# SUBMISSION

# TO THE SENATE COMMUNITY AFFAIRS COMMITTEE

# INQUIRY INTO GENE PATENTS


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The authors are both members of the Law Faculty at the University of Tasmania and members of the Centre for Law and Genetics. The Centre developed out of a project funded by the Australian Research Council (ARC) from 1994-1997. The primary focus of the project was the ethical and legal implications of advances in genetic technology. Since then, the Centre has had three further ARC and has expanded its areas of research to include broader issues associated with commercialisation of genetic technology, access to healthcare and biobanking.

Professor Dianne Nicol teaches in the areas of intellectual property law, equity, media law, IT law and biotechnology and the law. She is the Associate Dean for Research in the Law Faculty and Graduate Research Coordinator. Professor Nicol has a PhD in cell and developmental biology from Dalhousie University in Canada and an LLM in intellectual property law from the University of Tasmania. Her research interests particularly focus on the interface between innovation, research and access to healthcare in biomedicine. She has undertaken ARC funded research on cooperative strategies for managing intellectual property in biotechnology with colleagues from the Australian National University. She is currently in receipt of funding from the ARC for a project on patent pooling in biotechnology, in collaboration with Dr Nielsen and colleagues from Swinburne University and Japan. Dianne was appointed to the Advisory Board for the Australian Law Reform Commission (ALRC) inquiry into gene patenting and human health and was a consultant to that inquiry. Together with other members of the Centre for Law and Genetics, Dianne regularly makes submissions to public inquiries. With Dr Nielsen, she made a submission to the Advisory Council on Intellectual Property (ACIP) inquiry into patentable subject matter,[1] and she attended the ACIP public consultation in Canberra on 2 March 2009.

Dr Jane Nielsen teaches primarily in the areas of competition law and torts. She has a PhD from the University of Tasmania. Her thesis focused on the interaction between intellectual property and competition law in the biotechnology area. Her research interests continue to consider the intellectual property/competition law divide, and how innovation in biomedicine may be optimised. She also has a keen interest in issues associated with compulsory licensing and access to medicines. Jane has commenced work on the authors' ARC funded patent pooling project, and her research will now examine this aspect of innovation in biotechnology. With Dianne, Jane has regularly made submissions to public inquiries, including to the ALRC inquiry into gene patenting and human health, and to the ACIP inquiry into patentable subject matter.

[1] The submission is available at: http://www.acip.gov.au/reviewpatentable.html (accessed 16 March 2009).

**Summary of submission**

**Point (a)**

**We submit that the Community Affairs Committee may wish to consider the possibility of rolling out the Pharmaceutical Benefits Scheme to embrace genetic testing services and whether other aspects of government funding and purchasing power should be brought to bear in this area.**

**We submit that it is timely for Australian funding agencies to consider issues relating to patenting the outcomes of publicly funded research and make appropriate policies. The Community Affairs Committee may wish to consider whether to direct federal funding agencies to address these matters**

**We submit that the Community Affairs Committee should consult the ALRC Report for assistance in determining how the health and wellbeing of Australian people can best be protected.**

**Point (b)**

**We submit that the Community Affairs Committee may wish to explore the following measures:**

- **improvements to the quality of patent examination through increased funding to IP Australia;**
- **more stringent application of the novelty, inventive step, industrial applicability and disclosure requirements by patent examiners;**
- **the possibility of limiting gene patents to use-bound claims; and**
- **introducing post-grant opposition proceedings in the Patents Office to facilitate challenges to patents of uncertain validity.**

**We submit that the Community Affairs Committee may wish to explore the options for reforming the compulsory licensing and Crown use provisions in the *Patents Act 1990.***

**We submit that the Community Affairs Committee may wish to explore the ways in which industry initiatives for facilitating innovation in biomedicine could be encouraged.**

**Point (c)**

**We submit that the Community Affairs Committee should avoid focusing on the single issue of whether or not gene and related inventions should be excluded, but should take a more expansive approach, both with regard to the issue of how patentable subject matter should be dealt with in the *Patents Act 1990* and also with regard to the exploration of other legal and policy options for dealing with any potential adverse consequences resulting from gene and related patents on healthcare, research, innovation and the health and wellbeing of Australians.**

**Submission**

The purpose of this submission is to respond to the specific matters referred to the Community Affairs Committee for inquiry and report by the last sitting day of 2009. As such, this submission addresses the impact of the granting of patents in Australia over human and microbial genes and non-coding sequences, proteins and their derivatives, including those materials in an isolated form,[2] with particular reference to the three points raised in the letter of invitation.

