discussion in Chapter 5).

***Collection of patent data and information***

**Recommendation 1**

**3.156 The Committee recommends that the Government support and expand on the collection of data, research and analysis concerning genetic testing and treatment in Australia, in line with recommendation 19-1 of the 2004 Australia Law Reform Commission report *Genes and ingenuity*.**

***Establishing a patent transparency register***

**Recommendation 2**

**3.157 The Committee recommends that the Government conduct a public consultation and feasibility study regarding establishing a transparency register for patent applications and other measures to track the use of patents dealing with genes and genetic materials.**

185 Australian Law Reform Commission, *Genes and Ingenuity*, June 2004, p. 472.