CHAPTER 5

MEASURES TO AMELIORATE ANY ADVERSE IMPACTS OF GENE PATENTS

5.1 This chapter addresses term of reference (b), which directs the Committee to identify measures that would ameliorate any adverse impacts arising from the granting of patents over human genes and genetic materials, including whether the *Patents Act 1990* (the Act) should be amended, in light of the matters identified by the inquiry.

INTRODUCTION

5.2 As noted in the previous chapter, many stakeholders disagreed with any proposal for an express prohibition on gene patents, but instead supported measures to improve the quality of patents and reform the operation of the patent system more broadly. IP Australia, for example, argued that a range of reforms and strategies could preserve an appropriate balance between the incentives and benefits that flow from gene patents and their potential for adverse impacts on healthcare and medical research. Medicines Australia expressed a typical view about the goal of such reforms to the patent system:

> …any reform of the Australian patent system must embody the following guiding principles: the system must uphold the globally accepted balance between the incentive to innovation and a society's right to access innovative products at a fair and affordable price…[1]

5.3 The Committee notes that, while the recommendations in this chapter are posited in the particular context of gene patents, the measures identified are in fact general measures that would apply equally to all patent applications. In taking this approach the Committee acknowledges that, despite the inquiry's relatively narrow terms of reference, many of the actual and potential problems relating to gene patents that were identified arise in relation to the patent system more broadly.

5.4 The Committee notes that the recommendations contained in this chapter are to be understood implicitly or explicitly as being made in the context of the many previous and current inquiries into the issues raised by the inquiry's terms of reference.

Raising the thresholds of patentability

5.5 Recommendations going to the raising of the thresholds of patentability are concerned with the first element of patent quality: that is, the legislative requirements

1 Ms Deborah Monk, Medicines Australia, *Committee Hansard*, 5 August 2009, p. 31.

of patentability. The Committee considered evidence going to the following requirements:

- manner of manufacture;
- inventive step; and
- usefulness.

5.6 Many submitters and witnesses observed that the thresholds of patentability in Australia have been eroded through judicial and administrative decision-making. Dr Matthew Rimmer commented that there is a 'general consensus that there needs to be something done in relation to patent quality'.[2]

5.7 The Advisory Council on Intellectual Property (ACIP) options paper observes:

> …there are concerns that decision makers have extended the reach of patents on legal rather than economic grounds. The boundaries of patentable subject matter have expanded through administrative and judicial decisions...Venturous Australia (the Review of the National Innovation System) found the ease with which patents are granted in areas such as software and business methods may be hampering innovation.[3]

5.8 DIISR and IP Australia acknowledged the incremental changes to patentability thresholds as a result of decisions by Australian courts, and observed that, as a result, Australia has lower patentability thresholds than other jurisdictions.[4] The DIISR and IP Australia submission suggested that this carries broad implications for the operation of the patent system in the international context:

> For countries that are a net importer of technology, like Australia, it is advantageous to have patent thresholds set at least as high as thresholds set for countries with which we conduct the majority of our technology trade. Strong and aligned thresholds give Australian innovators confidence that having satisfied those [thresholds] in Australia they are likely to satisfy the requirements in their export markets. Aligned thresholds are also likely to reduce costs for Australian applicants seeking patent protection overseas. Conversely, differences that make Australia's patent law out of step with major jurisdictions may adversely affect Australian businesses wanting to develop their inventions and prosper in a global market place.[5]

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2 Dr Matthew Rimmer, *Committee Hansard*, 20 August 2009, p. 13.

3 Advisory Council on Intellectual Property, 'Patentable subject matter: options paper', September 2009, p. 2.

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

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

Manner of manufacture

5.9 The Australian Law Reform Commission (ALRC) in its 2004 report on gene patents, *Genes and ingenuity* (the ALRC report), concluded that aspects of the manner of manufacture test are ambiguous. It recommended:

> The responsible Minister should initiate a review of the appropriateness and adequacy of the 'manner of manufacture' test as the threshold requirement for patentable subject matter under Australian law, with a particular focus on the requirement that an invention must not be 'generally inconvenient.[6]

5.10 As noted in Chapter 2, ACIP is currently undertaking a review of patentable subject matter which encompasses the issues outlined in the ALRC's recommendation above. The ACIP review website notes that in recent years a variety of concerns have been raised about the sorts of things that can be patented in Australia, and draws attention to the findings of the ALRC report that the 'manner of manufacture' test is ambiguous and obscure. The review includes consideration of:

- the appropriateness and adequacy of the 'manner of manufacture' test as the threshold requirement for patentable subject matter under Australian law; and
- the historical requirement that an invention must not be 'generally inconvenient'.[7]

5.11 The submission of Professor Andrew Christie noted that those who object to the patentability of genetic inventions do so on either economic or social (non-economic) reasons. The submission stated that economic concerns are usually based on the view that these patents are overly broad and therefore anti-competitive, or impact adversely on healthcare and medical research. Concerns about overly broad patents are able to be addressed through the requirement of usefulness (discussed below); and concerns about impacts on healthcare and medical research are able to be addressed through Crown use provisions and development of a research exemption (also discussed below).[8]

5.12 However, in relation to socially based objections to gene patenting, Professor Christie observed that the 'manner of manufacture' test is the 'main mechanism' by which Australia's patent system is able to take account of social or non-economic considerations in relation to the granting of patents. The question of how well the current test accommodates or achieves social objectives, such as those based on moral or ethical concerns, is an important aspect of the current ACIP review.[9]

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6 Australian Law Reform Commission, *Genes and ingenuity*, June 2004, p. 132.

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

8 Professor Andrew Christie, *Submission 38*, p. 7.

9 Professor Andrew Christie, *Submission 38*, p. 8. Professor Christie is the Chair of the Advisory Council on Intellectual Property review of patentable subject matter. Professor Christie appeared before the inquiry in a private capacity.

5.13 The ACIP options paper on patentable subject matter notes that the threshold requirements for patentability—manner of manufacture, novelty, inventive step et cetera—have been described as being a 'rough proxy' for the benefits of a claimed invention. That is, 'these tests advance the economic goals of the system'.[10]

5.14 In contrast, the Act contains a number of express exclusions and discretions to refuse a patent. Human beings and the biological processes for their generation are not patentable inventions, and the Commissioner of Patents may refuse a patent where:

- the use of the invention would be contrary to law;
- a substance is capable of being used as a food or medicine and it is a mere mixture of known ingredients; or
- the name of a person is used as the name of the invention in a claim.[11]

5.15 The exclusions and discretions contained in the Act may be considered as acting to '[filter] out some subject matters where patents may be undesirable, taking social concerns into account'. Thus 'the threshold tests can be viewed as chiefly economic in nature, while the filters or exclusions for undesirable subject matter are predominantly social in nature'.[12]

5.16 In putting forward a number of specific options for reform of the manner of manufacture test, the ACIP options paper concluded:

> …our view is that the legislation must be able to regulate what can and cannot be patented, as determined both economically and socially. In addition, the legislation must be logical, compliant and practical. It must be logical in that it is internally consistent. It must be compliant in that it is not inconsistent with Australia's international obligations. And, it must be practical in that administration of the law is effective and transparent.[13]

5.17 In relation to the options being considered by ACIP:

> The options we have devised follow a similar approach, of economic tests and social filters, to define the field of patentable subject matter. In addition, there are a number of changes that could enhance the operation and administration of the law.[14]

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10 Advisory Council on Intellectual Property, 'Patentable subject matter: options paper', September 2009, p. 5.

11 Advisory Council on Intellectual Property, 'Patentable subject matter: options paper', September 2009, p. 5.

12 Advisory Council on Intellectual Property, 'Patentable subject matter: options paper', September 2009, p. 5

13 Advisory Council on Intellectual Property, 'Patentable subject matter: options paper', September 2009, p. 7.

14 Advisory Council on Intellectual Property, 'Patentable subject matter: options paper', September 2009, p. 7.

5.18 The ACIP options paper offers four mutually exclusive options for reform of the manner of manufacture test:

> A. Retain the manner of manufacture test. This option retains the requirement that an invention must be a 'manner of manufacture within the meaning of section 6 of the *Statute of Monopolies*'.
>
> B. Clarify the language of the definition of an invention, for example by using the NRDC requirements that an invention must be an artificially created state of affairs in a field of economic endeavour.
>
> C. Replace the manner of manufacture test with an alternative test, such as the TRIPS Agreement language that patents are available for any inventions in a field of technology.
>
> D. Delete the requirement for an invention. Under this option, the objective tests of novelty, inventive step and usefulness would do the economic work of limiting patentable subject matter.[15]

5.19 A number of submitters supported changes to the Act that fall within the scope of the ACIP options for reform of the 'manner of manufacture' test, such as by clarifying the current test or developing a new definition of invention. For example, Dr Graeme Suthers, from the Royal College of Pathologists of Australasia, submitted:

> The current patent legislation should be implemented using a rational interpretation of words such as 'invention' and 'discovery'. The problem principally has been with the interpretation of the law and the amendment required is one to ensure that this distinction between inventions and discoveries is made explicit…We must address the anomaly of patenting a discovery.[16]

5.20 Dr Hazel Moir submitted:

> If the *Patents Act 1990* were to be amended to provide guidance to the courts and IP Australia on when a discovery is not an invention, I would recommend an amendment focusing on these combined characteristics. This would not only prevent patenting of genetic information identical to that found in nature, but would also provide sound principles for future contentious areas.
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> …[The] policy the Committee might consider for adoption could be that…to be patentable an invention must be *substantially different* from anything found in nature and the *differences must contribute sufficient utility to provide a benefit* to the nation.[17]

5.21 Dr Rimmer noted:

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15 Advisory Council on Intellectual Property, 'Patentable subject matter: options paper', September 2009, p. 11.

16 Dr Graeme Suthers, Royal College of Pathologists of Australasia, *Committee Hansard*, 4 August 2009, p. 41.

17 Dr Hazel Moir, answer to question on notice, 16 September 2009, p. 3.

> …it would be much more worthwhile thinking about some of the issues in relation to manner of manufacture that need clarification, like stem cell patent…[The] Metabolite Laboratories case and the Australian case of Grant against the Commissioner of Patents shows that there are certain areas that do need clarification, particularly distinguishing between scientific discoveries and inventions and the scope of abstract ideas and products of nature. So I think there is a kind of in between position between the extremes of 'anything under the sun is patentable' and 'we should have broad prohibitions or exclusions of patentable subject matter'.[18]

5.22 In relation to specific exclusions and discretions to refuse, the ACIP paper offers three non mutually exclusive options for reform of the Act's 'social filters':

> E. Retain the current exceptions and filters;
>
> F. Add specific exclusions, such as a list of specific subject matters that are not patentable;[19] and
>
> G. Add general social filters, such as excluding inventions that are 'generally inconvenient' and/or 'contrary to *ordre public* or morality'.[20]

5.23 The ACIP paper notes that under Option F above it would be possible to have an exclusion for 'a mere discovery'. In relation to concerns about gene patents in particular, the Committee notes that this option would allow the excluding of specific subject matter of this type:

> This option…provides a list of things that are not patentable because they do not benefit society, regardless of whether they are inventions. Any exceptions would need to comply with Australia's international obligations.[21]

5.24 Further, the ACIP paper notes that this approach could 'promote greater certainty' in the patent system, provided interpretation issues can be properly managed'.[22]

5.25 Given the scope of the ACIP review and its relevance to the issue of gene patents, Professor Christie submitted:

> The appropriate response to the concern about the inherent patentability of genetic inventions is to determine whether—and, if so, how—the manner of

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

19 Chapter 4 considers the specific issue of whether the Act should contain a specific exclusion, or express prohibition, on gene patents.

20 The options paper notes, however, that the 'meaning and ongoing application of 'generally inconvenient' is unclear' (p. 16).

21 Advisory Council on Intellectual Property, 'Patentable subject matter: options paper', September 2009, p. 18.

22 Advisory Council on Intellectual Property, 'Patentable subject matter: options paper', September 2009, p. 18.

> manufacture test should be reformed. That is the topic of the ACIP review of Patentable Subject Matter. The appropriate action for the government, therefore, is to await, to consider and, if in agreement, to implement the recommendations resulting from that review.[23]

Inventive step

How inventive step is determined in Australia

5.26 As noted in Chapter 2, the requirement that an invention involve an inventive step is fundamental to the patent system, as it ensures that a monopoly is not awarded for knowledge that was obvious or that would have been available at the time of the patent application.