**(a) The impact which granting of patent monopolies over such materials has had, is having, and may have had on:**

**(i) the provision and costs of healthcare,**

**(ii) the provision of training and accreditation for healthcare professionals,**

**(iii) the progress in medical research, and**

**(iv) the health and wellbeing of the Australian people.**

**(i) Healthcare**

The ALRC, in its Genes and Ingenuity Report, was of the view that the policy impact of new genetic technologies on the healthcare system needs to be monitored closely, particularly the area of genetic testing.[3] The ALRC recommended that government funding and purchasing power be used to control the cost of goods and services that are subject to gene patents and used in the provision of healthcare.[4]

It is generally expected that new drugs and devices will be protected by patents as a matter of course, and that such patents will be aggressively enforced by their owners. Together, the National Medicines Policy, the Minimum Pricing Policy and the Pharmaceutical Benefits Scheme seek to:

- provide timely access to the medicines that Australians need, at a cost the community can afford;
- provide medicines that meet appropriate standards of quality, safety and efficacy;
- provide for quality use of medicines; and
- maintain a responsible and viable medicines industry. [5]

In achieving these objectives, at least some of the detrimental impact of monopoly pricing of patented drugs on the provision and cost of healthcare should be ameliorated. This should be the case irrespective of whether or not the drug in question was developed using biotechnology. However, the situation is different for genetic tests. In the past,

[2] We use the term 'gene and related patents' as shorthand to embrace all of these types of patents.
[3] ALRC Report 99, *Genes and Ingenuity: Gene Patenting and Human Health* (2004) at 470-471.
[4] ALRC Report, above n3, Recommendation 19-2.
[5] Available at: http://www.health.gov.au/internet/main/publishing.nsf/Content/nmp-objectives-policy.htm (accessed 16 March 2009).

aggressive enforcement of patents in the general area of diagnostic testing was much more rare (if it occurred at all) than for drugs. Patents are less necessary for diagnostic tests than for drugs because the costs of development and compliance with regulatory requirements is much lower. For example, in the area of genetic testing, once the gene sequence for a particular disease related gene has been identified and isolated, the development of a diagnostic test is not particularly onerous. At present only a small number of diagnostic genetic tests are covered by the Federal Government through its Medicare Benefits Scheme (MBS).

Evidence about the potential detrimental impacts of patents in the diagnostics field only emerged at around the turn of the century, from studies undertaken by Mildred Cho and Jon Merz and their colleagues in the US[6] and from more widespread media reports concerning enforcement actions against diagnostic service providers by Myriad Genetics relating to its BRCA patents.[7]

Merz and Cho's team reported that a number of gene patent and licence holders were actively enforcing their patents against providers of genetic tests by refusing to license or imposing restrictive terms in licences. These actions reportedly led to a number of test providers ceasing to perform genetic tests they had previously offered and to a number of others deciding not to develop or perform a test because of the patent considerations. In total, 22 patents were identified as being actively enforced, affecting 12 genetic tests, some of which related to common genetic disorders, including haemchromatosis, Fragile X syndrome, Duchenne muscular dystrophy and Huntington's disease. Others related to more complex disorders such as Alzheimer's disease and hereditary breast and ovarian cancer. It should be noted that, while not all of these patents exist in Australia, a number of them have been granted here.[8]

Myriad has been actively enforcing its patent rights against laboratories offering BRCA tests in a number of countries, requiring that samples are sent to Myriad's own laboratories in Utah for testing. A number of patents relating to the BRCA genes have been granted to Myriad in Australia.[9]

More recently, there has been ongoing media scrutiny of the actions of Genetic Technologies Ltd (GTG), a biotechnology company based in Melbourne, concerning its enforcement of its so-called 'junk DNA' patents. These patents do not claim DNA sequences as such, but claim methods of using non-coding regions of DNA to predict mutations in active coding regions.[10] GTG has successfully negotiated licensing

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[6] See, for example, M.K. Cho, S. Illangasekare, M.A. Weaver, D.G.B. Leonard and J.F. Merz, 'Effect of Patents and Licenses on the Provision of Clinical Genetic Testing Services' (2003) 5 *Journal of Molecular Diagnostics* 3; J.F. Merz, D.G. Kriss, D.G.B. Leonard and M.K. Cho, 'Diagnostic Testing Fails the Test' (2002) 415 *Nature* 577.

