Inquiry into Gene Patents

Intellectual Property Research Institute of Australia and Centre for Ideas and The Economy

Submission to the Senate Community Affairs Committee

Authors: **Chris Dent**[1] **and Kwanghui Lim**[2]

We thank Catherine Macneil and Megan Richardson of Melbourne Law School for helpful comments

Date: 19th March, 2009

[1] Senior Research Fellow, IPRIA and Melbourne Law School. Tel: +61-3-83441134. Email: c.dent@unimelb.edu.au

[2] Senior Lecturer in Strategic Management, Melbourne Business School. Associate Director, Intellectual Property Research Institute of Australia. Tel: +61-3-93498294. Email: k.lim@mbs.edu

About IPRIA (www.ipria.org)

The Intellectual Property Research Institute of Australia is a national centre for multi-disciplinary research on the law, economics and management of intellectual property. It is based at the University of Melbourne, and is a joint venture of the Faculty of Law, the Faculty of Economics and Commerce, and the Melbourne Business School. IPRIA's research focuses on ways to improve the protection, management and exploitation of intellectual property by business, research institutions and other users of the IP system, and on supporting high quality policy development by government in areas relating to intellectual property. It seeks to use the outcomes of its research to create and contribute to public debate on key issues relating to intellectual property.

About CITE (cite.org.au)

The Melbourne Business School is one of the leading providers of management education in the Asia-Pacific. The Centre for Ideas and the Economy (or CITE) is a newly created research centre residing within MBS. It is devoted to the creation and dissemination of academically evaluated, rigorous and practical policy ideas for application in the public and business spheres.

About the Authors

Chris Dent is a Senior Research Fellow with IPRIA at the Melbourne Law School. The focus of his work is on the patent system – ranging from a history of patents, empirical examinations of the system and critical approaches to the operation of patents within the broader community. His research also covers other areas of intellectual property such as copyright and trade marks. Prior to commencing work at IPRIA, Chris worked with the Centre for Media and Communications Law at the University of Melbourne. Before that he carried out research for the Law Reform Commission of Western Australia and the Victorian Law Reform Commission. His qualifications are from Murdoch University in Perth and include a PhD in Law, awarded in 2003, that was the application of Foucaultian ideas to a study of the history of negligence law.

Kwanghui Lim is a Senior Lecturer at Melbourne Business School, Associate Director at IPRIA and Research Associate at CITE. Kwanghui's research explores the strategies used by firms to manage intellectual property and the commercialisation process. His doctoral thesis at MIT won the Academy of Management and INFORMS Best Dissertation Award (2001) in the Technology Management area, as well as the 2001 Richard R. Nelson Best Dissertation Award. Prior to joining Melbourne Business School, Kwanghui was an Assistant Professor at the National University of Singapore. He founded the NUS-MBS Patent Database which is used at various universities around the world for academic research. He has conducted workshops and seminars for the World Intellectual Property Organization, Intellectual Property Office of Singapore and 3M-NUS innovation Program for School Teachers. Kwanghui's industry experience includes consulting experience at Booz Allen & Hamilton. See http://kwanghui.com for more details.

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Introduction

The Senate Community Affairs Committee has invited IPRIA to make a submission to the Committee's Inquiry into Gene Patents. The Committee is considering the impact that the granting of patents for inventions relating to genes, gene sequences, proteins and their derivatives has on the "provision and costs of healthcare, provision of training and accreditation for healthcare professionals, progress of medical research and the health and wellbeing of Australians". IPRIA is pleased, in conjunction with CITE, to be able to provide information concerning key aspects of this subject-matter – most notably, the law as it stands in relation to the patenting of genetic materials and the potential "chilling effect" that patents may have on future research in the area. This submission takes the form of a summary of the law in this area, a review of relevant work in Economics and Management, and a revisiting of the work that the Institute has conducted in relation to a "research use" exemption in patent law.

Legal Framework for the Granting of Patents over Genetic Material

It should not be forgotten that any patents granted for genetic inventions are only a subset of the patents granted by the patent office. Any patents, therefore, that are granted for genetic inventions have to comply with the requirements as set out in the *Patents Act 1990* (Cth) (the Patents Act). This section will briefly describe the basics of patent law and then relate them to the specific issues that arise for inventions of genetic materials.