5.27 In Australia, whether an invention involves an inventive step is judged by a comparison with the state of knowledge in the field relevant to the invention, referred to as the 'prior art base'. Section 7(2) of the Act provides:

> For the purposes of this Act, an invention is to be taken to involve an inventive step when compared with the prior art base unless the invention would have been obvious to a person skilled in the relevant art in the light of the common general knowledge as it existed in the patent area [ie in Australia] before the priority date of the relevant claim, whether that knowledge is considered separately or together with the information mentioned in subsection (3).

5.28 The Act defines 'prior art base' as including:

- information in a document that is publicly available, whether in or out of the patent area (ie anywhere in the world); and
- information made publicly available through doing an act, whether in or out of the patent area (ie anywhere in the world).

5.29 Section 7(3) of the Act then provides that the information for the purposes of Section 7(2) is (a) any single piece of prior art information; or (b) a combination of any two or more pieces of prior art information:

> …being information that the skilled person mentioned in subsection (2) could, before the priority date of the claim, be reasonably expected to have ascertained, understood, regarded as relevant and, in the case of information mentioned in paragraph (b), combined as mentioned in that paragraph.

Criticisms of current approach

5.30 Many submitters and witnesses objected to the grant of certain gene patents for the reason that they did not contain sufficient inventiveness to warrant the grant of monopoly. However, the Law Council of Australia questioned whether the level of

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23 Professor Andrew Christie, *Submission 38*, p. 8.

inventiveness required for the granting of a patent is too low, observing that there have been 'very few challenges to the validity of granted gene patents'.[24]

5.31 With particular reference to the inquiry's terms of reference, Dr Palombi called on the patent system to be adjusted to:

> …increase the inventive step threshold so that uses of such materials in applications that are routine and standard, such as in diagnostics, will no longer be patentable.[25]

5.32 However, IP Australia submitted that a number of common misconceptions operate in respect of the requirement of inventive step. In particular, it emphasised that inventive step is determined against the state of knowledge or prior art base at the time a patent claim was lodged:

> Some researchers query the validity of patents for isolating and determining the function of particular genes, as techniques to accomplish this are now quite routine and well-known. However, a misconception can arise from the application of hindsight and taking into account the knowledge base that exists now compared to when the patent application was assessed. Although isolating the gene sequence might be routine now, Inventive Step is assessed as at the 'priority date' of the patent claims, which could be many years in the past.[26]

5.33 IP Australia also pointed to a common misconception that patents are granted only for 'ground-breaking inventions':

> This misunderstanding is most often voiced by researchers. That belief is inconsistent with recent High Court authority which affirms that only the smallest level of inventiveness (i.e. a scintilla of inventiveness) is needed for the grant of a patent. Inventions as defined by patent law can be, and often are, incremental advancements over what has been done before.[27]

5.34 Despite any prevailing misconceptions, IP Australia supported changes to raise the threshold for inventive step. It noted:

> …lower inventive threshold requirements in Australia raise the question whether Australian law strikes the correct balance between the scope of monopolies and access to innovation and new technology.[28]

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24 Law Council of Australia, *Submission 57*, p. 2.

25 Dr Luigi Palombi, *Committee Hansard*, 14 September 2009, p. 12.

26 Department of Innovation, Industry, Science and Research and IP Australia, *Submission 19*, p. 22.

27 Department of Innovation, Industry, Science and Research and IP Australia, *Submission 19*, p. 22.

28 IP Australia, 'Getting the balance right: toward a stronger and more efficient IP rights system', IP Australia Consultation Paper, March 2009, p. 13.

5.35 An IP Australia consultation paper on reforms to the IP system noted that too low a threshold for inventive step could also involve a greater potential for the development of 'patent thickets', whereby overlapping sets of patent rights act as a barrier or disincentive to innovation.

5.36 IP Australia also pointed to trends in overseas jurisdictions towards the raising of inventive step thresholds. Similarly, Dr Rimmer noted:

> The approach of the United States Supreme Court…has been very interesting in terms of raising the standard of novelty and inventive step in applying a slightly higher threshold in terms of what is required. That is being applied in terms of biotechnological inventions…[and] I think that has been a very productive approach...[29]

Potential reforms affecting inventive step

5.37 In a recent discussion paper on possible reforms to the patent system, IP Australia identified three particular elements of the requirements of inventive step which are 'set at a lower level than those of other jurisdictions or of international norms':

- common general knowledge;
- prior art; and
- threshold test for inventive step.[30]

Common general knowledge

5.38 The IP Australia consultation paper on possible reforms to the patent system observes that the restriction of the prior art base to 'common general knowledge in the relevant art in Australia' is out of step with international approaches:

> [Australia's approach]…restricts common general knowledge in a way that it is not restricted in our major trading partners and under the PCT, where when assessing inventive step, common general knowledge anywhere in the world can be taken into account. Such a restriction is also at odds with deliberations in international forums…where there has been a consistent move to global concepts of prior art and validity on the basis that information that invalidates a patent in one jurisdiction should also invalidate patents in others. It also does not take account of the global research, information and innovation environment that exists today.[31]

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29 Dr Matthew Rimmer, *Committee Hansard*, 20 August 2009, p. 13.

30 IP Australia, 'Getting the balance right: toward a stronger and more efficient IP rights system', IP Australia Consultation Paper, March 2009, p. 9.

31 IP Australia, 'Getting the balance right: toward a stronger and more efficient IP rights system', IP Australia Consultation Paper, March 2009, p. 10.

5.39 Accordingly, IP Australia has proposed that the Act be amended to remove the limitation that common general knowledge be confined to that existing in Australia at the time a patent application is lodged.

5.40 The Committee notes that previous inquiries have considered this issue. The Ergas Report recommended that the prior art base for determining inventive step be expanded to include all information, including common general knowledge, anywhere in the world.

5.41 However, Dr Moir commented:

> Personally I consider that using a global standard for 'common general knowledge' would have almost no impact on the quantum of inventiveness required for a patent monopoly. The many rules and procedures about decisions on patent grant are each slanted in favour of the applicant. As the US Federal Trade Commission said in respect of the USA, a 'plethora of presumptions and procedures tip the scales in favor of the ultimate issuance of a patent, once an application has been filed' (US FTC 2003: 8). Australia uses many of the same rules, but excludes even more existing knowledge from decisions on inventiveness. In my view far more radical proposals are needed to set the patent system back on a path where it delivers benefits to the nation.[32]

Prior art

5.42 As noted above, the 'prior art base' against which inventive step is assessed is defined as including:

- information in a document that is publicly available, whether in or out of the patent area (ie anywhere in the world); and
- information made publicly available through doing an act, whether in or out of the patent area (ie anywhere in the world).

5.43 Such information may be considered as part of the prior art base if it is information that a skilled person in the relevant art could be 'reasonably expected to have ascertained, understood, regarded as relevant and…[if involving a combination of any two or more pieces of prior art information] combined'.[33]

5.44 The IP Australia consultation paper on reform of the patent system notes that Australia's approach places limitations on how prior art information can be considered that 'do not exist elsewhere':

> In Australia prior art information must be such that a skilled person in the art could be reasonably expected to have ascertained, understood and regarded [it] as relevant. This approach has led to circumstances where the

32 Dr Hazel Moir, answer to question on notice, 16 September 2009, p. 2.

33 IP Australia, 'Getting the balance right: toward a stronger and more efficient IP rights system', IP Australia Consultation Paper, March 2009, p. 11.

> Federal Court has found that information in US patents, although highly relevant and readily understood, would not have been ascertained in certain circumstances.[34]

5.45 In comparison, other jurisdictions did not have a requirement that the skilled person would have ascertained, or 'looked for and found the [relevant] prior art' information. IP Australia considered that this approach 'is more aligned with the global innovation environment that exists today where there is more ready access to information via the internet and electronic means'.[35]

5.46 Further, the need to establish that a skilled person would have found a relevant citation was not a feature of patent systems in other major countries. Parties seeking to challenge an Australian patent would need to carry the evidentiary burden on this question, which could increase the uncertainty and costs of patent litigation:

> The Federal Court also noted that when the ability of the skilled person to ascertain relevant prior art is in doubt it is necessary to have evidence to resolve the dispute. This has the potential to introduce significant additional costs to litigating patent disputes.[36]

5.47 IP Australia advised that it was currently considering changes to the Act to remove the requirement that prior art information for the purposes of inventive step must be that which could be reasonably expected to be 'ascertained'.[37]

Threshold test for inventive step

5.48 Dr Rimmer advised the Committee that there were concerns with the level of inventiveness credited to the person skilled in the art when assessing inventive step:

> A lot of commentators have…emphasised the role of a person skilled in the art. A great problem in terms of the judgments in relation to novelty and inventive step has been that a person skilled in the art is credited too little creativity. Some commentators…argue that [for] the reasonable person test, the person skilled in the art, you must attribute a greater level of creativity to them.[38]

5.49 In Australia, the threshold test for inventive step is formulated as an inquiry as to whether an invention lacks an inventive step, or in other words is obvious. IP

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34 IP Australia, 'Getting the balance right: toward a stronger and more efficient IP rights system', IP Australia Consultation Paper, March 2009, p. 11.

35 IP Australia, 'Getting the balance right: toward a stronger and more efficient IP rights system', IP Australia Consultation Paper, March 2009, p. 11.

36 IP Australia, 'Getting the balance right: toward a stronger and more efficient IP rights system', IP Australia Consultation Paper, March 2009, p. 11.

37 IP Australia, 'Getting the balance right: toward a stronger and more efficient IP rights system', IP Australia Consultation Paper, March 2009, p. 11.

38 Dr Matthew Rimmer, *Committee Hansard*, 20 August 2009, p. 13.

Australia's consultation paper on reform of the patent system notes that the test for obviousness is to ask whether or not the skilled person in the relevant art would be led directly as a matter of course to try a particular approach with a reasonable expectation of success.[39]

5.50 IP Australia was proposing that Australia adopt a test for obviousness similar to that which is employed by the European patent community, where the test is to ask: Would the invention have been obvious to try with a reasonable expectation of success? Specifically, IP Australia proposed that the inventive step test be revised so that a claimed invention is obvious if it was 'obvious for the skilled person to try a suggested approach, alternative or method with a reasonable expectation of success'.[40]

5.51 IP Australia argued that under such a test it would be easier to argue obviousness than under current Australian law, as it would account for 'situations where it is routine to conduct testing or combine particular approaches in order to solve a problem or find a better way of doing things'.[41]

5.52 In relation to such an approach, the ACIP options paper on patentable subject matter observes:

> The US Supreme Court has recently reinstated a similar test in that country. A submission to the Senate Gene Patent Inquiry by several US Law Professors has suggested that these developments in the US law are likely to call the validity of many patents for gene sequences into question, now that the methods of DNA isolation are conventional.[42]

Usefulness

5.53 The Committee heard that the usefulness of an invention is assessed both explicitly and implicitly under the Act.[43]

5.54 First, section 18(1)(c) of the Act requires that an invention be 'useful'. However, IP Australia advised that this requires only that an invention produce the result or effect that the patentee claims it can achieve:

> To satisfy the patentability criteria an invention must be useful. This does not mean the invention has some usefulness to society or that it is

39 IP Australia, 'Getting the balance right: toward a stronger and more efficient IP rights system', IP Australia Consultation Paper, March 2009, p. 12.

40 IP Australia, 'Getting the balance right: toward a stronger and more efficient IP rights system', IP Australia Consultation Paper, March 2009, p. 13.

41 IP Australia, 'Getting the balance right: toward a stronger and more efficient IP rights system', IP Australia Consultation Paper, March 2009, p. 12.

42 Advisory Council on Intellectual Property, 'Patentable subject matter: options paper', September 2009, p. 51.

43 Advisory Council on Intellectual Property, 'Patentable subject matter: options paper', September 2009, p. 21.

> commercially viable or successful. Rather Usefulness under patent law requires that the claimed invention be capable of achieving the result(s) that the patentee promises it can achieve.[44]

5.55 The ALRC report explains:

> …the usefulness criterion does not require that an invention be useful in the sense that it is worthwhile or commercially viable; only that if a particular result is claimed, it must be achievable.[45]

5.56 Professor Andrew Christie observed that this interpretation of usefulness was more limited than that which is applied in other jurisdictions:

> …the concept of 'useful' in Australian patent law is quite different from – and, in particular, is much more limited than – the concept of 'utility' in US patent law and the concept of 'industrial application' under the European Patent Convention.[46]

5.57 Second, along with the explicit requirement that an invention be 'useful' under section 18 of the Act, the 'manner of manufacture' requirement is also understood as containing an implicit requirement that an invention be useful. The ALRC report observes:

> In *NRDC*, the High Court stated that to constitute a manner of manufacture an invention must be one that offers some advantage which is 'material' and 'its value to the country is in the field of economic endeavour'.[47]

5.58 Third, the usefulness of an invention is also considered indirectly pursuant to the requirement in section 40 of the Act that a complete specification fully describe the use of the invention and how the result claimed can be achieved. The ALRC report explains that 'if a use for the invention described in the claims is not reasonably supported by the description, the claims in the patent application may not be fairly based'.[48]

5.59 Despite the various ways in which usefulness is currently considered under Australian patent law, the usefulness of an invention does not operate as an express requirement for examination of an Australian patent application. The ALRC report explains:

> Usefulness is addressed at the examination stage only as an aspect of the manner of manufacture test and through the disclosure requirements. The Commissioner of Patents does not have to be satisfied that an invention is

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44 Department of Innovation, Industry, Science and Research and IP Australia, *Submission 19*, p. 20.