[7] For a helpful review see J. Paradise, 'European Opposition to Exclusive Control Over Predictive Breast Cancer Testing and the Inherent Implications for United States Patent Law and Public Policy: A Case Study of the Myriad Genetics' BRCA Patent Controversy' (2004) 59 *Food & Drug Law Journal* 133.

[8] D. Nicol and J. Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (Hobart: Centre for Law and Genetics Occasional Paper No. 6; 2003), available at: http://www.lawgenecentre.org/pub.php (accessed 16 March 2009) at 62-63.

[9] Ibid at 9.

[10] Relevant US patents include: Simons M.J. Intron sequence analysis method for detection of adjacent and remote locus alleles as haplotypes. US5192659 (1993); Simons M.J. Genomic mapping method by direct

arrangements with universities, commercial entities and providers of molecular diagnostic services in various jurisdictions, allowing use of these patented research tools. While non-commercial organisations are offered research licences for nominal, one-off fees, commercial licensees pay significant fees for past infringement and future use. For example, in 2003 Myriad itself agreed to pay an upfront fee of US$1 million for a non-exclusive licence to GTG's patents, as well as annual licence fees and other non-monetary consideration. In the clinical context, GTG settled a dispute with the Auckland District Health Board in New Zealand relating to alleged infringement of its patents in diagnostic testing on undisclosed terms.[11] GTG's patents have been granted in Australia.[12]

As far as we are aware, these are the main examples of enforcement actions in the diagnostic genetic testing context outside Australia. That the reports of enforcement actions are so limited is perhaps surprising, given that many gene and related patents have been granted and that to date courts and patent offices around the world have not found that there is anything inherently unpatentable about them.

While the enforcement of patents over genetic tests has garnered some attention in Australia, at this stage there is very little indication that patent holders are actively enforcing their patents against Australian genetic testing laboratories. We conducted research in 2002-2003 involving surveys and interviews with Australian researchers, biomedical companies and genetic testing laboratories.[13] While we found that there was a great deal of concern about gene and related patents, there was little evidence at that time that these concerns were substantiated in that such patents were actively being enforced against genetic testing laboratories in Australia.

Concerns that GTG could enforce its own patents against Australian genetic testing laboratories continue to be raised, but it is difficult to know the state of play in this regard, since as far as we are aware nothing has been disclosed publicly.

It should also be noted that, as part of GTG's settlement with Myriad in 2003 it was given an exclusive licence to Myriad's BRCA patents in the Australasian region. Although GTG stated that these would be 'a gift to the Australian people' in 2003, it raised the spectre that enforcement actions would be taken against genetic testing laboratories in 2008.[14] Ultimately, however, the decision not to enforce was restored.[15] There are also anecdotal accounts that GTG is enforcing patent rights related to other genetic tests.[16]

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haplotyping using intron sequence analysis. US5851762 (1998); Simons M.J. Intron sequence analysis method for detection of adjacent and remote locus alleles as haplotypes. US5612179 (1997).

[11] Nicol provides further discussion of these matters in: 'Navigating the Molecular Diagnostic Patent Landscape' (2008) 18 *Expert Opinion on Therapeutic Patents* 461.

[12] Nicol and Nielsen, above n8 at 10-11.

[13] Ibid at 201-203. See also ALRC Report, above n3 at 503.

[14] A. Cresswell, 'A Price on Your Genes' *The Australian* 30 July 2008, available at: http://www.theaustralian.news.com.au/story/0,25197,24097920-28737,00.htm (accessed 16 March 2009).

[15] GTG Company Announcements, 'New Position re BRCA Testing' 2 Dec 2008, available at: http://www.gtg.com.au/index.asp?menuid=060.070.130&artid=10748&function=NewsArticle (accessed 16 March 2009).

[16] J. Rowbotham, 'Sick Babies Denied Treatment in DNA Row' *Sydney Morning Herald*, 28 November 2008, available at: http://www.smh.com.au/news/national/sick-babies-denied-treatment-in-dna-row/2008/11/28/1227491827171.html (accessed 16 March 2009).

