Medical Technology
Association of Australia

Senate Standing Committee on Community Affairs

Inquiry into Gene Patents

Submission by
Medical Technology Association of Australia

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1. Introduction

The Medical Technology Association of Australia (MTAA) represents the manufacturers, exporters, importers and distributors of medical technology products in Australia. Medical technologies are products used in the diagnosis, prevention, treatment and management of disease and disability. They include diagnostic tests for general pathology such as cholesterol and glucose, infectious disease tests such as HIV and Hepatitis along with more recent specialised testing such as markers for HER-2 antibodies for breast cancer and the K-RAS gene for bowel cancer.

The medical technology industry in Australia has an annual turnover of $6.0 billion (2007/2008), earns an export income of $1.3 billion (2007/2008) and employs in excess of 17,500 people. Of the member companies of MTAA, approximately 20% supply diagnostic testing assays to public and private pathology practices, research laboratories and universities.

2. Background – diagnostic testing

As disease-related genes are discovered, an increasing number of tests for genetic predisposition to diseases are being developed[1]. Disease gene patents generally claim "a gene sequence, one or more mutations which are found to be associated with disease or risk of disease…all uses of the chemical sequences… [and] also all methods of diagnosis of disease by identifying in a specific patient the disclosed genetic alleles, mutations, or polymorphisms"[2].

The recently released Australian Genetic Testing Survey 2006[3] found that the number of molecular genetic tests performed under Medicare rose by 90% from 2006 to 2007, against a background of 7% increase for all pathology tests. However the number of genetic tests remains small – just over 0.07% of the 60 million pathology tests covered by Medicare in 2006. In addition to those reimbursed by Medicare, there were 437 types of molecular tests that were not available under Medicare in 2006 which had to be paid for privately by the patient or provided free of charge through a state-run or other health service. Of these more than half (55%) were offered by only one laboratory.

The Survey indicates that while the number of tests is growing they remain a very small percentage of the overall diagnostic landscape.

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[1] Organisation for Economic Co-operation and Development (OECD), (2002) "Genetic Inventions, Intellectual Property Rights and Licensing Practices: evidence and policies", page 16

[2] Merz, JF, AG Kriss, DGB Leonard, and MK Cho, (2002) "Diagnostic Testing Fails the Test", *Nature*, 415, 7 February, pp 577-579 cited in OECD Report, supra page 16

[3] Suthers, G (2008) The Australian Genetic Testing Survey for the Royal College of Pathologists of Australasia and the Human Genetics Society of Australasia

3. Discussion of Terms of Reference

The issues raised by the Terms of Reference have been comprehensively canvassed by the Australian Law Reform Commission in its report, *Genes and Ingenuity: Gene Patenting and Human Health*[4]. Unfortunately the report has not yet been responded to by the Australian Government which leaves the public policy position in Australia unclear.

In this submission MTAA does not address the issue of patentability of genes within the intellectual property law framework. MTAA accepts that genes have been treated as patentable subject matter by the intellectual property agencies of Australia and trading partners for at least the past 25 years. MTAA's focus is to ensure that there are appropriate mechanisms in place for genetic diagnostic testing to be undertaken to assist patients and to deliver cost benefits to the health care system.

Jensen and Murray[5] in a 2004 survey identified 4,270 US patents that refer to at least one human gene in the patent claims and concluded that one-fifth of known human genes are referred to in patent claims. Notwithstanding these numbers, the argument that there is a problem with access to human gene patents, together with the negative impact of patent thickets (which present a need for multiple patent rights from multiple licensors), appears to have been overstated. Recent research indicates that there is little empirical evidence that the patents have had a substantial negative impact on research or the availability of diagnostic testing[6].

There has been a marked decrease in the filing and issuance of DNA patents in the US since 2001[7]. Similarly, the number of gene patent litigation cases pending at any one point in time has reduced rather than increased (the number peaked in 1997 and 1998 in the US[8]).

To test whether gene patents have had a limiting impact on access to genetic diagnostic tests or the capacity to undertake further research, Holman[9] studied all instances in which a human gene patent was asserted in an infringement lawsuit. He identified 31 human gene patent litigations dating back to 1987. Only seven of the 31 lawsuits involved patents identified by Murray and Jensen. Only five of the cases involved diagnostics, all of which were settled before any substantive decision.