45 Australian Law Reform Commission, *Genes and ingenuity*, June 2004, p. 143.

46 Professor Andrew Christie, *Submission 38*, p. 5.

47 Australian Law Reform Commission, *Genes and ingenuity*, June 2004, p. 143.i

48 Australian Law Reform Commission, *Genes and ingenuity*, June 2004, p. 144.

> useful under s 18(1)(c) before accepting a patent application. 'Lack of utility' (as the objection is phrased) can be raised as an express objection only in revocation proceedings. It is not a separate basis upon which a patent may be opposed or re-examined. There may, however, be scope to raise the usefulness of an invention claimed in an accepted application in opposition proceedings on the basis of failure to satisfy the manner of manufacture or disclosure requirements.[49]

5.60 IP Australia advised that it was proposing reforms which would introduce usefulness as an express requirement for examination, beyond the limited sense in which it is currently considered:

> IP Australia is proposing a number of changes to the Usefulness requirement under the Patents Act…Under the proposals, Usefulness would become a ground for consideration in examination and it would be clarified that the claimed invention would have to demonstrate 'specific, substantial and credible utility' similar to requirements in the United States. These changes are the same as those proposed by ALRC Report 99, recommendations 6-3 (a) - (c).[50]

5.61 The Committee notes that the proposal for the inclusion of usefulness as a requirement in patent examination was recommended by the ALRC in its 2004 report. The report also recommended that an invention only satisfy the usefulness requirement where a patent application discloses a 'specific, substantial and credible use'; that the question of usefulness be decided on the balance of probabilities; and that 'lack of usefulness' be available as a basis upon which a patent application may be opposed.[51]

5.62 This approach was endorsed in the ACIP options paper on patentable subject matter, which noted that the requirement that an invention have a specific, substantial and credible utility 'will provide additional clarity to the law'.[52] The paper described how these elements might apply to a patent application:

> [A requirement that an invention have a specific, substantial and credible utility would mean that]…an invention would need to be:
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> - specific – the use is specific to the subject matter of the invention and not a generic use;
> - substantial – no further research is required to identify a real or specific use;

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49 Australian Law Reform Commission, *Genes and ingenuity*, June 2004, p. 144.

50 Department of Innovation, Industry, Science and Research and IP Australia, *Submission 19*, p. 20.

51 Australian Law Reform Commission, *Genes and ingenuity*, June 2004, Recommendation 6-3, p. 157.

52 Advisory Council on Intellectual Property, 'Patentable subject matter: options paper', September 2009, p. 21.

- credible – the use is logical and consistent with the state of the art.[53]

5.63 IP Australia also commented on the expected scope of the new usefulness requirement:

> Concerning [stricter] requirements to prove an invention's usefulness at examination and require experimental results showing that the patented invention has utility…These changes to utility will not go so far as requiring applicants to demonstrate their invention's efficacy in humans (as has been suggested by some comments to the Inquiry) as that level of experimental evidence is unrealistic at the early stage of seeking patent protection.[54]

5.64 Professor Christie observed that the requirement of usefulness was connected with the question of overly broad patent claims, which were specifically identified as an issue in relation to gene patents.[55] He explained:

> Some stakeholders are of the view that patents are being granted for genetic inventions that are 'too wide', in the sense that the claims of the patent cover subject matter that goes beyond the actual invention made by the patentee. Because the exclusive rights of a patent apply to the subject matter of the claims of the patent, if the claims are too wide then the exclusive rights granted by the patent will also be too wide. [The requirements that a claimed invention is useful are] primary mechanisms for ensuring that the claims of a patent are not too wide…
>
> The appropriate response to the concern about the width of the exclusive rights provided by patents for genetic inventions is to require that the claims of the patent do not go beyond the actual invention made and disclosed by the patentee.[56]

5.65 Mrs Beattie acknowledged that the proposed usefulness requirement could operate to limit overly broad patent claims:

> …some of the initial patents did have broad claims that may not have been supported as well as they could have been, but patent reforms that we are proposing would limit the scope of those claims to the extent that you would have to demonstrate utility. So we would be examining for specific utility and it would have to be specific, substantial and credible. To that effect you would not be able to say that a particular nucleic acid has a therapeutic effect, full stop. You would have to be very specific about the nature of the therapeutic effect that you expected this to have and provide

53 Advisory Council on Intellectual Property, 'Patentable subject matter: options paper', September 2009, p. 23.

54 IP Australia, *Submission 19*, supplementary submission, 30 September 2009, p. 5.

55 See, for example, Professor Ian Olver, Chief Executive Officer, Cancer Council Australia, *Committee Hansard*, 5 August 2009, p. 10.

56 Professor Andrew Christie, *Submission 38*, p. 5.

> some support for those claims. So, yes, I think some of the original patents that were broader may have been granted…[57]

5.66 Mrs Beattie noted that some patents granted in the past may have been refused if subject to the proposed new test:

> In terms of what we are proposing with the patent reforms some of those [overly broad] patents may have failed. If we were able to, for example, examine on utility, they may have failed on specific, substantial and credible.[58]

5.67 The ACIP options paper observes that the usefulness requirement also bears on the issue of distinguishing between inventions and discoveries in determining patentability of subject matter:

> Both the ALRC and IPCRC considered that the requirement for usefulness has taken on greater importance in some new technologies, where the dividing line between mere discovery and invention has become difficult to define. This option would also require patent examiners to assess, and report on, the usefulness of an invention as a separate requirement.[59]

5.68 In relation to gene patents in particular, the paper noted the view of the IPCRC that the requirement of a specific, substantial and credible utility 'would exclude the mere identification of a gene sequence from patentability'.[60]

5.69 Dr Rimmer noted that the proposed usefulness requirement had effectively operated to exclude certain gene patents in the US:

> The other very important thing on questions of patent quality is introducing the US standards in relation to utility, for there to be a substantial specific and credible utility. There is a big biotechnology case in the United States in re Fisher dealing with the patentability of expressed sequence tags in relation to maize. The Court of Appeals for the Federal Circuit rejected the particular patent application by Monsanto…on the grounds of utility.[61]

Full description and fair basis

5.70 IP Australia advised that it was considering reforms to section 40 of the Act which could also help to address concerns about the granting of overly broad patents. Section 40 requires that a patent specification provide sufficient detail to describe an

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57 Mrs Fatima Beattie, IP Australia, *Committee Hansard*, 20 August 2009, p. 30.

58 Mrs Fatima Beattie, IP Australia, *Committee Hansard*, 20 August 2009, p. 32.

59 Advisory Council on Intellectual Property, 'Patentable subject matter: options paper', September 2009, p. 23.

60 Advisory Council on Intellectual Property, 'Patentable subject matter: options paper', September 2009, p. 36.

61 Dr Matthew Rimmer, *Committee Hansard*, 20 August 2009, p. 13.

invention, and that a claim is 'fairly based on the matter described in the specification'. IP Australia's consultation paper on patentability standards explains:

> It is a fundamental basis of the patent system that the patentee describe their invention fully and that the scope of protection obtained does not go substantially beyond what has been described [in the patent specification] (ie is 'fairly based').
>
> This is the *quid pro quo* that forms the basis of the patent system: the patentee is given a time limited monopoly in exchange for public disclosure of their invention and detailed information about how to make and use the invention.[62]

5.71 The IP Australia consultation paper notes that 'there is a notable difference between full description and fair basis requirements in Australia and requirements in the US, Europe and Japan'. In these jurisdictions a patent specification must provide 'sufficient details of the invention to enable the reader to produce anything across the full scope of the invention claimed'. In contrast, the requirement in Australia is 'simply that there is sufficient detail to produce something, potentially only one thing, within the scope of the claim'. In relation to 'fair basis' requirements:

> This fair basis requirement has come to be understood as one of consistency between the specification and the claims. It is not a test [of] whether the description of the invention and technical detail in the body of the specification is sufficient to support the scope of the invention that is claimed...[63]

5.72 The consultation paper concludes that the lower Australian requirements in relation to full description and fair basis 'allows a patentee to monopolise a greater field than they have disclosed to the public', raising issues as to 'whether an invention may be afforded substantially broader protection in Australia than could be obtained in other jurisdictions'.[64]

5.73 IP Australia was proposing that section 40 of the Act be amended to:

> …introduce descriptive support requirements analogous to those applied in other jurisdictions including that the whole scope of the claimed invention be enabled and that the description provide sufficient information to allow the skilled addressee to perform the invention without undue experimentation.[65]

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62 IP Australia, 'Getting the balance right: toward a stronger and more efficient IP rights system', March 2009, p. 6.

63 IP Australia, 'Getting the balance right: toward a stronger and more efficient IP rights system', March 2009, p. 7.

64 IP Australia, 'Getting the balance right: toward a stronger and more efficient IP rights system', March 2009, pp 7-8.

65 IP Australia, 'Getting the balance right: toward a stronger and more efficient IP rights system', March 2009, p. 8.

5.74 IP Australia expected that raising the threshold for disclosure requirements in this way would 'limit the reach of claims so that the protection given to an inventor is not disproportionate with what has been described'.[66]

OTHER MEASURES

5.75 Apart from suggestions for reform of the patent system that went to the legal requirements for patentability, the Committee received numerous suggestions for reform going to other aspects of the Act, such as the Crown use and compulsory licensing provisions, and the lack of an explicit research exemption. Yet other suggested reforms went to what might be termed external measures or strategies to improve the operation of the patent system more generally, and in this way address particular concerns around gene patents and their actual and potential impacts.

Crown use provisions

5.76 A number of submitters and witnesses suggested that the existing Crown use provisions in the Act (ss 163-170) could be employed to ameliorate any potentially adverse impacts of gene patents on the healthcare and medical research sectors. Regarding the scope and operation of the Crown use provisions IP Australia advised:

> The Crown Use provisions of the Patents Act permit certain government entities to use, and to authorise others to use, patented inventions, without permission from the patent owner in certain circumstances. The use is only permissible where such use is for the [proper provision of] services of the Commonwealth, the State or a Territory. The government would have to pay the patent owner or exclusive licensee remuneration for that use, in accordance with the Patents Act.[67]

5.77 A 2005 ACIP report on the Crown use provisions notes:

> The ultimate purpose of the provisions is to ensure that governments in Australia can balance the grant of exclusive patent and design rights to IP owners, with the needs of the Australian public.[68]

5.78 Professor Christie noted that the Crown use provisions had potential to address concerns about the effect of gene patents—notably that in some situations a patent for a genetic invention has been, or will be, used to preclude wide public access to that invention, such as in the case of the BRCA genes and the attempt by Genetic Technologies to enforce its exclusive right to conduct BRCA testing in Australia. Professor Christie submitted:

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66 IP Australia, *Submission 19*, supplementary submission, 30 September 2009, p. 5.

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

68 Advisory Council on Intellectual Property, *Review of Crown use provisions for patents and designs*, November 2005, p. 1.

