18 March 2009

The Secretary
Senate Community Affairs Committee
PO Box 6100
Parliament House
Canberra ACT 2600

BY EMAIL

Dear Sir

RE: SENATE COMMUNITY AFFAIRS COMMITTEE: INQUIRY INTO GENE PATENTS

I welcome this opportunity to provide a response to the Senate inquiry into Gene Patents. I respond in particular to part (a) of the Terms of Reference.

This response is based on research conducted in the United Kingdom. I am currently completing my doctorate of philosophy in law at the University of Oxford. The project uses socio-legal methodology to consider the impact of human gene patents on the process of developing genetic diagnostic tests for use in the National Health Service (NHS). Specifically, I have examined how existing patents, held by parties other than the NHS, are relevant in the translation of basic scientific research into genetic tests for rare genetic disorders. The focus of the work has been on genetic tests for single gene disorders as these are most widely offered in clinical practice at present.

In the United Kingdom, the majority of molecular genetic testing is conducted by the NHS in Regional Genetics Centres.[1] These centres tend to develop their own tests for most individual diseases (so called 'home-brew' tests) as opposed to buying commercially produced kits, and some samples are sent away to specialist diagnostic laboratories (in the UK or overseas) and other samples are sent to research laboratories. Each of the tests carried out will examine a patient's genetic sequence for disease causing mutations.

As discussed in academic and policy literature,[2] an examination of the law alone does suggest that human gene patents could be problematic for genetic diagnostic testing. The most significant legal issues which have emerged from my research include the

---

[1] M Kroese and others, 'How can genetic tests be evaluated for clinical use? Experience of the UK Genetic Testing Network' (2007) 15 European Journal of Human Genetics 917.

[2] See for example S Soini, S Ayme and G Matthijs, 'Patenting and licensing in genetic testing: ethical, legal, and social issues' (2008) 16 (S1) Eur J Hum Genet S10; Nuffield Council on Bioethics, *The Ethics of Patenting DNA: A Discussion Paper* (Nuffield Council on Bioethics, London 2002); Organisation for Economic Co-operation and Development, *Genetic Inventions, Intellectual Property Rights & Licensing Practices* (Organisation for Economic Co-operation and Development Publications 2002); MA Heller and RS Eisenberg, 'Can Patents Deter Innovation? The Anticommons in Biomedical Research' (1998) 280 Science 698.

difficulties of due diligence, and the associated potential problems of a crowded patent landscape. Due diligence can be complex, and costly in terms of both time and money. Those involved in developing genetic tests do not have the necessary training or the time to conduct this, and there are rarely the funds or the inclination to employ a professional to carry out this process. Moreover, for a single genetic disease, there may be many possible causative mutations in many difference genes. This can result in multiple potential patents which may be infringed in order to reach a diagnosis for a single patient. As a result, there could be many different licences which would need to be negotiated, and many different royalties, which in total could cause a diagnostic test to be very expensive.[3]

Whilst these concerns exist in the abstract, it is important to consider how they play out in practice. Empirical research in other jurisdictions has indicated that providers may refuse to offer genetic tests because of patents.[4] In order to examine the law-in-practice in this field in the UK, I conducted an empirical study of those developing genetic diagnostic tests in the public sector in the UK to investigate the potential issues. The results of this empirical work suggest that in actual fact gene patents have minimal impact on those in the public sector who develop and deliver genetic diagnostic tests to patients.[5] This is not however because patents are appropriately managed. It is instead because patents are essentially ignored by those who develop genetic tests in the public sector, and patent holders do not tend to take any enforcement action.

It may be that the situation in the UK is particular to the circumstances existing in that jurisdiction. The central role and perceived altruistic nature of the NHS in UK public health service provision are factors which influence those who are motivated to 'ignore' patents on human genes. Other important empirical research likely to be relevant to the current inquiry has been conducted in Australia[6] and the United States.[7]

Even though this empirical research showed there is minimal impact of gene patents on genetic testing development and provision in the public sector in the UK, this does

---

[3] The specific difficulties experienced by a centre developing a molecular genetic test are discussed in J Kaye, N Hawkins and J Taylor, 'Patents and translational research in genomics' (2007) 25 Nature Biotechnology 739.

[4] See for example JF Merz and others, 'Diagnostic testing fails the test' (2002) 415 Nature 577.

[5] This work is not yet published. It will be submitted as part of the Doctorate in Philosophy in Law at the University of Oxford in 2009.

[6] D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry - Occasional Paper No. 6* (Centre for Law and Genetics, Faculty of Law, University of Tasmania, Hobart 2003).

[7] JF Merz and others, 'Diagnostic testing fails the test' (2002) 415 Nature 577. The US Secretary's Advisory Committee on Genetics Health and Society released a Public Consultation Draft Report on Gene Patents and Licensing Practices and Their Impact on Patient Access to Genetic Tests (available at http://oba.od.nih.gov/oba/SACGHS/SACGHS%20Patents%20Consultation%20Draft%203%209%202009.pdf) for public comment before 15 May 2009.

not mean that the situation is unproblematic, or that action should not be taken to change the law. The situation is not stable; should patent holders decide to take action to sue, then those developing and offering genetic tests could be exposed to liability. This tension should arguably be resolved, either through a change to practice (by programmes of due diligence and licensing for example) or by a change to the law. However, any changes to the law in Australia should only be made after full consideration of the Australian circumstances.

Consideration should also be made of the impact of any changes to the law on future developments in genomics. Current genetic diagnostic tests tend to be for rare diseases for which there is a relatively small patient population, and for which there will be a relatively small number of genes which will be tested. Should current genomics research result in clinically useful predictive tests for common complex disorders such as heart disease, then it seems likely that there will be a multitude of genes to be tested, as well as a much broader cross section of the population who might be consuming the tests. These tests are much more likely to be developed by commercial entities than provided as 'home-brew' tests by public sector laboratories.

If I can be of any further assistance, please do not hesitate to contact me.

Yours faithfully

Naomi Hawkins BSc, LLB (Hons) UQ; Grad Dip L Prac; BCL (Oxon)

The Ethox Centre, Department of Public Health
University of Oxford
Old Road Campus
Headington
Oxford OX3 7LF

Email: naomi.hawkins@law.ox.ac.uk