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Senate Community Affairs Committee

Inquiry into Gene Patents

Submission by Professor Andrew Christie

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1. SUMMARY

Many of the concerns expressed by stakeholders to this Inquiry about patents for genes, genetic materials and related technologies (herein 'genetic inventions') are valid and significant. A number of previous inquiries have addressed, and a current inquiry is addressing, the issues at the heart of these concerns. Those previous inquiries have identified, and the current inquiry will identify, the changes needed to remedy these concerns. Therefore, the appropriate action for the government is to implement the recommendations of the previous inquiries, and of the current inquiry when completed, as soon as possible.

In particular, the government should:

1. implement the recommendations with respect to amending the *Patents Act 1990* (Cth) provisions on the requirement of usefulness, as contained in the Australian Law Reform Commission's 2004 report on *Gene Patenting and Human Health*;
2. implement the recommendations with respect to amending the *Patents Act 1990* (Cth) provisions on Crown use of patented inventions, as contained in the Advisory Council on Intellectual Property's 2005 report on the review of the *Crown Use Provisions for Patents and Designs*;
3. implement the recommendations with respect to amending the *Patents Act 1990* (Cth) to introduce an express experimental use defence to infringement, as contained in the Advisory Council on Intellectual Property's 2005 report on *Patents and Experimental Use*; and
4. await, consider and, if in agreement, implement the recommendations with respect to amending the *Patents Act 1990* (Cth) provisions on manner of manufacture and other requirements for patentability, that will result from the Advisory Council on Intellectual Property's review of *Patentable Subject Matter.*

2. BACKGROUND

2.1. Experience and Expertise

I make this submission in my individual professional capacity – that is, as an academic and professional lawyer with more than 25 years experience in intellectual property matters, with a particular focus on patents.

I am internationally recognised as having expertise on patent law matters. I hold the Davies Collison Cave Chair of Intellectual Property in the Melbourne Law School at the University of Melbourne, where I have worked since 1993. I have held appointments at law schools at the University of Cambridge, the University of Toronto and Duke University. I have authored more than 100 publications on

intellectual property, with many of those dealing with patents. My academic expertise is complemented by practical experience in patent law. I am admitted to legal practice in Australia and the United Kingdom, and I worked for a number of years in the intellectual property departments of major law firms in Melbourne and London. I was a member of the Law Council of Australia's Intellectual Property Committee for 10 years.

I am an active advisor to international organisations and to the Australian government on intellectual property law and policy. I have been commissioned to undertake a number of studies on intellectual property issues for the World Intellectual Property Organization and the Organisation for Economic Co-operation and Development. I was a member of the Advisory Committee on Genetics, Intellectual Property and Human Health, appointed by the President of the Australian Law Reform Commission (ALRC) to assist the ALRC in with its inquiry into *Gene Patenting and Human Health*. Since 2002 I have been a member of the Advisory Council on Intellectual Property (ACIP), a body appointed by the Minister for Innovation, Industry, Science and Research to advise him on intellectual property policy and administration.

2.2. Specific Interest in this Inquiry

I am currently chairing the ACIP review of *Patentable Subject Matter*. That review has received written submissions from the public, and has undertaken public consultations in four capital cities. A number of the submissions and comments made to the ACIP have expressed concern about the availability of patents for genetic inventions. Those submissions and comments, together with my academic expertise and practical experience, have informed my views on the matters addressed in this submission. In addition, I have reviewed the early submissions to this Inquiry (up to and including submission number 11) and I have taken the views expressed in those early submissions into account in formulating this submission.

2.3. Importance and Relevance of this Inquiry

I commend the Senate for establishing this Inquiry. The issue of patenting genetic inventions is of great economic and social significance to Australia. Many of the issues addressed by the Inquiry's terms of reference, and various related issues, have been the subjects of previous inquiry by bodies in Australia, including in particular the ALRC inquiry into *Gene Patenting and Human Health* (2003-2004), the ACIP review of *Crown Use Provisions for Patents and Designs* (2004-2005), and the ACIP review of *Patents and Experimental Use* (2004-2005).