> It must be noted…that the Australian patent legislation contains a mechanism by which the government can compulsorily acquire a right of access to an invention: the Crown use provisions.[69]

5.79 IP Australia submitted that :

> These provisions might be able to assist government bodies where they can establish that such use is necessary for the proper provision of government services within Australia.[70]

5.80 However, Dr Palombi submitted that there was 'no evidence of the exercise of Crown use [provisions]', and questioned whether these provisions would be effective to address issues around exclusive patent rights:

> There is no evidence that...Crown use provisions—which would be useful in ameliorating some of the worst excesses of the patent system in this instance—have [ever] been effectively used. So we are unfortunately in a situation where, as with the BRCA1, we have an Australian company that, had it acted within its rights, could have actually sought injunctions to close down all of the public testing in this country for breast and ovarian cancer.[71]

5.81 IP Australia acknowledged that there was some uncertainty around the operation of the Crown use provisions, commenting that, 'to IP Australia's knowledge, these provisions have been rarely litigated and interpreted by the courts'.[72]

5.82 The Committee notes that in its 2004 report the ALRC made a number of recommendations to ensure that the Crown use provisions are sufficient to specifically address health issues, and that the circumstances justifying their use are sufficiently well defined. The ALRC recommended:

- that the Australian Health Ministers' Advisory Council develop a policy regarding the circumstances in which it may be appropriate for the Commonwealth or a state to exploit a patented invention under the Crown use provisions for the purposes of promoting human health;
- that the Department of Health and Ageing develop a policy regarding the circumstances in which it may be appropriate for the Commonwealth to acquire a patent for the purposes of promoting human health;
- that the Act be amended to clarify that, for the purposes of the Crown use provisions, an invention is exploited 'for the services of the Commonwealth or of a State' if the exploitation of the invention by a Commonwealth or State

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

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

71 Dr Luigi Palombi, *Committee Hansard*, 14 September 2009, p. 22.

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

authority (or by an authorised person) is for the provision of healthcare services or products to members of the public; and

- that the Act be amended to provide that, when a patent is exploited under the Crown use provisions, the remuneration that is to be paid by the relevant authority must be paid promptly and must be just and reasonable having regard to the economic value of the use; and that the Act be amended to ensure that remuneration for an acquired patent is paid promptly, and is just and reasonable.[73]

5.83 In relation to the ALRC's recommendations, Dr Rimmer observed:

> I think they [the ALRC] need to go further and pick up the requirements under the TRIPS Agreement to adequately have domestic and export mechanisms to deal with essential medicines.[74]

5.84 Professor Christie noted that ACIP had also conducted a review of the Crown use provisions:

> The scope and operation of the Crown use provisions was the subject of a review by the ACIP in 2004-2005. That review concluded that entitlement of the Crown to access an invention in the public benefit should be maintained, but that the provisions should be amended to ensure a more transparent and accountable process for their utilisation. The government has not, as yet, implemented these recommendations.[75]

Compulsory licensing

5.85 IP Australia advised that 'a compulsory licence can be sought where the patent holder fails to meet the reasonable requirements of the public or where they engage in anticompetitive conduct (ss 133-140)'.[76] The Act sets out the circumstances where, for the purposes of granting a compulsory licence, the 'reasonable requirements of the public with respect to a patented invention' are to be taken not to have been met. These include:

- where an existing trade or industry in Australia, or the establishment of a new trade or industry, is unfairly prejudiced, or the demand in Australia for the patented product, or for a product resulting from the patented process, is not reasonably met, because of the patentee's failure:

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73 Australian Law Reform Commission, *Genes and ingenuity*, June 2004, p. 34.

74 Dr Matthew Rimmer, *Committee Hansard*, 20 August 2009, p. 22.

75 Professor Andrew Christie, *Submission 38*, pp 5-6.

76 Mrs Fatima Beattie, IP Australia, *Committee Hansard*, 20 August 2009, p. 29. As well as showing the reasonable requirements of the public have not been met the applicant must show that the patentee has no satisfactory reason for failing to exploit the patent; and that the applicant has tried unsuccessfully to obtain a licence from the patentee (see section 133(2)(a)(i)-(iii)).

- to manufacture the patented product to an adequate extent and supply it on reasonable terms; or
- to grant licences on reasonable terms.[77]

5.86 Dr Charles Lawson noted that the purpose of the compulsory licensing of patents is 'to encourage the licensing and working of inventions sooner, serving as an effective incentive for patent holders to grant a licence voluntarily and on their own terms'.[78]

5.87 Dr Lawson observed that:

> …compulsory licensing is one of the very few avenues available to limit patent abuse and misuse, and has become (potentially) increasingly important with the lowering of the patent threshold standards of subject matter and obviousness.[79]

5.88 Many submitters and witnesses identified the compulsory licensing provisions of the Act as having the potential to ameliorate any adverse impacts of gene patents on healthcare and medical research. The ALRC submitted:

> …the key factor in ensuring both the accessibility of quality health care and the facilitation of further research is the smooth functioning of the system regulating licensing and use.[80]

5.89 Professor Ron Trent, University of Sydney, noted that he had not witnessed significant problems arising from gene patents per se, but identified exclusive licences as having the potential to adversely impact on the availability and quality of healthcare:

> To me, [exclusive licensing] is the real key issue in terms of the sorts of patents that we have. In the breast cancer example, if an exclusive licence is given to one company…I have concerns that this will impact negatively on both the availability of the test as well as the quality of the test.[81]

5.90 Similarly, Dr Suthers submitted:

> For existing gene patents, our principal concerns would be addressed by ensuring that the patents do not provide a monopoly on medical testing. Gene patents must be broadly licensed so that laboratories are free to

77 *Patents Act 1990*, section 135(1)(a)(i) and (iv).

78 Dr Charles Lawson, *Submission 5*, p. 1.

79 Dr Charles Lawson, *Submission 5*, Attachment 1, p. 3.

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

81 Professor Ron Trent, *Committee Hansard*, 5 August 2009, p. 53.

> perform the test and improve on it as required. However, unrestrictive licensing is not the whole solution.[82]

5.91 Dr Gillian Mitchell, Director, Familial Cancer Centre, Peter MacCallum Cancer Centre, also called for compulsory licence provisions to be used to ensure that patent holders did not use their rights in such a way as to slow the delivery of healthcare services, such as diagnostic tests, and the development of research.[83]

5.92 With particular reference to the BRCA gene patents, Dr Rimmer observed:

> …once patents are granted there will be some patents—for instance, the BRCA 1 patent—which might still be valid in some form but that you might think have some negative consequences in terms of…social impact. If you really want to better control the behaviour of patent holders, it is very important to have a strong, modern and efficient compulsory licensing regime.[84]

5.93 Dr Rimmer emphasised, however, that the compulsory licence provisions were important in a range of different contexts:

> Compulsory licensing…is very important in a range of different contexts—biotechnology patents for pharmaceutical drugs, especially in the context of access to essential medicines. Interestingly enough, in relation to clean technologies as well at the moment there is a great deal of debate in the lead-up to Copenhagen.[85]

Reasonable requirements provisions

5.94 Despite the apparent ability of the compulsory licence provisions to ameliorate any actual or potential adverse impacts of gene patents, the Committee heard that the reasonable requirements provisions have not been successfully used for the grant of a compulsory licence. IP Australia advised:

> IP Australia has only been able to identify three applications for compulsory licences in Australia since 1903; none under the *Patents Act 1903*, two under the *Patents Act 1952* and one under the *Patents Act 1990*…
>
> In each case a compulsory licence was sought to enable use of a patentee's invention in order to satisfy perceived unmet 'reasonable requirements of

82 Dr Graeme Suthers, Royal College of Pathologists of Australasia, *Committee Hansard*, 4 August 2009, p. 41.

83 Dr Gillian Mitchell, Peter MacCallum Cancer Centre, *Committee Hansard*, 4 August 2009, pp 116-117.

84 Dr Matthew Rimmer, *Committee Hansard*, 20 August 2009, p. 22.

85 Dr Matthew Rimmer, *Committee Hansard*, 20 August 2009, p. 22.

> the public' for the patented invention. No compulsory licenses were granted.[86]

5.95 However, IP Australia submitted that 'the mere availability of this option lends strength to prospective licensees in private negotiations'.[87] Similarly, the Law Council of Australia commented that the few or no cases of use of the compulsory licence provisions did not necessarily indicate that the provisions were ineffective, given the fact that their potential or threat did in some cases act as an incentive for patent holders to negotiate commercial arrangements providing access to a patent.[88]

5.96 In contrast, Dr Charles Lawson submitted that 'in [their] present form the compulsory licensing provisions in the [Act] are effectively a barrier to the working of inventions in Australia'.[89]

5.97 Dr Lawson provided a textual analysis which argued that the threshold criteria for the grant of a compulsory licence in s 133(2)(a)(i) to (iii) are 'practically uncertain and probably very limited' in meaning:[90]

> …it is apparent that the uncertain meanings impose significant thresholds for evidence (proof), qualifications, discretions, expense and uncertain access to the know-how necessary to actually exploit the invention. The conclusion…must be that the uncertain meanings, evidentiary requirements, and the likely considerable expense with little prospect of gauging the likely success of an application are unlikely to encourage a potential applicant. Rather, these thresholds appear as a likely barrier to a potential applicant and undermine any incentive the provision might hold for a patent holder to license and work the invention sooner.[91]

5.98 Dr Lawson concluded that significant reform of the compulsory licence provisions was required:

> …to satisfy its policy objectives the meaning of the compulsory licensing provisions should be clear, so that patent holders really are 'incentivised' to license and work their inventions earlier and potential compulsory license applicants can structure their affairs so as to avoid the unnecessary expense of pursuing uncertain license grants.[92]

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86 Department of Innovation, Industry, Science and Research and IP Australia, *Submission 19,* p. 10.

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

88 Mr Richard Hamer, Law Council of Australia, *Committee Hansard,* 4 August 2009, p. 86.

89 Dr Charles Lawson, *Submission 5,* p. i.

90 Dr Charles Lawson, *Submission 5,* Attachment 1, p. 1.

91 Dr Charles Lawson, *Submission 5,* Attachment 1, pp 31-32.

92 Dr Charles Lawson, *Submission 5,* Attachment 1, p. 3.

5.99 Dr Rimmer noted that there was also potential for reform of the compulsory licensing provisions in relation to essential medicines:

> …the Joint Standing Committee on Treaties said two years ago that it would modernise the compulsory licensing regime in line with TRIPS to deal with the issues in relation to access to essential medicines, especially in relation to the export of essential medicines. I think it is very important that our compulsory licensing regime adequately deals with concerns about competition and public non-commercial use, but also about health concerns and health crises [such as SARS], which can cross over into the field of gene patents...[93]

5.100 The Committee notes that in its 2004 report the ALRC concluded there was significant potential for anti-competitive exploitation of biotechnology inventions due to their unique nature and 'possible lack of substitutability'. Accordingly, it proposed certain reforms to the compulsory licence provisions to address those 'circumstances in which there is a public interest in enhanced competition in a market, and the patent holder has not met reasonable requirements for access to the patented invention'.[94] Specifically, the ALRC proposed that the Act be amended to clarify the scope of the 'reasonable requirements of the public test', in particular the circumstances in which the reasonable requirements of the public are taken not to have been satisfied.[95]

Competition based test

5.101 In addition, the ALRC recommended that the competition-based test recommended by the Intellectual Property and Competition Review Committee (IPCRC) be inserted into the Act as an additional ground for the grant of a compulsory licence.[96] This recommendation was based on the IPCRC's view that intellectual property laws and competition policy are 'largely complementary', because the former promotes innovation 'which is a key form of competition'.[97]

5.102 The IPCRC had originally recommended that the competition-based test replace the 'reasonable requirements of the public' test and contain the following conditions:

- access to the patented invention is required for competition in the (relevant) market;
- there is a public interest in enhanced competition in that market;

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93 Dr Matthew Rimmer, *Committee Hansard*, 20 August 2009, p. 14.

94 Dr Matthew Rimmer, 'The alchemy of junk: patent law and non-coding DNA', *Intellectual property and biotechnology*, p. 234 (2008).

95 Australian Law Reform Commission, *Genes and ingenuity*, June 2004, p. 34.

96 Australian Law Reform Commission, *Genes and ingenuity*, June 2004, p. 34.

97 *Review of property legislation under the Competition Principles Agreement*, 30 September 2000, p. 6, cited in Parliamentary Library, 'Intellectual Property Laws Amendment Bill 2006', *Bills Digest No. 159 2005-06*, 19 June 2006, p. 9.

- the reasonable requirements for such access have not been met;
- the order will have the effect of allowing these reasonable requirements to be better met; and
- the order will not compromise the legitimate interests of the patent holder, including the patent holder's right to share in the return society obtains from the owner's invention, and to benefit from any successive invention, made within the patent term, that relies on the patent.[98]

5.103 In response to the IPCRC report, the Government indicated in-principle support for making the compulsory licence regime subject to a competition test. However, it argued the competition based test should be additional to the existing reasonable requirements test, on the grounds that in some circumstances:

- the competition based test might not apply; or
- could be harder to satisfy than the existing test.[99]

5.104 In 2006, the *Intellectual Property Laws Amendment Act 2006* amended the Act to provide that a compulsory license may be granted where the patentee has been found guilty of any proscribed anti-competitive conduct under the *Trade Practices Act 1974*. Section 133(2)(b) now provides that a person may apply for a compulsory licence on the grounds that:

> …the patentee has contravened, or is contravening, Part IV of the *Trade Practices Act 1974* [to do with restrictive trade practices] or an application law (as defined in section 150A of that Act) in connection with the patent.