Among the recently-released preliminary findings of the Secretary's Advisory Committee on Genetics, Health and Society[10] (SACGHS) in the United States

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[4] Australian Law Reform Commission (2004), *Report 99 Genes and Ingenuity: Gene Patenting and Human Health*

[5] Jensen, K and F Murray (2005) "Intellectual property landscape of the human genome", *Science* 310:329-240

[6] Holman, CM (2008) "Trends in Human Gene Patent Litigation" Vol 322 *Science* page 198

[7] Holman op cit page 198

[8] Holman op cit page 199

[9] Holman, CM (2007), "Human Gene Patent Litigation", Vol 76:2 *UMKC Law Review* 295

[10] Secretary's Advisory Committee on Genetics, Health and Society (2009), "Public Consultation Draft Report on Gene Patents and Licensing Practices and their Impact on Patient Access to Genetic Tests"

are that it is the use and enforcement of intellectual property rights, and not so much whether a gene is patented or not, that could potentially create barriers to clinical use of a gene. The Committee found that there is no clear relationship between patents, license exclusivity, and the price of a genetic diagnostic test. Various factors other than patenting and licensing affect the price of genetic tests, including ordinary market forces, such as demand and market size[11].

SACGHS commissioned the Centre for Genome Ethics, Law & Policy within Duke University's Institute for Genomic Sciences & Policy to conduct case studies of 10 clinical conditions. The case studies provided examples of genes that have been patented and the way in which they are licensed. Each case involved an inherited disorder or cluster of disorders associated with a clinical syndrome for which genetic tests are available[12]. The Duke team was unable to access the licensing arrangements for each of the patents under examination (presumably for confidentiality reasons).

The Duke team examined 'access to genetic testing'[13]. The parameters for what constitutes 'access' include:

- Whether a diagnostic test is available and whether improvements are also available
- Whether the cost of the test is reasonable to both provider and patient
- Quality of the testing services
- How quickly the test is available following discovery of the connection between a particular genotype and phenotype and how rapidly the test evolves and improves with use and future discoveries
- Existence of mechanisms for payment of the test
- Number of distinct test providers that are available.

Evidence from the case studies indicates that clinical access can be affected by the use and enforcement of intellectual property rights. Patent protection of a genetic test may limit clinical access to a test, but limited clinical access to a test does not always result in limited patient access to a test[14].

A 1999 survey of the licensing practices of holders of patents that cover the diagnosis of genetic disorders showed that all the patents were being licensed exclusively which gave rise to a concern about monopolization of genetic testing services[15]. The fear was that the patents were being offered at a cost that prohibited provision of genetic testing services. However SACGHS found[16] that the evidence from its commissioned case studies did not reveal widespread overpricing for genetic diagnostic tests that were patented and

[11] SACGHS Draft Report op cit page 102
[12] SACGHS supra page 14
[13] SACGHS supra page 70
[14] SACGHS supra page 109
[15] Schissel, A, JF Merz and MK Cho (1999), "Survey Confirms Fears about Licensing of Genetic Tests" *Nature*, 402 11 November, page 118 cited in OECD Report supra page 16
[16] SACGHS supra page 108

exclusively licensed relative to tests that were either unpatented or non-exclusively licensed.

SACGHS also states[17] that to date patents covering genetic tests and related licensing practices do not appear to be causing widespread or lasting barriers to patient or clinical access. Where initially patient access may have been impeded, for the most part cases have been resolved. Issues have generally arisen not from the patent but from the way in which it was licensed.

In the Australian context access may be impeded where there is no payment for the test through Medicare. As the recent Genetic Testing Survey shows, a significant number of tests are provided outside the scope of Medicare coverage. There is less certainty about the quality of the test where the test is not Medicare funded because it is currently not subject to significant regulatory oversight in Australia, and laboratories using these tests have not necessarily been accredited by the National Association of Testing Authorities (NATA). This lack of certainty about genetic testing quality should change with the arrival of regulatory oversight of genetic testing through the *in vitro* diagnostic (IVD) regulatory framework to be administered by the Therapeutic Goods Administration, anticipated for late 2009. Human genetic diagnostic tests will be regulated as Class 3 IVD medical devices if there is a patient outcome connected with the test. This will apply to both in-house and commercial assays, with in-house assays having the requirement that the laboratories that develop them must be accredited by NATA. The same standards will therefore apply whether or not the test is reimbursed by Medicare.

4. Conclusion

With the growth in genomics and the drive towards personalised medicine, the use of patented genes to develop diagnostic tests will continue to grow. Pharmacogenomics has the potential to deliver considerable savings to the health care system through targeted use of expensive pharmaceuticals, as well as more directed patient care. MTAA supports the facilitation of an environment where gene patents are accessible on a commercially reasonable basis to enable the development of relevant diagnostic tests.

MTAA also supports assurance that a system under which reimbursement is provided is adequate to encourage further development of appropriate genetic testing. To the extent that many tests are currently provided outside the Medicare reimbursement framework, we need to ensure affordable and equitable patient access. We also need to ensure appropriate quality of testing. These are the more compelling issues to be considered when looking at the health and wellbeing of the Australian people.

[17] Supra page 109