Unfortunately, the Australian government has failed to act on the recommendations produced by these previous inquiries – with the consequence that a range of stakeholders are rightly concerned about the way in which Australian patent law

currently applies to genetic inventions. It is my hope that this Inquiry will ensure that those actions that should have been taken by the legislature in response to the past inquiries will be taken as soon as possible. Doing so will address the rightful concerns of the stakeholders, and will result in an appropriately balanced patent system as it applies to genetic inventions.

3. MAIN ISSUES

The majority of the concerns that are expressed about patents for genetic inventions fall into one of four categories:

(i) concern with the width of the exclusive rights provided by patents for genetic inventions – i.e. concern that patents are being granted in respect of genes, genetic materials and related technologies where the claims of the patent are too wide;

(ii) concern that patents for genetic inventions restrict access to medical treatment – i.e. concern that patients will not be able to access diagnostic tests or therapies due to the existence of patents for genes, genetic materials and related technologies;

(iii) concern that patents for genetic inventions preclude medical research – i.e. concern that medical researchers will not be able to undertake future research on genes, genetic materials and related technologies due to the existence of patents for genetic inventions; and

(iv) concern that genetic inventions are inherently patentable subject matter – i.e. concern with the very fact that patents can be granted in respect of genes, genetic materials and related technologies.

3.1. Width of Exclusive Rights provided by Gene Patents

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. Australian patent law has two primary mechanisms for ensuring that the claims of a patent are not too wide: (i) usefulness, a requirement of section 18(1)(c) of the *Patents Act 1990* (Cth); and (ii) fair basis, a requirement of section 40(3) of the Act.

Although it is a requirement of patentability that the claimed invention is useful, this requirement is not a direct ground of examination by the Australian Patent Office. The usefulness of an invention is only examined indirectly, as part of the manner of manufacture test in section 18(1)(a) and as part of the requirement of full description in section 40(2)(a). Furthermore, 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.

Two earlier reviews – one by the Intellectual Property and Competition Review Committee in its *Review of Intellectual Property Legislation under the Competition Principles Agreement* (1999-2000), and the other by the ALRC in its inquiry into *Gene Patenting and Human Health* – have recognised that the usefulness requirement in Australian patent law has an especially important role to play in ensuring that the exclusive rights provided by patents for genetic inventions are appropriate in width. Those two reviews made express recommendations to the effect that a US-style utility requirement be adopted in Australian law. The ALRC also made a recommendation that utility be a direct ground of examination by the Australian Patent Office. Unfortunately, none of these recommendations have, as yet, been implemented.

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. This requires, among other things, that the patentee disclose a specific, substantial and credible use for the invention as claimed, and that the Australian Patent Office examine for this requirement. Thus, the appropriate action for the government on this issue is to implement recommendations 6.1, 6.2, 6.3 and 6.4 contained in the ALRC 2004 report on *Gene Patenting and Human Health*.

3.2. Restriction on Access to Genetic Inventions

Stakeholders have expressed concern that, because a patent for a invention provides the patentee with the exclusive right to exploit the invention, in some situations a patent for a genetic invention has been, or will be, used to preclude wide public access to that invention. A commonly provided example is Myriad Genetics' patents in relation to the BRCA1 and BRCA2 genes. Stakeholders are concerned that the licensing strategy adopted by Myriad Genetics' exclusive licensee of the Australian patents has made diagnostic testing for mutations to these genes unaffordable to many, and hence has unduly restricted patient access to this important innovation.

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. It must be noted, in this regard, 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. These provisions entitle an authority of the Commonwealth or of a State to use a patented invention without the consent of the patentee if such use is necessary for the proper provision of services of the Commonwealth or of a State. Where such use occurs, the Crown must financially compensate the patentee.

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.