5.105 An analysis of this provision by Dr Lawson, however, suggests that in practice the competition based test may be of little effect:

> …[The analysis shows that] the discretion [to award the compulsory licence] may not be exercised for reasons that may be outside the knowledge of an applicant, that the scope of a compulsory license order is limited, that there are significant difficulties with treaty interpretation, and that there are particular difficulties with the restrictive terminology and other provisions in the *Patents Act* limiting the scope of any compulsory license order.[100]

5.106 Dr Lawson concludes:

> …the 'competition test' amendment is unlikely to be a practical remedy for contravention of Pt IV of the *Trade Practices Act* because of the limited scope of a compulsory license order under the *Patents Act*. These hurdles

98 Australian Law Reform Commission, *Genes and ingenuity*, June 2004, p. 619.

99 Parliamentary Library, 'Intellectual Property Laws Amendment Bill 2006', *Bills Digest No. 159 2005-06*, 19 June 2006, p. 12.

100 Dr Charles Lawson, *Submission 5*, Attachment 2, p. 25.

> seem unattractive when the same, or an arguably superior, remedy is already available under the *Trade Practices Act*.[101]

5.107 Dr Rimmer also observed that the competition amendments to the compulsory licensing regime 'are minor, and will do little to address the policy issues raised by the [ALRC]',[102] while noting that a competition based approach was still a potential strategy in relation to ameliorating the potential adverse impacts of certain patents:

> ..it would be useful to have a regulator who had a greater purview of some of the [competition] impacts of some applications of certain patents. Interestingly enough, in relation to non-coding DNA patents, Myriad Genetics accused GTG of anti-competitive conduct in their initial skirmish before they reached a settlement.[103]

Research exemption

5.108 Much of the evidence to the inquiry concerned the need for Australia's patent system to contain an explicit research exemption. A 2009 IP Australia consultation paper on exemptions to patent infringement provided the following summary of the present status of such an exemption in Australia:

> …the *Patents Act 1990* does not contain a specific research or experimental use exception and IP Australia is not aware of any legal cases in Australia where experimental use was argued as a defence against infringement litigation. As a consequence it is unclear whether an experimental use exemption exists in Australia, and if it does, the extent to which it applies. Experiences in other countries where there are no statutory experimental use provisions indicate that courts have struggled to ascertain the scope of the experimental use defence or have applied restrictive tests that are potentially detrimental to research.[104]

5.109 Many submitters and witnesses raised concerns about the impact of the uncertain status of the research exemption on research both in relation to human genes and genetic material and more broadly. With reference to gene patents, the Committee notes the conclusion of the ALRC that the uncertain status of the research exemption for patent infringement in Australia is:

> …unhelpful to the research community and commercial organisations. It has the potential to result in under-investment in basic research; and to hinder innovation if researchers become concerned that their activities may lead to legal action by patent holders.[105]

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101 Dr Charles Lawson, *Submission 5*, Attachment 2, p. 5.

102 Dr Matthew Rimmer,'The alchemy of junk: patent law and non-coding DNA', *Intellectual property and biotechnology* (2008), p. 238.

103 Dr Matthew Rimmer, *Committee Hansard*, 20 August 2009, p. 22.

104 IP Australia, 'Exemptions to patent infringement', Consultation paper, March 2009, p. 3.

105 Australian Law Reform Commission, *Genes and ingenuity*, June 2004, p. 331.

5.110 There was widespread support for an amendment to the Act to introduce an explicit research exemption into Australia's patent law. Dr Cudmore advised:

> …where possible, the intellectual property environment should operate such that researchers can conduct their research in good faith, with a minimum level of encumbrance from the law…
>
> The ability to conduct research on the gene sequence, without necessarily using a proprietary, therapeutic or diagnostic downstream development from that gene sequence, is something that we believe would significantly enhance researchers' comfort zones in the area that we are discussing, simply because they would have confidence that working on the gene itself does not give rise to legal liability.[106]

5.111 Professor Christie encouraged the Committee to consider 'making a recommendation in relation to a clear and express exemption for experimental and research purposes'.[107] He observed:

> The appropriate response to the concerns about patents for genetic inventions retarding innovation by precluding follow-on research is to ensure that Australian patent law recognises that acts done for experimental purposes do not infringe a patent. This requires that the patent legislation be amended, by introducing an express experimental use defence to infringement.[108]

5.112 The Law Council Australia also indicated that it supported a 'specific and express experimental use exception in the law'.[109]

5.113 Dr Cudmore suggested that any amendment to support a research exemption could take the form of a specific provision for academic licensing:

> …a specific provision for academic licensing in the law would more likely than not be a stimulant to desirable medical research activities. The way that we would see that provision being constructed is that it would allow activities in particular environments—NHMRC accredited environments or something similar to that—and would constitute a protection for research.[110]

5.114 The Committee notes that a number of inquiries into gene patents or aspects of the patent system have supported the introduction of a research exemption into

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106 Dr Gerard Cudmore, Department of Industry and Investment (NSW), *Committee Hansard*, 5 August 2009, p. 92.

107 Professor Andrew Christie, *Committee Hansard*, 4 August 2009, p. 69.

108 Professor Andrew Christie, *Submission 38*, pp 6-7.

109 Mr Richard Hamer, Law Council of Australia, *Committee Hansard*, 4 August 2009, p. 80.

110 Dr Gerard Cudmore, Department of Industry and Investment (NSW), *Committee Hansard*, 5 August 2009, p. 93-94.

Australian patent law. In its 2004 report the ALRC recommended that a research exemption be incorporated into the Act:

> The Commonwealth should amend the [Act]…to establish an exemption from patent infringement for acts done to study or experiment on the subject matter of a patented invention; for example, to investigate its properties or improve upon it. The amendment should also make it clear that:
>
> (a) the exemption is available only if study or experimentation is the sole or dominant purpose of the act;
>
> (b) the existence of a commercial purpose or objective does not preclude the application of the exemption; and
>
> (c) the exemption does not derogate from any study or experimentation that may otherwise be permitted under the Patents Act.[111]

5.115 Dr Rimmer indicated that the ALRC's was the 'best' of the suggested approaches to implementing a research exemption in Australia.[112]

5.116 The Victorian government indicated that it supported a consideration of 'the feasibility of implementing the ALRC…[recommendation for a] statutory exemption for patent infringement in the case of non-commercial experimental use (as applies in some jurisdictions internationally).'[113]

5.117 ACIP has also recommended that the Act be amended to include an explicit experimental research exemption, following its inquiry into this issue in 2005. It suggested the following provision be introduced to the Act:

> The rights of a patentee are not infringed by acts done for experimental purposes relating to the subject matter of the invention that do not unreasonably conflict with the normal exploitation of a patent. Acts done for experimental purposes relating to the subject matter of the invention include:
>
> -determining how the invention works;
>
> -determining the scope of the invention;
>
> -determining the validity of the claims;
>
> -seeking an improvement to the invention.[114]

5.118 In addition, ACIP made a number of recommendations intended, inter alia, to clarify the interpretation and application of the research exemption by IP Australia and to harmonise the Australian exemption with international practice.

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111 Australian Law Reform Commission, *Genes and ingenuity*, June 2004, p. 335.

112 Dr Matthew Rimmer, *Committee Hansard*, 20 August 2009, p. 13.

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

114 Advisory Council on Intellectual Property, 'Patents and experimental use', October 2005, p. 5.

5.119 The NHMRC supported the ACIP proposal for a research exemption. Dr Clive Morris, Chief Knowledge and Development Officer, stated:

> The NHMRC, in its submissions to the Australian Law Reform Commission in 2003 and, I think, subsequently to this committee, has spoken about the researchers' exemption and the need for clarity which researchers have expressed. We have said recently that we support the position of the Advisory Council on Intellectual Property that this should be made more clear in legislation.[115]

5.120 In contrast, Cancer Council Australia, which supported an express prohibition on gene patents, argued that the recommendations of the ALRC and ACIP on a research exemption would not offer sufficient protection:

> While we commend the Advisory Council on Intellectual Property and the Australian Law Reform Commission for proposing an experimental use exemption for patented genes in some medical research, in our view the recommendations are not sufficiently extensive. For example, exemption should also apply to research on the patented tests for identifying certain genes, to encourage continuous improvement; just because a commercial interest discovered a particularly gene or developed a test for its isolation does not mean that the test could not be improved (e.g. made more accessible and affordable) by a separate research entity. There are numerous other examples where exemption for experimental use would not be sufficient. Applying for the exemption could also impose administrative burden for not-for-profit and academic institutions involved in medical research.[116]

5.121 In its recent consultation paper on exemptions to patent infringement, IP Australia has also set out the broad intent of the research exemption it is proposing:

> A person may, without infringing a patent, do any act on a patented invention which is solely for the purpose of:
>
> - determining how the invention works
> - seeking an improvement to the invention
> - testing the validity of a patent
> - determining the scope of the patent claims
> - determining whether an act or product infringes a patent
>
> or
>
> - obtaining the information required for regulatory approval under Australian law or the law of any other country that regulates the manufacture, construction, use or sale of the patented invention.

115 Dr Clive Morris, National Health and Medical Research Council, *Committee Hansard*, 20 August 2009, p. 48.

116 Cancer Council Australia, *Submission 50*, p. 8.

> The statutory exemption will not apply where the invention is used in, but is not the subject of, an experiment.[117]

5.122 IP Australia submitted that its suggested approach:

> …would clarify the current situation and clearly delineate that research on the patented invention is allowed, for example: to determine how the invention works; to seek improvements to the invention; to determine unknown and useful properties of the invention; and to undertake trials for the purposes of obtaining regulatory approval for its exploitation.[118]

5.123 However, Dr Moir criticised IP Australia's proposal as being overly narrow:

> IP Australia recently circulated their discussion paper on the research exemption and they framed it quite narrowly. They said the exemption should apply where the sole purpose was research. But purposes are very rarely sole. For example, a university undertaking research might also be undertaking education, and I can tell you that a patent lawyer would say, 'Well, that means that it is not solely for research and therefore you cannot claim the exemption.' So I would look very closely at propositions in regard to the long-awaited research exemption and make sure it is very tight and very broad, because it is that cumulative research that is very important.[119]

5.124 Dr Palombi also criticised the scope of the research exemption suggested by IP Australia:

> …the test that is proposed by IP Australia is completely unworkable. They use a sole purpose test. If the sole purpose of the experimentation is experimentation, non-commercial, then it is exempted. How many universities, how many people, these days actually do experimentation solely for the sake of experimenting? They don't. Everything is applied, everything has got a commercial link. It is so easy to get around that exemption that it is hardly worth the trouble of even making it legislation.[120]

5.125 Similarly, Dr Rimmer commented:

> I share…concerns about the very narrow way in which IP Australia has put forward their proposal in relation to a defence of experimental use. The sole purpose test I think is used in the Netherlands and has not proved to be a very effective way of dealing with that scope.[121]

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117 IP Australia, 'Exemptions to patent infringement', Consultation paper, March 2009, p. 5

118 Mrs Fatima Beattie, IP Australia, *Committee Hansard*, 20 August 2009, p. 30.

119 Dr Hazel Moir, *Committee Hansard*, 20 August 2009, p. 8.

120 Dr Luigi Palombi, *Committee Hansard*, 14 September 2009, p. 18.

121 Dr Matthew Rimmer, *Committee Hansard*, 20 August 2009, p. 13.

Inclusion of anti-avoidance provisions in *Patents Act 1990*

5.126 A number of submitters and witnesses discussed the issue of patent drafting and the extent to which creative drafting of patent claims had contributed to the broadening scope of patentable subject matter in the past. Dr Moir offered the following example to indicate the prevalence and impact of creative legal drafting in the patent system:

> In my recent in-depth study of 72 Australian business method patents, 50 of the 72 applications were amended during negotiations with the examiner, and in many cases it was the amendment that was instrumental in allowing the grant…[The] triviality of these amendments indicates the problem of clever legal drafting.[122]

5.127 Professor Drahos indicated that the problem of creative legal drafting was widespread:

> …if you look at the effect of exclusions in the European Patent Convention you see that there are a number of exclusions to do with, for example, the patentability of computer programs, the patentability of plant varieties and so on. I can show you in the European Patent Office many thousands of patents—probably tens or hundreds of thousands of patents—on computer programs and on plant varieties.[123]

5.128 Professor Drahos noted that the problem arising from creative legal drafting would also be relevant in the event that specific exclusions of any sort were introduced into the Act in future. He explained:

> Unfortunately, I think it is unlikely that you will ever achieve very clear statutory language. Most patent attorneys will tell you that there is not an exclusion they cannot draft around. So essentially the patent attorney profession you should think of as a bunch of tax evaders. Tax evaders always think of new ways to get around our tax laws…Relying on the words of the statute alone probably will not be enough.[124]

5.129 Dr Moir commented:

> Legal semantics in patent law is the parallel of crafting financial products to avoid paying tax; it involves using words to provide a veneer of inventiveness to something that would not otherwise merit a patent monopoly.[125]

5.130 Professor Drahos suggested that the inclusion of anti-avoidance provisions in the Act could be a suitable remedy to the problem of creative legal drafting. In simple

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122 Dr Hazel Moir, answer to question on notice, 16 September 2009, p. 8.