Patents are legally enforceable rights that are granted to applicants who demonstrate, among other things, that the invention described and delimited in the patent application meets all the requirements of patentability. These rights are provided as an incentive for individuals and firms to invest in research and development. Section 18 of the Patents Act sets out the requirements of patentability. To comply with the section, an invention must:

- Be a manner of manufacture within the meaning of s. 6 of the 1624 Statute of Monopolies;
- Be novel;
- Involve an inventive step (or innovative step for innovation patents[3]); and
- Be useful.[4]

Further, the Patents Act states that 'human beings, and the biological processes for their generation, are not patentable inventions'.[5]

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[3] The Patents Act makes provision for two types of invention – standard patents and innovation patents. This submission will focus on the requirements relating to standard patents as they are more restrictive than innovation patents. Further, the reduced period of protection for innovation patents means they are likely to be less attractive for firms that have invested significant sums of money into genetic research and the production of genetic inventions.

[4] There is an additional test that the invention must not have been used, in secret, prior to the date upon which the invention is claimed to be inventive: *Patents Act 1990* s. 18(1)(d).

[5] *Patents Act 1990* s. 18(2).

The reference to the *Statute of Monopolies* has been interpreted to mean that mere discoveries are not patentable and that an invention has to belong to the 'useful arts'.[6] According to Nicol and Nielsen, 'products of nature have been considered to be one of the traditional exclusions from patenting on the basis that products of nature are already in existence and generally do not have the requisite industrial applicability'.[7] This accords with the view of the Deputy Commissioner of Patents: a patent 'claim directed to naturally occurring DNA characterized by specifying the DNA coding for a portion of that molecule would likely to be claiming no more than a discovery per se and not be a manner of manufacture[8] within the meaning of the *Statute of Monopolies*.[9]

The law relating to the patenting of genetic material has been interpreted to mean 'gene sequences in their natural state are not patentable. It is only when they have been isolated and synthetically produced and when a function has been ascribed to them that they become patentable'.[10] This is because products of nature themselves are not patentable and the *Statute of Monopolies* requires that the invention to be protected has to have 'industrial application' – it has to be useful. That is, a claim to a gene sequence or other biological material, without reference to a specific use or practical application thereof, would not be a claim to patentable subject matter and therefore would not be granted patent protection.[11]

Regardless of this understanding of the law, there have been calls to treat genetic inventions differently from other inventions – that is, reforms can be made to the Patents Act that will only impact on the manner in which patents are to be granted for one category of innovation.[12] This may not be as easy as it appears. If the Committee was to consider that the Act should be changed, as a result of the submissions receives, then it seems that two options are possible – either the tests of patentability

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[6] *National Research Development Corporation v Commissioner of Patents* (1959) 102 CLR 252, 275.

[7] D. Nicol and J. Nielsen, 'Patents and Medical Technology: An Empirical Analysis of Issues Facing the Australian Industry', *Intellectual Property Research Institute of Australia Report 01/04*, 23.

[8] *Kirin-Amgen v Board of Regents of the University of Washington* (1995) 33 IPR 557, 569.

[9] It may be noted that the Advisory Council on Intellectual Property is currently undertaking a review of the manner of manufacture test in the Patents Act: ACIP, *Patentable Subject Matter*, Issues Paper, 2008.

[10] Nicol and Nielsen, above n 5, 232.

[11] Such a claim would also fail to meet the disclosure requirements set out in s 40(2)(a) of the Patents Act.

[12] It should also not be forgotten that the Australian patent law sits within a framework of international agreements; and therefore, the Act may not be amended in such a way as to contravene Australia's international obligations. One of the most significant international agreements in this area is the TRIPS Agreement (Agreement On Trade-Related Aspects Of Intellectual Property Rights). Article 27(1) of the Agreement states that 'patents shall be available for any inventions' and that 'patents shall be available and patent rights enjoyable without discrimination as to … the field of technology'. The Agreement allows signatory states to exclude from patentability those inventions that go against '*ordre public* or morality' (Art. 27(2)) and 'diagnostic, therapeutic and surgical methods for the treatment of humans or animals; plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and micro-biological processes' (Art. 27(3)).

are altered for inventions relating to genetic material[13] or a broader limitation is applied to the application of the Patents Act, again with the purpose of modifying the impact of the Act on inventions relating to genetic material.[14] Neither option may be particularly effective. The most obvious difficulty would be definitional – the crafting of an exclusion to the operation of the Act that would only impact on the desired areas of technology that would withstand legal attack and not add to the uncertainty of researchers in the area would pose significant challenges.