In summary, there appear to be some isolated examples of enforcement of gene and related patents against genetic testing laboratories around the world, with rather more evidence of such actions in the US than elsewhere. Although there are threats of enforcement actions in Australia, it is difficult to find concrete evidence that this is occurring. Research that parallels the Australian study that we performed in 2002 and 2003 in the UK and New Zealand found that there were similar concerns about the impact of gene and related patents on genetic testing, but that there was a similar lack of evidence of actual enforcement.[17]

This does not necessarily mean that we should be complacent. The fact is that many relevant patents do exist and their owners could choose to enforce them at any time. From the UK perspective, it has been suggested that their new National Health Service Pharmaceutical Price Regulation Scheme (NHS PPRS) could be rolled out to NHS genetic testing services.[18]

**We submit that the Community Affairs Committee may wish to consider the possibility of rolling out the Pharmaceutical Benefits Scheme to embrace genetic testing services and whether other aspects of government funding and purchasing power should be brought to bear in this area.**

### (ii) Training and accreditation for healthcare professionals

We are unaware of any particular issues with respect to the impact of gene and related patents on training and accreditation for healthcare professionals.

### (iii) Progress in medical research

Research and development in medical biotechnology is conducted on a cumulative basis. This means that basic research lays the foundation for later research and development, and there are many steps between initial pioneering research and what consumers would consider to be end products. Different stakeholders conduct research at each stage of the research-development spectrum, developing products, methods or technologies that can be characterised as inputs into subsequent steps in the development of drugs, therapies, and diagnostic methods. There is little doubt that the situation is complicated when patents are granted on inputs at early stages of the research-development pipeline (i.e. on gene and related inventions).

We acknowledged in our submission to ACIP in its inquiry into patentable subject matter that there are genuine concerns about the potential for patents to detrimentally impact on the primary research conducted in universities and other public research organizations that feeds in to the innovation cycle. Patenting will not always be the optimal strategy for

[17] See Nicol, above n11.
[18] A. Odell-West, 'The Legacy of *Myriad* for Gene-based Diagnostics: a New Policy and Regulatory Option' (2009) 4 *Journal of Intellectual Property Law and Practice* 267.

disseminating university knowledge.[19] Funding agencies in a number of countries are already heeding the call to keep research open. Some have already adopted policies of open dissemination of research results, including the US National Institutes of Health,[20] the UK Wellcome Trust[21] and Genome Canada.[22]

Genes and related inventions are particularly powerful tools in biomedical research and product development because they have wide ranging applications. Where access to any one of these critical inputs is restricted, there is likely to be a detrimental effect on subsequent downstream research and development. Given that the essence of a patent right is the right to exclude others, there will invariably be some routine under-use in any well functioning patent system, and this may simply be a cost we pay for the operation of a patent system that otherwise benefits society. But what we are talking about here is restrictions on access to foundational inputs that open up whole new areas of research and development.

It is becoming widely accepted that an appropriate policy option may be to allow patents over foundational innovations, but to ensure that they are widely licensed for small upfront fees with no ongoing obligations to the original innovator. The Organisation for Economic Cooperation and Development, in particular, endorses this approach.[23] In the US, the National Institutes of Health (NIH) released Guidelines relating to the dissemination of biomedical research resources in 1999[24] and Best Practices for Licensing of Genomic Inventions in 2005.[25] Together, these NIH Guidelines and Best Practices emphasise the importance of broad dissemination of genomic inventions and other foundational research tools with minimal encumbrances. For example, the 2005 NIH Best Practices state that:

> Whenever possible, non-exclusive licensing should be pursued as a best practice. A non-exclusive licensing approach favors and facilitates making broad enabling technologies and research uses of inventions widely available and accessible to the scientific community.[26]

In fact, it seems that most foundational research inputs are already dealt with in this way. For example, a comprehensive empirical study of licensing practices reported in 2006

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[19] Nicol discusses this point further in 'Strategies for Dissemination of University Knowledge' *Health Law Review* in press (copies available on request).
[20] NIH *Statement on Sharing Research Data* (2003) available at: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-032.html (accessed 27 August 2008).
[21] Wellcome Trust, *Policy on Data Management and Sharing* (2007) available at: http://www.wellcome.ac.uk/About-us/Policy/Policy-and-position-statements/WTX035043.htm (accessed 27 August 2007).
[22] Genome Canada, *Data Release and Resource Sharing Policy* available at: http://www.genomecanada.ca/en/about/governance/policies.aspx (accessed 27 August 2008).
[23] OECD, *Guidelines for the Licensing of Genetic Inventions* (2006), approved by the OECD Council 23 February 2006.
[24] NIH, 'Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources: Final Notice' (1999) 64 *Federal Register* 72090. See also National Research Council, *Intellectual Property Rights and the Dissemination of Research Tools in Molecular Biology* (1997).
[25] NIH, 'Best Practices for the Licensing of Genomic Inventions: Final Notice' (2005) 70 *Federal Register* 18413.
[26] Ibid at 18451.

indicates that a diverse array of strategies are used for transferring technology to the private sector.[27] It was found in this study that where exclusive licensing of genetic inventions is required, it tends to be restricted to particular fields of use, with non-exclusive licensing in other fields.