123 Professor Peter Drahos, *Committee Hansard*, 20 August 2009, p. 21.

124 Professor Peter Drahos, *Committee Hansard*, 20 August 2009, p. 21.

125 Dr Hazel Moir, answer to question on notice, 16 September 2009, p. 7.

terms, anti-avoidance tax provisions operate to ensure that artificial or blatant schemes cannot be used to avoid paying tax, even where such a scheme might be otherwise in conformity with the legal requirements of the tax legislation. Professor Drahos explained:

> [Tax acts]…contain provisions that encourage courts to look at the substance of the particular tax scheme. Is it really a tax minimisation scheme or is it an anti-avoidance scheme? So what we need in our [patent] statute is language that encourages courts to look beyond the claiming format, because what we have to remember is that patent offices accept particular claiming formats…What they are worried about is the form of the words. They do not worry about effects.[126]

5.131 Dr Moir also supported this approach:

> …the patent system has been heavily under-mined by those using it. It is rife with legal pretence: that software is not software; that methods of medical treatment are patentable despite longstanding traditions that they are not; and that minimal difference equates with inventiveness even if that difference is in the words not the substance. Without a parallel to the anti-avoidance principles now used in the tax acts, legal drafters will simply work round this and any other amendments the Committee proposes.[127]

Inclusion of objects in *Patents Act 1990*

5.132 Some submitters and witnesses commented on the fact that the Act does not set out specific objects, as is common in much legislation. Dr Moir suggested that the inclusion of objects may be desirable to provide guidance to courts in interpreting the Act:

> It might also be useful to write an objective into the Patent Act, because there is no objective at present. I understand that lawyers are very much divided as to whether or not they think it is useful to write objectives into a statute. But it is not surprising that when there is not a stated objective the courts can misinterpret the parliamentary intent.[128]

5.133 The ACIP options paper on patentable subject matter also notes briefly that it 'may be desirable for an express statement of objectives to be included in the legislation'.[129]

5.134 The government of South Australia supported this approach to provide a guide to patent examiners.[130]

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126 Professor Peter Drahos, *Committee Hansard*, 20 August 2009, p. 21.

127 Dr Hazel Moir, answer to question on notice, 16 September 2009, p. 2.

128 Dr Hazel Moir, *Committee Hansard*, 20 August 2009, p. 4.

129 Advisory Council on Intellectual Property, 'Patentable subject matter: options paper', September 2009, p. 60.

130 South Australian Government, *Submission 16*, p. 4.

'PBS' style approach

5.135 With respect to the potential for gene patents to restrict the availability and affordability of healthcare, such as gene-dependent diagnostic tests or gene therapies, a number of submitters and witnesses suggested that such impacts could be effectively managed through regulatory measures. A common example was the Pharmaceutical Benefits Scheme (PBS), through which the Government subsidises the cost of medicines that would otherwise be unaffordable for many people. IP Australia submitted:

> The Committee may also wish to take advantage of non-patent policy levers. For example, healthcare and ethical issues respectively have been managed via the Pharmaceutical Benefits Scheme to ensure affordable access to cost-effective drugs, while stem cell research is currently regulated to uphold ethical and community standards in that area.[131]

5.136 Professor Christie noted that, in respect of the concerns raised about the BRCA patents' actual or potential impacts on the provision of healthcare, a pricing mechanism akin to the PBS or Medicare would be an effective and appropriate measure:

> The Australian government is rightly concerned to ensure that medical treatment is available to each individual who requires it, irrespective of the individual's financial means. This is the motivation behind the government's subsidisation of the cost of medical treatment, through the Medicare system. It is also the motivation behind the government's subsidisation of the cost of pharmaceuticals, through the Pharmaceutical Benefits Scheme (PBS). It is noteworthy that most of the top-selling pharmaceuticals subsidised by the PBS are pharmaceuticals in respect of which patents exists. Thus, the government has found a mechanism by which it can facilitate wide access to pharmaceuticals, while leaving in place the availability of patent protection for those pharmaceuticals.
>
> In the event that it is found that patents on genetic inventions are unduly restricting patient access to diagnostic tests or other medical treatment, the Australian experience with pharmaceuticals suggests that the remedy to the access problem lies with a pricing mechanism, not with removing patent protection for these inventions.[132]

5.137 Mrs Jennifer West, Secretary, Australian Marfan Foundation, was supportive of establishing a PBS-style arrangement for genetic testing, noting that availability of testing for a syndrome such as Marfan was essentially dictated by availability of funding, which was inconsistent:

> I would gladly welcome a system where people with Marfan syndrome, suspected Marfan syndrome or a known history of Marfan syndrome had

131 IP Australia, *Submission 19*, supplementary submission, 30 September 2009, p. 5.

132 Professor Andrew Christie, *Submission 38*, pp 5-6.

> access to that genetic screening like they do for other genetic abnormalities at the moment.[133]

5.138 Dr Suthers, however, cautioned that any such approach would likely need to be more responsive than the current PBS in order to adequately account for the development and management of gene patents:

> My big concern is that the PBAC [Pharmaceutical Benefits Advisory Committee, which assesses applications for listing of medicines on the PBS] has been a superb and innovative mechanism for Australian health, but it is slow. When we look at the rapidity with which gene tests are added, modified, improved, changed, et cetera, in Australia at the moment we find that no vehicle of that ilk would be able to respond quickly enough. When we did this national survey looking at genetic testing across Australia in 2006 with projections into 2007 we found that the diversity of genetic testing increased by seven per cent just in that period. This is a very rapidly moving field, and we would need to have a very responsive mechanism if that were to be successful.[134]

5.139 Professor Bowtell noted that public funding through PBS-style arrangements could see an increasing burden being placed on the taxpayer, given the level of public funding going to health and medical research.[135]

External accountability/patent quality mechanisms

5.140 A number of submitters and witnesses expressed the view that the IP system operates too far in favour of commercial interests, and that this is reflected in the low thresholds for patentability that have allowed human genes and genetic materials to be patented with relative ease in Australia. Dr Suthers commented:

> What is one-sided about [the IP system]…is that the framework has been set up principally as a commercial IP issue where the principal players involved in running those processes are members of the IP industry rather than professional service providers, such as ourselves, patient groups, ethicists, health economists and so on.[136]

5.141 The submission of Professor Peter Drahos also pointed to the dominance of commercial interests and patent industry 'insiders' in the patent system:

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133 Mrs Jennifer West, Australian Marfan Foundation, *Committee Hansard*, 4 August 2009, p. 99.

134 Dr Graeme Suthers, Royal College of Pathologists of Australasia, *Committee Hansard*, 4 August 2009, p. 56.

135 Professor David Bowtell, Peter MacCallum Cancer Centre, *Committee Hansard*, 4 August 2009, p. 130.

136 Dr Graeme Suthers, Royal College of Pathologists of Australasia, *Committee Hansard*, 4 August 2009, p. 41.

> Patent systems in their present form represent deep concentrations of power and dominance in which networks of big business, patent attorneys and patent offices co-operate to produce an insider governance of the system.[137]

5.142 Professor Drahos concluded that patent offices had 'abdicated their responsibilities to their respective publics under their respective national patent social contracts';[138] and that the 'densely technocratic' nature of the patent system was acting as a barrier to reform of the patent system to promote a proper balance between the economic and social interests which underpin the patent social contract:

> The patent system is so densely technocratic that politicians do not take the lead on patent policy unless an industry lobby dictates a clear direction…The real accountability of patent offices lies with the private governance network of the large businesses that dominate patent applications.[139]

5.143 In light of these issues, Professor Drahos called for the development of external accountability mechanisms to operate as a counterweight to the established interests in the patent system.[140] The rationale underlying the development of such bodies was that:

> General accountability mechanisms such as ministerial responsibility cannot provide the kind of close oversight that is needed of patent office decision-making. Instead, there has to be a long term strategy based on building a counter network to the private governance network that has absorbed patent offices. This counter network should be guided by the separation of powers principle...The basic idea is to contest the power of the private network at every point where key decisions are made and where possible to create veto rights or checks over patent office decisions.[141]

5.144 Professor Ian Olver, Chief Executive Officer, Cancer Council Australia, also called for a greater involvement of broader interests in the operation of the patent system:

> …one of the things that we would be encouraging in this whole debate is that, if there is going to be reform, the people who should be involved should be more than patent lawyers. We should look at the scientists, the clinicians and the consumers—the patients—who have a stake in that.[142]

5.145 Dr Palombi called for an extensive system of external oversight of IP Australia and the patent profession:

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137 Professor Peter Drahos, *Submission 60*, p. 427.

138 Professor Peter Drahos, *Submission 60*, p. 428.

139 Professor Peter Drahos, *Submission 60*, p. 429.

140 Professor Peter Drahos, *Submission 60*, p. 431.

141 Professor Peter Drahos, *Submission 60*, p. 431.

142 Professor Ian Olver, Cancer Council Australia, *Committee Hansard*, 5 August 2009, p. 6.

> Third, that there be the Office of the Regulator of Intellectual Property established to monitor, audit and ensure that IP Australia and patent attorneys and lawyers act lawfully.[143]

External patent audit committee

5.146 In specific terms, Professor Drahos proposed the establishment of an external patent audit committee. Such a body could act as a counterweight to commercial dominance of the patent system by providing to government an independent source of credible advice and information in relation to patents and the patent system:

> Legislators and ministers in many countries generally do not understand the extent of the regulatory capture of patent offices and tend to be excessively reliant on them for advice, advice that tends to be of a predictable kind. External audit mechanisms for patent offices would catalyse different information flows about patents to legislators, something needed in many, if not most, countries.[144]

5.147 Professor Drahos offered the following description of how such a body might be comprised, and the scope of its interests and activities:

> I hasten to add this committee would not have formal powers, it would not be a formal regulator; rather, it would be an information gathering body. It would be staffed by scientists of considerable stature, of independence, of integrity, who were concerned about the public interest dimensions of patents in particular areas. They would, on perhaps a yearly or biannual basis, with the assistance of members of the profession perhaps or legal expertise at any rate, conduct an independent audit of a selection of patents. …They would essentially conduct an independent audit of the quality of patents that were being granted in [a chosen area]…and then…report to whatever body was thought suitable. That would be one way in which we would have independent information about what was going on in patent offices.[145]

Advisory panel to Commissioner of Patents

5.148 The Committee notes that ACIP, as part of its current review of patentable subject matter, was considering recommending the establishment of an advisory panel to assist the Commissioner of Patents and patent examiners to decide on matters of

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

144 Professor Peter Drahos, *Submission 60*, p. 439.

145 Professor Peter Drahos, *Committee Hansard*, 20 August 2009, p. 15.

social policy.[146] The ACIP paper notes that such a panel 'may be particularly valuable if a general social exclusion was introduced [to the Act]'.[147]

5.149 However, the ACIP paper also acknowledges potential problems with such an approach:

> Arguments advanced against having such a panel relate to difficulties of implementation and the potential for additional costs and delays to the processing of patent applications. There are also concerns about the composition of a panel and the possibility that inconsistent positions may be taken by differently constituted panels.[148]

5.150 The government of South Australia supported the use of expert advisory panels to assist with the assessment of gene patent applications.[149]

Patent pools

5.151 IP Australia identified the development of patent pools as a possible strategy to overcome problems arising from fragmented patent ownership. In relation to gene patents in particular it was suggested that the number of separately owned patents relating to human genes and genetic materials could act as a disincentive to research due to increased transaction costs and uncertainty (see Chapter 3). IP Australia advised:

> Patent pools can be defined as an agreement between two or more patent owners to license one or more of their patents to one another and/or third parties. The key benefit of patent pools is in reducing transaction costs for users having to identify relevant patents and then seek cross licensing arrangements with multiple individual patent holders. Patent pools are particularly beneficial in cases where the relevant technology is subject to fragmented patent ownership.[150]

5.152 Dr Trevor Davies, Councillor, Institute of Patent and Trade Mark Attorneys of Australia (IPTMAA) also suggested that patent pools could overcome some of the difficulties around patents relating to human genes and genetic material:

> In areas where there have been a large number of patent applications filed or patents granted, one way of moving forward is…patent pools…I would not be surprised going forward in the area of biotechnology that there will

146 Advisory Council on Intellectual Property, 'Patentable subject matter: options paper', September 2009, p. 21.

147 Advisory Council on Intellectual Property, 'Patentable subject matter: options paper', September 2009, p. 53.

148 Advisory Council on Intellectual Property, 'Patentable subject matter: options paper', September 2009, p. 53.

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

150 IP Australia, supplementary submission, 30 September 2009, p. 3.

> be more examples of patent pools in which technology is cross-licensed so that ultimately it will made available to the public.[151]

5.153 IP Australia noted that, while the establishment of patent pools tended to be 'driven by industry on a voluntary basis', government could 'play an important role in incentivising the creation of patent pools', particularly through providing an 'appropriate institutional framework'. However, given the lack of government experience in this area, IP Australia suggested any action on this front 'should be contingent on further analysis'.[152]

CONCLUSION

5.154 The inquiry received a range of evidence going to term of reference (b), which asked the Committee to identify measures that would ameliorate any adverse impacts arising from the granting of patents over human genes and genetic materials. However, given the predominant focus of the inquiry on the question of whether gene patents should be expressly prohibited, and the relatively narrow focus of the inquiry on the impacts of gene patents on healthcare, medical research and the health and wellbeing of Australians, the Committee notes that it did not conduct an exhaustive consideration of potential reforms to the patent system. In relation to the measures discussed above, the Committee has focussed on those suggestions that appeared to have particular relevance to the issues of concern to the inquiry, that have been prominent in the reviews conducted in the past and currently, or which highlight areas of potential reform that in the Committee's view appeared to merit further consideration.

5.155 While there was in some cases a clear and broad consensus about the benefits of instituting a specific reform, such as in the case of the 'usefulness' requirement for patentability, in many cases there were differing views on the specific form, scope and effectiveness of a suggested reform. In yet other cases, the evidence presented concerning the specific form, scope and effectiveness of a suggested measure was limited, in that it was relatively brief or was not commented on by a range of stakeholders.

Ensuring that the Government responds to past and current inquiries

5.156 The Committee notes also that much of the evidence it received in relation to term of reference (b) referenced the work of past and current inquiries into the patent system and gene patents. In particular, many of the recommendations from the ALRC's 2004 review of gene patents, and of reviews of elements of the patent system conducted by ACIP, were identified as being capable, if implemented, of addressing

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151 Dr Trevor Davies, Institute of Patent and Trade Mark Attorneys, *Committee Hansard*, 4 August 2009, p. 35.

152 IP Australia, *Submission 19*, supplementary submission, 30 September 2009, p. 4.

specific concerns with the impacts of gene patents on the specific areas of healthcare and medical research.

5.157 Further, the work of current reviews being conducted by ACIP, into patentable subject matter, and IP Australia, into the patent system more generally, was also identified as relevant to the concerns underpinning the inquiry's terms of reference. In both cases, these bodies have put forward proposals for reform of the patent system that it is claimed will improve the quality of patents and the operation of the patent system, and therefore address many of the specific concerns about the impacts of gene patents on healthcare and medical research. The Committee understands that the ACIP and IP Australia processes should be completed by the end of 2010.

5.158 The Committee notes in particular that the 2004 ALRC report on gene patents had not received any formal response from Government at the time of preparing this report. Given the importance of the issues addressed in that report, and the continuing relevance of much of its analysis and recommendations, the Committee considers the lack of a Government response to be a serious failure that must be addressed with particular urgency.

5.159 However, given the current reviews being conducted by ACIP and IP Australia, the Committee agreed that it would make sense for the Government to commit to a consolidated response addressing the three reports as well as the Committee's report, following the completion of the ACIP and IP Australia reviews. The fact that there is likely to be a high degree of overlap across the issues raised in these four inquiries and reviews will allow the Government to provide a single response addressing the multiple inquiries.

5.160 The Committee agreed that it will maintain a watching brief over the area of gene patents, particularly in light of its recommendations for improved systems of data collection and transparency, and national and international legal developments relating to the patentability of isolated genetic materials. The Committee intends that, by ensuring a comprehensive Government response to the reviews conducted in relation to gene patents and the patent system more generally, any future inquiry by the Committee will be informed by that response. Accordingly, the Committee agreed that, at an appropriate time following the publication of the review of ACIP and IP Australia, the Senate should require the Committee to inquire into the Government's response to and implementation of the recommendations arising from both those reviews and this report.

Recommendation 4

5.161 The Committee recommends that the Government provide a combined response addressing the Committee's inquiry into gene patents; the 2004 report on gene patents by the Australian Law Reform Commission; the review of patentable subject matter by the Australian Council on Intellectual Property (ACIP); and the review of Australia's patent system by IP Australia. The

Committee recommends that the response be provided not later than mid-2011 or three months after the release of the findings of all reviews.

Recommendation 5

5.162 The Committee recommends that, at an appropriate time following the release of the ACIP review of patentable subject matter and the IP Australia review of the patent system, the Community Affairs References Committee be tasked with inquiring into the Government's response to, and implementation of, the recommendations of those reviews, as well as the recommendations of the Committee's report on gene patents.

Amendments relating to 'inventive step', 'full description' and 'fair basis'

5.163 In relation to measures going to the raising of the thresholds of patentability, the Committee considers that a comprehensive set of reforms to the patent system in this area could substantially address many of the concerns raised about the impacts of gene patents on healthcare and medical research, particularly in relation to inappropriate grants of patents over human genes and genetic material and the granting of overly broad patents in relation to such subject matter.

5.164 The Committee heard that social—that is, moral and ethical—concerns about the granting of gene patents could be addressed through reform of the 'manner of manufacture' test, which governs the scope of patentability; and reform of the specific exceptions contained in the Act, which may be used to 'filter out' certain subject matter on the basis of social objections. The Committee notes that the current test is regarded by some as 'ambiguous and obscure', and it was the view of some submitters and witnesses that the Act was not operating to exclude subject matter that should not be patentable, such as gene patents.

5.165 The Committee heard that these issues are currently under consideration as part of the ACIP review of patentable subject matter, which has proposed a number of different options for reform of the manner of manufacture test. Of the four options put forward (one of which is to retain the existing approach), the Committee considers that only the proposal to clarify the definition of 'invention' could act to prevent the patenting of human genes and genetic materials. However, this would require a definition that offered some guidance on the invention/discovery distinction in relation to materials isolated from nature. While such an approach is not apparently precluded by ACIP's proposal, it may also recommend just that 'invention' be defined to reflect the current requirements that an invention must be an artificially created state of affairs in a field of economic endeavour, which have not operated thus far to preclude the patenting of human genes and genetic materials in an isolated or purified form.

5.166 Of the three options put forward by ACIP in relation to reform of the express exceptions contained in the Act (one of which is to retain the existing approach), the Committee notes that one of these is to include specific exclusions to patentable subject matter in the Act. If this option were pursued, governments could in future consider an express exclusion relating to gene patents, provided that any such

exclusion could be sufficiently well crafted to avoid any adverse impacts on innovation in healthcare and research, as well as other fields of technology.

5.167 While the Committee acknowledges that some of ACIP's reform proposals could potentially exclude gene patents, and thus in theory ameliorate any actual or potential impacts of gene patents on healthcare and medical research, there was no indication given to the Committee as to which of these proposals ACIP is likely to endorse in its final report. Given the closeness of the issues under review to the question of whether the Act should expressly exclude gene patents, and the Committee's concerns about this approach as outlined in Chapter 4, the Committee considered that it would be prudent to make no recommendation in relation to reform of the manner of manufacture test and specific exceptions contained in the Act. However, given the longstanding nature of concerns about the operation of Act in relation to patentable subject matter, the Committee urges the Government to promptly consider and respond to the ACIP review, once the review has reported its findings.

5.168 In relation to the inventive step threshold, the Committee acknowledges that care must be taken not to apply current standards of knowledge and technology to assessing the objective inventiveness of a patent, as the inventive step requirement must be assessed as at the time of the patent application. Despite this, it is also clear that the inventive step threshold in Australia is lower than in comparable jurisdictions, which is in part due to the definitions of 'common general knowledge' and 'prior art base', and the lower threshold test for inventive step relating to the 'obviousness' of a claimed invention.

5.169 The Committee outlined above a number of reforms proposed by IP Australia intended to bring the elements of Australia's inventive step requirements into line with international settings, and in so doing increase the inventive step threshold. The proposed change to the test for inventive step in particular was identified as potentially making it harder to claim patents over gene sequences, given the current state of knowledge and technology in relation to the isolation of human genes and genetic materials. Reforms to the tests or standards associated with the assessment of inventive step were also suggested to ensure that patents are only granted where there is sufficient inventiveness, as judged by reasonable standards of 'common general knowledge' and 'prior art information'.

5.170 IP Australia's proposed reforms also include changes to the 'full description' and 'fair basis' requirements of the Act, which may address concerns about overly broad patents.

5.171 The Committee regards the reforms suggested by IP Australia as having the potential to improve the operation of the patent system in relation to the grant of patents for inventions that are not sufficiently inventive or contain overly broad claims, and notes that the proposed reforms will also serve to bring Australia's requirements for patentability into conformity with other patent jurisdictions. Given this, the Committee regarded the proposed reforms as uncontroversial and relatively

straightforward in terms of their intended and expected impact on the operation of Australia's patent system, and endorses their implementation.

Recommendation 6

5.172 The Committee recommends that the *Patents Act 1990* be amended so that the test for obviousness in determining inventive step is that a claimed invention is obvious if it was 'obvious for the skilled person to try a suggested approach, alternative or method with a reasonable expectation of success'.

Recommendation 7

5.173 The Committee recommends that the *Patents Act 1990* be amended to remove the limitation that 'common general knowledge' be confined to that existing in Australia at the time a patent application is lodged (that is, that 'common general knowledge' anywhere in the world be considered).

Recommendation 8

5.174 The Committee recommends that the *Patents Act 1990* be amended to remove the requirement that 'prior art information' for the purposes of determining inventive step must be that which could reasonably have been expected to be 'ascertained' (that is, that the 'prior art base' against which inventive step is assessed not be restricted to information that a skilled person in the relevant field would have actually looked for and found (ascertained)).

Recommendation 9

5.175 The Committee recommends that the *Patents Act 1990* be amended to introduce descriptive support requirements, including that the whole scope of the claimed invention be enabled and that the description provide sufficient information to allow the skilled addressee to perform the invention without undue experimentation.

Raising the thresholds of patentability: 'usefulness'

5.176 In relation to the evidence received concerning the requirement of 'usefulness' under the Act, the Committee notes that there was widespread and consistent support for an amendment to the Act to introduce the concept of 'usefulness' as an express ground for consideration in patent examination; and that this require a claimed invention to demonstrate a 'specific, substantial and credible utility'.

5.177 The Committee notes that the suggested amendment could address concerns going to the granting of overly broad patent claims; and could be of greater importance in relation to gene patents or other technologies where the distinction between mere discovery and invention is less clear.