It may be noted that, after reviewing the submissions it received on the matter, the Australian Law Reform Commission (ALRC) recommended that 'patent applications relating to genetic materials and technologies should be assessed according to the same legislative criteria for patentability that apply to patent applications relating to any other type of technology'.[15] No evidence has been found that causes us to recommend against the recommendation of the ALRC.[16] To render genetic inventions non-patentable may be seen as a challenge to the policy basis of the entire patent system as currently understood – this would, therefore, require significant consideration of the change from the other policy bases of the patent law, such as the economic justifications for patents.

Economic and Managerial Perspectives on Gene Patenting

The key economic issues concerning gene patenting are discussed by Scherer[17] and Adler.[18] The main benefit, as with other usual patents, is the provision of incentives for individuals and organizations to invest in research and development. As well, patenting compels participants to disclose knowledge for which a patent is awarded, and this would benefit consumers after the patent expires, as well as trigger the development of complementary inventions based on that knowledge even during the life of the patent. Gans and Stern show how strong intellectual property protection allows upstream biotechnology firms to sell or license technology that is protected by IP to downstream pharmaceutical companies that are better able to nurture those technologies through the commercialization process.[19]

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[13] The tests for patentability in the Patents Act, as it stands, apply equally to all areas of innovation. There is, however, a separate set of provisions for the extension of term for pharmaceutical patents (Patents Act, Ch. 6, Part 3); however, this does not deal with the patentability of pharmaceutical substances.

[14] In another area of intellectual property law, the *Copyright Act 1968* was amended to make specify that computer programs were literary works (s. 10); however, this was a process of inclusion, rather than exclusion.

[15] Australian Law Reform Commission, *Genes and Ingenuity: Gene Patenting and Human Health*, Report 99, 2004, Recommendation 6-1.

[16] The ALRC also notes that the Senate Standing Committee on Industry, Science and Technology also rejected an exclusion for genetic materials and technologies prior to the passing of the current Patents Act: ibid, 169.

[17] F. Scherer, 'The Economics of Human Gene Patents' (2002) 77 *Academic Medicine: Journal of the Association of American Medical Colleges* 1348.

[18] R. Adler, 'Genome Research: Fulfilling the Public's Expectations for Knowledge and Commercialization' (1992).257 *Science* 908.

[19] J. Gans and S. Stern, 'The Product Market and the Market for "Ideas": Commercialization Strategies for Technology Entrepreneurs' (2003) 32 *Research Policy* 333.

These benefits are not specific to gene patenting. Gene patents also give rise to the usual problems associated with patents: the granting of a monopoly leads to deadweight loss, and the licensing and sale of property rights are difficult to contract upon.

Prior research highlights several issues that are especially salient to gene patents:

1. Patent scope: overly broad patents may prevent follow-on innovations. This is of concern, to some commentators, because genes are not just chemical substances, but they also encode information that is used to "program" the creation of life, making it difficult to judge the appropriate scope of a gene patent and its effect on innovation.[20] Hence, Scherer suggests that 'to ensure that promising future lines of research are not impeded, existing genome patent claims and any claims allowed in the future ought to be interpreted narrowly'.[21]

2. Cumulative nature of invention: the cumulative nature of scientific invention is of great concern in areas like genetics. Scherer, for example, articulates the need of a careful balance between the incentives of early innovators versus later innovators, whose inventions might be blocked by the earlier patents.[22] While this problem could ideally be solved by cross-licensing agreements, such agreements are often difficult to reach in practice due to information asymmetry and bargaining issues.

3. Anti-commons effects: the issue here is that upstream intellectual property may stifle downstream innovations. The argument goes that as a result of the potential fragmentation of ownership over gene patents, multiple owners have a right to exclude others from scarce resources, with the result that no one has an effective way to use them.[23] So, a failure to contract with sufficient numbers of upstream gene patent owners may render a downstream innovator (e.g., a healthcare provider) unable to make use of its innovations.[24]

Three things may be noted with respect to the economics and managerial commentary. First, the commentators may not be fully cognisant of the law or they may have produced their commentary

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[20] See B. Jackson, 'Innovation and Intellectual Property: The Case of Genomic Patenting' (2003) 22 *Journal of Policy Analysis and Management* 5.

[21] Scherer, above n 15, 1364.

[22] Ibid.

[23] See M. Heller and R. Eisenberg, 'Can Patents Deter Innovation? The Anticommons in Biomedical Research' (1998) 280 Science 698; and N. Gallini, 'The Economics of Patents: Lessons from Recent U.S. Patent Reform' (2002) 16 *The Journal of Economic Perspectives* 131.