The ALRC recommended that the ARC and the NHMRC should develop guidelines with regard to the 'public benefit' in the context of publicly funded research[28] and should recognise the public benefit in ensuring the wide dissemination of research tools.[29]

**We submit that it is timely for Australian funding agencies to consider issues relating to patenting the outcomes of publicly funded research and make appropriate policies. The Community Affairs Committee may wish to consider whether to direct federal funding agencies to address these matters.**

### (iv) Health and wellbeing of the Australian people

The purpose of the patent system is to encourage innovation by creating property rights in the intangible fruits of inventive activity. Patent owners are provided with a period of market exclusivity in which to develop their innovations and sell their products free from the fetters of competition. As a trade off for the period of market exclusivity, the patent owner is required to fully disclose the invention and the best method of performing it. With this knowledge, competitors are encouraged to work around the patented territory and, once the period of exclusivity has come to an end, move into that territory. As a consequence, they, too, are encouraged to innovate.

In the area of biomedicine, innovation could lead to improved access to healthcare as well as the more obvious economic benefits to the industry. Hence, if we have a well functioning patent system, patents should serve the socially valuable purpose of enhancing the health and wellbeing of the Australian people.

It is difficult to know precisely how well the patent system is operating in the field of biomedicine at the present time: whether patents actually encourage or discourage innovation and, even if they do encourage innovation, whether there are other adverse social consequences in terms of freedom of research and scientific discovery and access to healthcare. With regard to the innovation question, on the one hand, it seems logical that, if investment in the biotechnology industry is to be fostered, the provision of appropriate patent protection is a desirable policy objective. But on the other hand, if the protection afforded by patents is too strong, then, rather than opening up the biotechnology market and encouraging innovation, it could create a barrier for entry to new players into the market and threaten the survival of existing players. Although the justification for patents is that they enable innovations in biotechnology to be commercialised, they could, at the same time, be used to block others from innovating.

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[27] L. Pressman, R. Burgess, R.M. Cook-Deegan, S.J. McCormack, I. Nami-Wok, M. Soucy and L. Walters, 'The Licensing of DNA Patents by US Academic Institutions: an Empirical Study' (2006) 24 *Nature Biotechnology* 31.

[28] ALRC, above n3, Recommendations 11-1 to 11-4.

[29] Ibid, Recommendation 12-1.

There is growing concern internationally that gene and related patents could prove detrimental to innovation rather than having a positive effect. Owners of patents claiming broadly applicable foundational technology could refuse to license or license on a restrictive basis, blocking off whole areas of downstream innovation.[30] And if the patent landscape is too cluttered, necessitating entry into licence negotiations over multiple patents, innovation could be further impeded or delayed, creating what has become known as a tragedy of the anticommons.[31] Such negative impacts on innovation would be likely to have flow on effects in terms of consumer access, and could extend to basic upstream research as well.

Our 2002-2003 Australian study, as well as research carried out by John Walsh, Ashish Arora and Wesley Cohen in the US[32] and others elsewhere at around the same time suggest that there is little factual proof of significant adverse impacts on innovation. A later report by the US-based Committee on Intellectual Property Rights in Genomic and Protein Research and Innovation of the National Research Council, published in 2006,[33] confirms these findings. However, there is no doubt that the increasing complexity of the patent landscape is creating hurdles for the industry. In particular, searching obligations are onerous and expensive, and where a high level of encumbrance is found it is likely that research efforts will be redirected. It is difficult to state with any level of precision the number of research projects that are abandoned for the reason that there are too many problematic patents in the area, but it is acknowledged that this problem does exist. Project abandonment could have flow on consequences for the health and wellbeing of Australian people.

It appears that biomedical research and development is advancing, and biomedical researchers, the medical biotechnology industry and end consumers could all be benefiting. However, this does not necessarily mean that everything is working at an optimal level. It is important to recognise that the situation is complex and there is no one simple solution to any of the actual or perceived problems raised above. The ALRC addressed these issues in detail and made extensive recommendations.

**We submit that the Community Affairs Committee should consult the ALRC Report for assistance in determining how the health and wellbeing of Australian people can best be protected.**

[30] J.P. Walsh, A. Arora and W.M Cohen, 'Effects of Research Tool Patenting and Licensing on Biomedical Innovation. In: *Patents in the Knowledge-Based Economy*. (ed. W.M. Cohen and S.A. Merrill) (Washington DC, US: National Academy Press; 2003).