5.178 Given the broad support for the proposals going to 'usefulness' and their apparent effectiveness in other jurisdictions, the Committee supports the introduction of 'usefulness' as a requirement in the examination of a patent; and for this

requirement to be satisfied where an application discloses a 'specific, substantial and credible use'. The Committee notes and endorses the ALRC's comprehensive recommendations on this issue in its 2004 report, which also covered inclusion of 'usefulness' as a ground for examination of an innovation patent; inclusion of 'lack of usefulness' as a basis for opposing patents; defining the relevant standard of proof for establishing 'usefulness'; and the development of guidelines by IP Australia to assist patent examiners in applying the 'usefulness' requirement. Specifically, the Committee endorses Recommendations 6-3 and 6-4 of the ALRC report as follows:

> **Recommendation 6–3**
>
> The Commonwealth should amend the *Patents Act 1990 (Cth)* (Patents Act) to:
>
> (a) include 'usefulness' as a requirement in the examination of an application for a standard patent and in the certification of an innovation patent;
>
> (b) provide that an invention will satisfy the requirement of 'usefulness' only if the patent application discloses a specific, substantial and credible use;
>
> (c) require the Commissioner of Patents to be satisfied on the balance of probabilities that the requirement of 'usefulness' is made out in order to accept an application for a standard patent or to certify an innovation patent; and
>
> (d) include 'lack of usefulness' as a basis upon which an accepted application for a standard patent may be opposed, in addition to its current role as a ground for revocation…
>
> **Recommendation 6–4**
>
> IP Australia should develop guidelines, consistent with the Patents Act, the Patents Regulations 1991 (Cth) and existing case law, to assist patent examiners in applying the 'usefulness' requirement. The guidelines should outline factors relevant to determining whether a use disclosed in a patent application is specific, substantial and credible to a person skilled in the relevant art…[153]

Recommendation 10

5.179 The Committee recommends that the *Patents Act 1990* be amended to provide that an invention will satisfy the requirement of 'usefulness' in section 18(1) only in such cases as a patent application discloses a 'specific, substantial and credible' use; the Committee recommends that such amendments incorporate the full set of recommendations on this issue from the Australian Law Reform Commission's 2004 report, *Genes and ingenuity* (Recommendations 6-3 to 6-4).

153 Australian Law Reform Commission, *Genes and ingenuity*, June 2004, Recommendations 6-3 to 6-4, pp 130-157.

Strengthening Crown use provisions and government policy

5.180 In relation to the issue of Crown use provisions, a number of submitters and witnesses noted that the current provisions in the Act provide a means for governments to use, and to authorise others to use, patented inventions in certain circumstances—that is, governments may compulsorily acquire a right of access to an invention where such use is 'necessary for the proper provision of government services within Australia'.

5.181 However, the Committee heard that there were few if any cases of the Crown use provisions being exercised in relation to gene patents. Further, the provisions had been rarely litigated and interpreted by the courts, suggesting there may be some uncertainty about their scope and effectiveness.

5.182 The Committee notes that governments need access to a range of options to address potential impacts of not only gene patents but also patents more generally, particularly where patents impact on areas of critical importance to social and human welfare, such as healthcare. While the apparent under-use of the Crown use provisions, at least in relation to the areas of healthcare and medical research, may reflect a lack of suitable occasion for their use, the Committee notes that it may also be due to potential uncertainty around their application.

5.183 The Committee notes that in its 2004 report the ALRC produced a broad set of recommendations going to clarifying the application of the Crown use provisions in circumstances involving the provision of healthcare service or products to the public; establishing clear government policies regarding the circumstances in which it may be appropriate for governments to acquire a patent under the Crown use provisions for the purposes of promoting human health; and ensuring that just and reasonable remuneration is paid promptly where a patent is acquired under the Crown use provisions. The Committee endorses the ALRC's recommendations on clarifying the application and use of the Crown use provisions in relation to healthcare delivery, specifically Recommendations 26-1 to 26-3 as follows:

> **Recommendation 26–1**
>
> The Australian Health Ministers' Advisory Council should develop a policy regarding the circumstances in which it may be appropriate for the Commonwealth or a State to exploit a patented invention under the Crown use provisions of the Patents Act 1990 (Cth) (Patents Act) for the purposes of promoting human health. Similarly, the Department of Health and Ageing should develop a policy regarding the circumstances in which it may be appropriate for the Commonwealth to acquire a patent for the purposes of promoting human health. Decisions about Crown use in specific cases must be made on their individual merits.
>
> **Recommendation 26–2**
>
> The Commonwealth should amend the Patents Act to clarify that, for the purposes of the Crown use provisions, an invention is exploited 'for the services of the Commonwealth or of a State' if the exploitation of the invention by a Commonwealth or State authority (or by an authorised

person) is for the provision of healthcare services or products to members of the public.

Recommendation 26–3

The Commonwealth should amend the Patents Act to provide that, when a patent is exploited under the Crown use provisions, the remuneration that is to be paid by the relevant authority must be paid promptly and must be just and reasonable having regard to the economic value of the use. Similarly, the Act should be amended to provide that, when a patent is acquired under the Crown acquisition provisions, compensation must be paid promptly and must be just and reasonable having regard to the economic value of the patent.[154]

5.184 The Committee agrees that any guidelines or amendments to the Act in relation to the exercise of Crown use provisions should require the Government to consider, as a relevant factor, the extent to which public funding contributed to the invention that is the subject of the patent for which it is contemplated that the Crown use provisions will be exercised.

Recommendation 11

5.185 The Committee recommends that the *Patents Act 1990* be amended to clarify the circumstances in which the Crown use provisions may be employed; and that the Government develop clear policies for the use of the Crown use provisions. The Committee recommends that the Government adopt the Australian Law Reform Commission's recommendations on this issue from its 2004 report, *Genes and ingenuity* (Recommendations 26-1 to 26-3).

Clarifying the operation of compulsory licence provisions

5.186 In relation to compulsory licensing, there was significant support among submitters and witnesses for the use of compulsory licences to ameliorate potentially adverse impacts arising from certain patents.

5.187 The Committee heard that there have been few if any grants of compulsory licenses in Australia, which may suggest that the provisions are not operating effectively. In contrast, it was argued by some parties that this may be an indication of the effectiveness of the provisions as an incentive for parties to successfully negotiate license arrangements.

5.188 The Committee notes that the 2004 report of the ALRC into gene patents called for the Act to be amended to clarify the scope of the 'reasonable requirements of the public test' on which the grant of a compulsory licence may be based; and the introduction of a competition based test to make a compulsory licence also available

154 Australian Law Reform Commission, *Genes and ingenuity*, June 2004, Recommendations 26-1 to 26-3, p 608.

where a patentee has engaged in anti-competitive conduct under the *Trade Practices Act 1974* (TPA). Specifically, recommendation 27-1 stated:

> **Recommendation 27–1**
>
> The Commonwealth should amend the provisions of the *Patents Act 1990* (Cth) relating to compulsory licences by:
>
> (a) inserting the competition-based test recommended by the Intellectual Property and Competition Review Committee as an additional ground for the grant of a compulsory licence; and
>
> (b) clarifying the scope of the 'reasonable requirements of the public' test.[155]

5.189 The Committee found that there remains considerable doubt as to the operation of the compulsory licence provisions. In particular, the threshold criteria for the grant of a compulsory licence relating to, inter alia, the 'reasonable requirements of the public' are uncertain and possibly limited in effect, and may in fact be operating as a barrier to applications under these provisions. Further, the Committee notes that the recently introduced competition based test requires review by the Government to ensure that it is working effectively, particularly in relation to its interaction with the TPA.

Recommendation 12

5.190 The Committee recommends that the Government amend the *Patents Act 1990* to clarify the scope of the 'reasonable requirements of the public' test, taking into account the recommendation of the Australian Law Reform Commission on this issue in its 2004 report, *Genes and ingenuity* (Recommendation 27-1); the Committee recommends that the Government review the operation of the competition based test for the grant of a compulsory licence, with particular reference to its interaction with the *Trade Practices Act 1974*.

Including a broad research exemption in the Act

5.191 In relation to a research exemption, the Committee heard that it is unclear whether there is any such common law exemption under Australian patent law; and there is no such exemption expressly provided for in the Act. Despite the apparent widespread reliance by Australian researchers on a research exemption, the Committee found that the existence and, if it does exist, scope of any such exemption is very uncertain; and that this uncertainty could be acting to hinder innovation and investment in research.

5.192 The Committee notes there was widespread support for the inclusion of an express research exemption in the Act; and that various bodies such as the ALRC, ACIP and IP Australia have previously examined, or are currently examining, this

155 Australian Law Reform Commission, *Genes and ingenuity*, June 2004, Recommendations 26-1 to 27-1, p 625.

issue and have proposed particular approaches to formulating a research exemption. Concerning these suggested approaches, some submitters and witnesses objected strongly to formulations of a research exemption in which the exemption will apply only where the otherwise infringing act is for the *sole purpose* of research or experimentation. It was argued that the sole purpose test is overly restrictive, particularly in the modern environment where research is increasingly undertaken with commercial motives.

5.193 The Committee supported calls for the inclusion of an express research exemption in the Act. However, the Committee believes that any such exemption must be carefully designed to ensure that it is not overly restrictive. The Committee notes the terms of the exemption proposed by IP Australia in its March 2009 paper, 'Exemptions to patent infringement':

> A person may, without infringing a patent, do any act on a patented invention which is solely for the purpose of:
>
> - determining how the invention works;
> - seeking an improvement to the invention;
> - testing the validity of a patent;
> - determining the scope of the patent claims;
> - determining whether an act or product infringes a patent or
> - obtaining the information required for regulatory approval under Australian law or the law of any other country that regulates the manufacture, construction, use or sale of the patented invention.
>
> The statutory exemption will not apply where the invention is used in, but is not the subject of, an experiment.[156]

5.194 The Committee agreed that an appropriately generous and broad research exemption could be modelled on the words proposed by IP Australia, with the removal of the word 'solely' and, possibly, with the removal of the final paragraph.

Recommendation 13

5.195 The Committee recommends that the *Patents Act 1990* be amended to include a broad research exemption.

Inclusion of anti-avoidance and objects provisions in the Act

5.196 In relation to other potential amendments to the Act to ameliorate any actual or potential impacts of gene patents, the Committee was asked to consider the introduction of anti-avoidance provisions into the Act; and for the inclusion of specific objects. It was argued that both of these approaches would assist the courts and patent examiners in interpreting and applying the Act, and ensuring that the patent system

156 IP Australia, 'Exemptions to patent infringement', March 2009, p. 5.

achieves a proper balance between its economic and social objectives. The Committee believes that such approaches merit consideration by Government, as part of developing a suite of strategies to promote the effective operation of the patent system.

Recommendation 14

5.197 The Committee recommends that, to assist courts and patent examiners with the interpretation and application of the *Patents Act 1990*, the Government consider amending the Act to include anti-avoidance provisions.

Recommendation 15

5.198 The Committee recommends that, to assist courts and patent examiners with the interpretation and application of the *Patents Act 1990*, the Government consider amending the Act to include objects provisions.

Developing external accountability/patent quality mechanism

5.199 In relation to external measures to improve the operation of the patents system, the Committee received a number of notable suggestions which clearly would have potential to ameliorate any actual or potential impacts of gene patents. A number of submitters and witnesses endorsed consideration of a PBS or Medicare style approach to the funding of medicines, therapies or techniques that may rely on genetic inventions. The Committee notes that the ALRC considered these issues in some detail in its 2004 report on gene patents, and made a recommendation that the Australian Health Ministers' Advisory Council (AHMAC) conduct a broad examination of 'options for using government funding and purchasing power to control the cost of goods and services that are subject to gene patents and used in the provision of healthcare'.[157] Specifically, recommendation 19-2 stated:

> **Recommendation 19–2**
>
> AHMAC should examine options for using government funding and purchasing power to control the cost of goods and services that are subject to gene patents and used in the provision of healthcare.[158]

5.200 The Committee offers in-principle support for a broad-ranging inquiry on such terms, and expects that the long-awaited Government response to the ALRC's recommendations will offer a considered response to this recommendation.

5.201 In relation to calls for the establishment of some form of external mechanism to provide oversight of the patent system, the Committee heard a variety of suggestions, ranging from an apparently comprehensive patent system regulator, in the form of an Office of the Patent Regulator, to a more limited patent audit committee

157 Australian Law Reform Commission, *Genes and ingenuity*, June 2004, pp 473-474 (Recommendation 19-2).

158 Australian Law Reform Commission, *Genes and ingenuity*, June 2004, pp 473-474.

with specific expertise and interests in issues of patent quality in emerging and challenging fields of technology. The Committee believes that the establishment of such a body would be an important step to address many of the concerns relating to gene patents and, indeed, the patent system more broadly, and to establish an objective source of advice and guidance for governments in relation to, for example, the impact of patents in emerging or complex fields of technology, patent quality and the exercise of Crown use and compulsory licence provisions. The Committee therefore agreed that the Government should establish a patent audit committee as described by Professor Drahos. Whether there is a need for a more comprehensive Office of the Patent Regulator is a question that could be re-examined at an appropriate time in the future, and the Committee acknowledges that such an approach would need to be fully examined in terms of its regulatory impacts.

Recommendation 16

5.202 The Committee recommends that the Government establish a patent audit committee.

Senator Rachel Siewert

Chair