[24] It has been noted that 'the existence of an anti-commons effect … of patents has not been validated by comprehensive empirical data': B. Verbeure, E. van Zimmeren, G. Matthijs and G. Van Overwalle, 'Patent Pools and Diagnostic Testing' (2006) *Trends in Biotechnology* 115, 115.

prior to a relevant legal change.[25] Second, the commentary, if from overseas, may refer to laws or legal rules that are not identical in Australia.[26] Third, much of the commentary relates to the ethics of gene patenting. IPRIA and CITE for not have significant expertise in the area; and therefore, discussions of the ethical dimensions of patenting are not included here.[27]

The Lack of Empirical Evidence

This submission considers that there may be significant problems that arise from the terms of reference for the Committee's Inquiry; in particular, with respect to the inclusion of the 'impact' of the granting of patents relating to genetic materials in Australia – the problem is that there is little empirical work that has been carried out that will demonstrate, to any rigorous standard of proof, the impact of such patenting.[28] It is likely that many of the submissions received will be based on individual assumptions or, at best, anecdotal data. To base reforms to the *Patents Act 1990* (Patents Act), an important tool in the encouragement of technological innovation, on such evidence is, to say the least, problematic. It would be preferable for any reforms in this area to be based on methodologically appropriate research – such research, however, is not possible in the timeframe of the Committee's Inquiry.

There is now an extensive empirical literature on patenting behaviour among biotechnology firms, the importance of scientific knowledge to such firms, as well as the success of alliances among biotechnology and pharmaceutical firms. However, little work has been done to link patenting behaviour to downstream outcomes (healthcare costs, investment in healthcare, progress in medical research, measures of public health success). This is unsurprising given that drugs based on genetic technology are only just reaching the market.

What limited work that exists reports that, by 2005, 20% of human genes had been patented in the US.[29] A recent IPRIA study shows that the impact of biotechnology patents is enhanced with moderate degrees of 'knowledge brokering' (the use of ideas from other technical domains to

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[25] The discussion of Jackson, above n 18, for example, does not seem to acknowledge the guidelines in the United States Patent and Trademark Office Manual of Patent Examination Procedure that state that a patent applicant must demonstrate a utility for an invention that is 'specific, substantial and credible' rather than just listing a description of the invention: UPSTO MPEP at §2107.

[26] The discussion of Scherer, above n 15, for example, is linked to the US "doctrine of equivalents" that is used to interpret patent claims. The Australian courts do not follow the same doctrine, and therefore, there may be limitations on the relevance of Scherer's insights.

[27] For a thorough discussion of the ethics of patenting, see Nuffield Council of Bioethics, *The Ethics of Patenting DNA*, Discussion Paper, 2002.

[28] It may be noted that there is a review under way of the impact of gene patents on patient access to genetic tests in the United States: Secretary's Advisory Committee on Genetic, Health and Society, *Public Consultation Draft Report on Gene Patents and Licensing Practices and their Impact on Patient Access to Genetic Tests*, 2009. More research would have to be carried to investigate whether the conclusions drawn from that review are relevant to the Australian patent and healthcare system.

[29] K. Jensen and F. Murray, 'Intellectual Property Landscape of the Human Genome' (2005) 310 *Science* 239.

innovate in biotechnology), suggesting that some degree of openness in scientific exploration is important.[30]

Many of the relevant publications in scientific journals have been on the *perceptions* of scientists towards gene patenting. A recent survey (Nature Biotechnology, Jan 2009) found that a majority of respondents perceive patent protection to have a negative effect on scientific progress in their area of work. The survey was done on a small sample of 93 scientists. An Editorial in the British Medical Journal[31] articulated concerns that the patenting of genes is "unlikely to lead to the maximal intellectual exploitation of this resource". An article in Nature[32] expresses misgivings about gene patenting, suggesting that it impedes diagnosis and treatment (e.g., in the case of the BRCA1 breast cancer gene).

While such opinions are often strongly expressed, they are not based on carefully constructed large sample studies. There is as yet no empirical work available that carefully examines the relationship between gene patenting and the costs of providing healthcare, the training and accreditation of healthcare professionals, and progress in medical research. A small number of interesting case studies exist, but it would be unwise to generalize from them as the basis for public policy. For example:

- Matthijs and Hodgson[33] offers three examples of gene patents, the first which reflects an "open" model, the second for which no one was allowed to use the technology but everyone infringed upon, and a third patent that was so expensive that no one could afford to use it.[34] The underlying message is that healthcare providers may sometimes be unable to access valuable genetic treatments for clinical use.

- Bar-Shalom and Cook-Deegan[35] present a case study of a cancer treatment. Their case study raises important issues about the relevant breadth of patent claims, problems with patent licensing, and difficulties that arise when access to research results are restricted.