[31] M.A. Heller and R.S. Eisenberg, 'Can Patents Deter Innovation? The Anticommons in Biomedical Research' (1998) 280 *Science* 698.

[32] Walsh, Arora and Cohen, above n30.

[33] Committee on Intellectual Property Rights in Genomic and Protein Research and Innovation, National Research Council, *Reaping the Benefits of Genomic and Proteomic Research: Intellectual Property Rights, Innovation and Public Health* (Washington DC, US: The National Academies Press; 2006).

**(b) Identifying measures that would ameliorate any adverse impacts arising from the granting of patents over such materials, including whether the *Patents Act 1990* should be amended, in light of any matters identified by the inquiry.**

We have three suggestions to make with regard to this point.

1. There are a whole range of measures that might ameliorate any adverse impacts arising from the granting of gene and related patents. There is little support in policy debates for excluding genes and related inventions from patenting (we return to this point again in our response to the third point raised by the Committee). Rather, there are common calls for other reforms to patent law and practice.

**We submit that the Community Affairs Committee may wish to explore the following measures:**

- **improvements to the quality of patent examination through increased funding to IP Australia;**
- **more stringent application of the novelty, inventive step, industrial applicability and disclosure requirements by patent examiners;**
- **the possibility of limiting gene patents to use-bound claims; and**
- **introducing post-grant opposition proceedings in the Patents Office to facilitate challenges to patents of uncertain validity.**

2. Patent legislation often includes other provisions allowing use of the patented invention without the permission of the patent owner, which may be triggered when the patent holder is failing to provide sufficient pubic benefit from the patent grant. For example, a compulsory licence is a court or administrative order requiring the patent holder to allow others to work the invention. Government use (or Crown use, as it is called in Australia) is use of the invention by the government for the purposes of the state without having to obtain permission from the patent owner. The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) lays down fairly stringent prescriptions on what provisions are allowed to be included in national patent laws. Article 31 allows use without authorisation subject to certain limitations. One significant restriction is that prior to such use, the proposed user must have made efforts to obtain authorisation from the patent holder on reasonable commercial terms and conditions, where such efforts have not been successful within a reasonable period of time. This requirement may be waived in limited circumstances, including national emergency, other circumstances of extreme urgency and public non-commercial use.

Australia has both compulsory licensing and Crown use provisions in *Patents Act 1990.* In a recent article we argued that a number of opportunities to reform these provisions in

Australia have been missed.[34] In 2006, despite being presented with the opportunity to implement wholesale reform of the provisions relating to use without authorisation, the result of the Government's reform package was the insertion of a single provision into s 133 of the *Patents Act 1990* providing for the issue of a compulsory licence for anti-competitive conduct. This amendment has given rise to many new issues.[35] As a result, these provisions are unlikely to assist greatly in providing access to patents where that access is denied.

**We submit that the Community Affairs Committee may wish to explore the options for reforming the compulsory licensing and Crown use provisions in the *Patents Act 1990*.**

3. Academic commentators, policy makers and the industry itself are also looking at other non-legislative solutions. It is recognised that, at the very least, licensing negotiations and agreements need to be streamlined. Another option that has been mooted to facilitate licensing arrangements is to establish some type of collective rights arrangement. To date, most of the commentary on such arrangements has focused on patent pooling and cross licensing. These arrangements enable the consolidation of intellectual property rights so that negotiating licenses is streamlined and transaction costs are consequently reduced. Some commentators have suggested that these types of private arrangements could ameliorate some of the problems arising from the proliferation of gene and related patents,[36] while others have expressed doubt as whether there is sufficient incentive for patent holders to willingly enter into voluntary arrangements of this nature.[37] We have recently commenced a four year ARC funded project analysing the role that patent pools might play in facilitating innovation in the Australian biotechnology industry.

**We submit that the Community Affairs Committee may wish to explore the ways in which industry initiatives for facilitating innovation in biomedicine could be encouraged.**

## (c) Whether the *Patents Act 1990* should be amended so as to expressly prohibit the grant of patent monopolies over such materials.