The appropriate response to the concern about wide patient access to genetic diagnostic tests is to adopt a pricing mechanism that ensures patients in need can receive the necessary testing irrespective of their financial capacity to pay for it. This response may, in certain situations, require utilisation of the Crown use provisions of the patent legislation. Any such utilisation should be transparent and accountable. Thus, the appropriate action for the government on this issue is to implement the recommendations contained in the ACIP 2005 report on the review of the *Crown Use Provisions for Patents and Designs*.

3.3. Preclusion of Follow-on Genetic Research

The economic objective of the patent system is to increase innovation by providing incentives to inventors to invent and disclose their inventions to the public. The incentives provided by a patent are the monopoly rights to exploit an invention, for a time-limited period. As the Cutler 2008 *Review of the National Innovation System* recognises, however, a patent is not just a stimulus to innovation – it is also a retardant of innovation. This is because the monopoly rights of a patent for an invention may impede follow-on innovators from making use of that invention. To optimise the patent system's contribution to innovation, therefore, it is necessary to have a patent law that both maximise the incentives to invention and minimise the impediments to follow-on innovation.

Certain stakeholders have expressed the concern that patents for genetic inventions preclude follow-on innovation in areas related to the invention, because researchers are not able to undertake research without infringing the patent. These stakeholders point to the fact that the Australian patent legislation does not contain an express exemption of research activities from infringement, and to the fact that it is

debateable whether such an exemption will be implied by the common law. Because of this concern, in 2003 the Parliamentary Secretary to the Minister for Industry, Tourism and Resources requested the ACIP to undertake a review of *Patents and Experimental Use*. As a result of this review, the ACIP in 2005 recommended that the Patents Act be amended to include an express provision that the rights of a patentee are not infringed by acts done for experimental purposes relating to the subject matter of the invention. (A similar conclusion had been reached by the ALRC in its 2004 inquiry on *Gene Patenting and Human Health*.) Although the government has accepted in principle the ACIP recommendation, the recommendation has not, as yet, been implemented.

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. Thus, the appropriate action for the government on this issue is to implement the recommendations contained in the ACIP 2005 report on *Patents and Experimental Use*.

3.4. Inherent Patentability of Genetic Inventions

Those who hold the view that patents should never be available for genetic inventions appear to do so either for economic or for social (non-economic) reasons. Where the reason is economic, the concern is generally that these patents are 'too wide' (and hence unduly anti-competitive), restrict patient access and/or preclude follow-on research. Those concerns were considered above.

Where the reason for the view that genetic inventions should not be patentable is social, the concern is generally couched in moral or ethical terms – e.g. 'it is contrary to our humanity', or 'no-one should own nature'. It is no counter to this view to assert that the primary justification for the patent system is economic and therefore that genetic inventions should, in principle, be as capable of protection by a patent as any other invention. The patent system, like any other form of legal regulation, must take into account social (non-economic) considerations, even if its primary justification is economic.

The key question is *how* should the patent system take account of social (non-economic) considerations. The ALRC recognised that the main mechanism by which the patent system does this is through the test for inherent patentability – which, in Australia, is referred to as the 'manner of manufacture' test. The ALRC, after careful consideration, concluded that genetic inventions should not be excluded from patentability, but that the manner of manufacture test should be reviewed because aspects of this test are ambiguous and obscure and the test may warrant reform. The Minister for Innovation, Industry, Science and Research has requested the ACIP to conduct such a review, and such a review is in progress. As the ACIP Issues Paper of

2008 demonstrates, an important aspect of this review is whether the manner of manufacture test is achieving the required social (non-economic) objectives.

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

4. CONCLUSION

Many of the concerns expressed by stakeholders to this Inquiry about patents for genetic inventions are valid and significant. What is important for this Committee to recognise is that a number of other inquiries have addressed, or are addressing, the issues at the heart of these concerns. Furthermore, those other inquiries have identified, or will identify, the changes needed to remedy these concerns. Thus, the appropriate action for the government is to implement the recommendations of those inquiries as soon as possible.