Such case studies illustrate that thorough and careful empirical studies are needed – and on a broader scale – to gain a better understanding of the impact of gene patenting, and to form the basis of policy decisions.

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[30] D. Hsu and K. Lim, 'The Antecedents and Innovation Consequences of Organizational Knowledge Brokering Capability' *Intellectual Property Research Institute of Australia Working Paper* 11/2007.

[31] A. Caplan and J. Merz, 'Patenting Gene Sequences' (1996) 312 *British Medical Journal* 926.

[32] L. Andrews, 'Genes and Patent Policy: Rethinking Intellectual Property Rights' (2002) 3 *Nature Reviews: Genetics* 803.

[33] G. Matthijs and S. Hodgson, 'The Impact of Patenting on DNA Diagnostic Practice' (2008) 8 *Clinical Medicine* 58.

[34] The second example in this paper is that of Myriad Genetics, a company that is described in detail in B. Williams-Jones 'History of a Gene Patent: Tracing the Development and Application of Commercial BRCA Testing' (2002) 10 *Health Law Journal* 123. The firm's aggressive attempts to protect its intellectual property have led to heated debate in Canada and Europe, and it features prominently in many research articles.

[35] A. Bar-Shalom and R. Cook-Deegan 'Patents and Innovation in Cancer Therapeutics: Lessons from CellPro' (2002) 80 *The Milbank Quarterly* 637.

"Research Use" Exemption in Patent Law

IPRIA has done little work that has focused on the patenting of genetic material. This submission, therefore, cannot provide significant new research that goes to the impact of the patenting of genetic material on the provision and costs of healthcare, the provision of training and accreditation for healthcare professionals and the health and wellbeing of the Australian people. IPRIA has conducted work into the impact of patenting on scientific research generally[36] and, as a result, offers a summary of this work as a more general response to the issue of whether the patenting of genetic material impacts on progress in medical research.

As was stated above, patents confer monopoly rights that exclude others from using the invention protected by the patent. These statutory rights prevent anyone who does not have a licence from the patentee from using the invention – no matter what the purpose of the use. This means that those who wish to use an invention for the purposes of scientific research may be prevented from doing so (unless they seek a licence from the patentee). There is some doubt because it has been suggested that there is, in Australia, a common law research use exemption. This perception is based on the 19th century decision of *Frearson v Loe*, where it was held that

> …no doubt if a man makes things merely by way of bona fide experiment, and not with the intention of selling and making use of the thing so made for the purpose of which a patent has been granted, but with the view to improving upon the invention the subject of the patent, or with the view to seeing whether an improvement can be made or not, that is not an invasion of the exclusive rights granted by the patent.[37]

There has been little judicial discussion of this decision and, therefore, the existence and extent of the exemption remains uncertain. This uncertainty may act as a chilling effect on the use, by researchers, of inventions protected by patents (whether those inventions relate to genetic materials or to any other area of scientific endeavour).[38]

To date, there has been little empirical evidence of the impact patents have on the conduct of research in Australia;[39] the research conducted overseas,[40] however, is sufficient to suggest that the Patents Act should be amended to make provision for a research use provision. We note that the Advisory Council on Intellectual Property (ACIP) has also recommended such a change[41] and that the

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[36] C. Dent, P. Jensen, S. Waller and B. Webster, 'Research Use of Patented Knowledge: A Review', *Organisation for Economic Co-Operation and Development STI Working Paper*, 2006/2.

[37] (1876) 9 ChD 48, 66-67.

[38] The research of Nicol and Nielsen, however suggests that some researchers assume that their work is exempt from the patent infringement provisions: above n 5, 218.

[39] One survey-based study indicated that 68% of company respondents and 50% of research institution respondents had positive views on the impact of patents in research: ibid, 83. One of the problems that was raised with patents was that researchers felt that they could not publish their results in a timely manner because of the need to keep the information secret for the purposes of gaining patent protection: ibid, 126-127.

[40] For a discussion of the overseas research, see Dent et al, above n 35, Ch IV.

[41] Advisory Council on Intellectual Property, *Patents and Experimental Use*, Report, 2005, Recommendation 1.

Federal Government, in 2007, accepted, in principle, that recommendation. The inclusion of an experimental use exception may not alleviate all the concerns of researchers who feel limited by the existence of patents for genetic inventions; it may, nonetheless have a positive impact on research in this area. As we have found no contrary evidence, we agree with the recommendation of ACIP.