The Committee will doubtless receive submissions urging it to recommend exclusion of gene and related inventions from patenting and criticising the ALRC review for failing to make such recommendations. However, we submit that in our view there is no basis on which to amend the *Patents Act 1990* to prohibit the grant of such patents. We base this submission on the following points:

[34] J. Nielsen and D. Nicol, 'Whither Patent Use Without Authorisation?' (2008) 36(3) *Federal Law Review* 333.
[35] Ibid, canvassed at 348-356.
[36] J. Clark, J. Piccolo, B. Stanton and K. Tyson, 'Patent Pools: A Solution to the Problem of Access in Biotechnology Patents' (2000) www.uspto.gov/web/offices/pac/dapp/opla/patentpool.pdf
[37] For example, Heller and Eisenberg, above note 31.

- there is no convincing proof that such an exclusion is necessary;
- there is no convincing proof that such an exclusion would satisfy any perceived need to better protect the provision of healthcare, medical research, innovation and the health and wellbeing of Australians;
- there is no appropriate model from other jurisdictions on which to base an exclusion for gene and related inventions in Australia;
- the presence of a list of excluded subject matter in European legislation has not noticeably provided better protection for the provision of healthcare, medical research, innovation and the health and wellbeing of Europeans;
- it is doubtful that it is possible to craft an exclusion in sufficiently clear and certain language to provide adequate assistance to patent examiners and applicants in determining what is and is not patentable;
- such an exclusion could create more detriment to innovation than the status quo;
- such an exclusion could create lack of confidence and uncertainty in the biotechnology industry, threatening the viability of some sectors; and
- ultimately, such an exclusion may have more adverse than positive effects on the health and wellbeing of Australians.

We are, however, of the view that some amendments to the *Patents Act 1990* are warranted, and these were canvassed in our submission to ACIP. In our view, the issues being investigated in this inquiry are far broader than the narrow question of whether or not gene and related inventions should be excluded from patenting.

The submissions that we make in response to the Committee's points (a) and (b) illustrate the breadth of the issues before the Committee from the healthcare perspective. We also argue in relation to point (c) that the question of what should or should not be patented is not simply an issue about patenting genes and related inventions. The Committee also needs to consider the appropriateness of patents in other areas of high technology, particularly software and business methods. Taking all of these considerations into account, we do believe that amendments to s 18(1) of the *Patents Act 1990* are warranted. In our submission to ACIP we suggested that they might take the following form:

> Section 18(1) Subject to subsection (2),[1] a patentable invention must satisfy the following criteria for the purposes of a standard patent, so far as claimed in any claim:
>
> (a) it is an invention in a field of technology;[2]
>
> (b) when compared with the prior art base as it existed before the priority date of that claim:
>
> (i) it is novel; and
>
> (ii) it involves an inventive step; and
>
> (c) it has industrial applicability;[3] and
>
> (d) it was not secretly used in the patent area before the priority date of

that claim by, or on behalf of, or with the authority of, the patentee or nominated person or the patentee's or nominated person's predecessor in title to the invention.

Notes:

[1] We have some doubt that subsection (2) (excluding human beings and the biological processes for their generation) is actually needed. Subject matter of this nature would either fail to satisfy the requirement of being an invention or would fall foul of the contrary to law provision already existing in section 51 and/or the contrary to morality provision that we propose should be included in section 51.

[2] We submit that the requirement for there to be an invention in a field of technology should be listed as one of the criteria for patenting so that patent examiners explicitly address this requirement when considering patentability. The existing body of case law relating to the manner of manufacture test should continue to provide guidance in this assessment task. We submit that it is important to continue to make the distinction between inventions and discoveries, theories etc. While the option of including the requirement for the invention to be in a field of technology in Australian law was rejected in the ACIP *Report on a Review of the Patenting of Business Systems* (2003), we submit that this option should be revisited. In the first place, this is simple adoption of the language in the TRIPS Agreement. Secondly, in our view, the requirement that the invention is in a field of technology is not a major extension of the requirement specified by the High Court in *National Research and Development Corporation v Commissioner of Patents* (1959) 102 CLR 252 that the invention belongs to the useful rather than the fine arts. There may be some business methods that do not satisfy this requirement, but in our view they will be rare and the extent to which patenting of such subject matter actually encourages innovation is highly uncertain.

[3] We submit that the industrial applicability/utility requirement should be given explicit recognition in Australian patent law. At present, the manner of manufacture test incorporates this requirement in part, and the usefulness requirement adds gloss, but greater clarity is desirable. To avoid confusion with terminology between old and new laws, we suggest that the language of industrial applicability is adopted, rather than usefulness or utility. If Australian law includes an industrial applicability requirement, then the old usefulness ground becomes otiose and should be deleted.

We also submit that the definition of invention in Schedule 1 should be deleted and with it any reference to section 6 of the *Statute of Monopolies* and to the concept of general inconvenience. It may be appropriate to include a definition of invention that includes requirements of physicality and technicality, but it may be preferable to specify these requirements in guidelines that assist examiners in determining whether the invention requirement has been satisfied.

We reiterate our submission to ACIP that there is a need for guidelines to assist patent

examiners in the process of considering whether the subject matter requirements have been satisfied. We recognize that IP Australia provides guidance to assist patent examiners in its *Manual of Practice and Procedure* and that this is regularly updated. We do not question the quality or accuracy of this document. However, we submit that additional guidance may be required for some areas of technology, particularly for fields of technology where there is little or no guidance from the courts. We strongly support recommendation 8-2 from the ALRC Report *Genes and Ingenuity* that:

> IP Australia should develop examination guidelines, consistent with the *Patents Act 1990* (Cth), the *Patents Regulations 1991* (Cth) and existing case law, to explain how the criteria of patentability apply to inventions involving genetic materials and technology.

We submit that this recommendation could be expanded to include other fields of technology, particularly business methods and software. The guidelines could cover all of the patent and disclosure requirements, particularly the new industrial applicability requirement which, we have submitted, should be explicitly provided for in section 18. We further submit that these guidelines should be formulated in consultation with stakeholders.

It may also be appropriate to open the guidelines for a period of public comment to improve transparency and consultation, as was done for the US Utility and Written Description Guidelines. We note that under the US *Administrative Procedure Act*, agency rulemaking (including rulemaking at the USPTO) is usually subject to 'notice and comment' requirements - i.e., release for a period of public comment followed by final rulemaking. There may be some justification for including such a requirement in Australian law, either generally for all administrative decision making or more specifically for patent guidelines.

We also noted in our ACIP submission that even greater assistance could be provided to examiners in difficult cases. One option might be to provide an expert review panel, which could make decisions on such issues as physicality and technicality with regard to the invention requirement, the distinction between inventions and discoveries and the morality exclusion. The ALRC Report provides information on some precedents for specialized patent advisory bodies in other jurisdictions and specialized bodies in other regulatory regimes in Australia, but only with regard to ethical matters.[38]

While the ALRC reported that they saw some merit in the establishment of a new ethics advisory body as a better mechanism for addressing social and ethical concerns than leaving such matters to patent examiners, it was concluded that such a mechanism would inevitably add to the cost and complexity of the patent system. However, we submit that if an expert body were given a broader mandate to advise on invention, industrial applicability and other matters in controversial areas of technology as well as ethical considerations, then the benefit from the perspective of facilitating innovation and protecting the provision of healthcare, research and the health and wellbeing of Australians would outweigh the cost of increased complexity of the patent system.

We reiterate our submission to ACIP that there should be scope for dealing with ethical

[38] ALRC, above n3 at 185-186.

concerns in patent law, provided that these concerns relate solely to exploitation of the invention, as prescribed in TRIPS. It is important to separate out ethical concerns relating to patenting of technology and ethical concerns relating to the technology itself. The latter should not be dealt with through the patent system but through direct regulation of research and development activities. But there will be some instances where it would be contrary to morality to allow the patent system to be used to facilitate the commercial development of certain technologies.

We expect that, as a general rule, few patent applications will fall foul of an exclusion centred on ethical grounds. Nevertheless, it is appropriate that such an exclusion is explicitly provided for in our patent legislation. Article 6 of the European Biotechnology Directive provides some useful examples of the types of subject matter that should be considered to be unpatentable on ethical grounds:

(a) processes for cloning human beings;

(b) processes for modifying the germ line genetic identity of human beings;

(c) uses of human embryos for industrial or commercial purposes;

(d) processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes.

We emphasise that this list provides examples only and is not intended to be exhaustive. Some of the examples provided above may fall within the 'human beings' exclusion in section 18(2). However, we suggest that Section 51 of the *Patents Act 1990* (Cth) should be amended to include inventions that are contrary to morality as well as law.

**In conclusion, we submit that the Community Affairs Committee should avoid focusing on the single issue of whether or not gene and related inventions should be excluded, but should take a more expansive approach, both with regard to the issue of how patentable subject matter should be dealt with in the *Patents Act 1990* and also with regard to the exploration of other legal and policy options for dealing with any potential adverse consequences resulting from gene and related patents on healthcare, research, innovation and the health and wellbeing of Australians.**