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Compulsory Licensing of Patents
Productivity Commission
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NHMRC Submission to the Productivity Commission's Inquiry into the Compulsory Licensing of Patents

The National Health and Medical Research Council (NHMRC) welcomes the opportunity to provide a submission to the Productivity Commission's Inquiry into the Compulsory Licensing of Patents (the Inquiry). NHMRC is Australia's principal agency for funding health and medical research; for developing health advice for the Australian community, health professionals and governments; and for providing advice on ethical behaviour in health care and in the conduct of health and medical research. As the Australian Government's key agency for managing investment in health and medical research, NHMRC is focused on encouraging excellence in health and medical research to improve the health of all Australians.

While gene patents comprise only a small proportion of patents that are issued, they are contentious and raise community concerns over their potential to limit access to affordable health care and ethical issues about commercialising the human body and its genetic material. While NHMRC understands these concerns, on balance, NHMRC's view is that the patent system in its current form has served Australia well and is important for stimulating and protecting research and innovation.

Licensing arrangements

Most concerns about licensing arrangements relate to the potential for exclusive licensing to significantly increase the cost of genetic testing compared to broad licensing. Other

concerns relate to the availability and quality of testing, and the inability to obtain a second opinion in the case of a single provider[1,2].

As noted in the Issues Paper, community concerns in regard to gene patenting and licensing in Australia and the US have focused on the patents for the two breast cancer susceptibility genes, BRCA1 and BRCA2, which are owned by the United States based company Myriad Genetics Incorporated. Genetic Technologies Limited (GTG) has exclusive licensing rights for these two patents in Australia and in 2008 GTG announced that it would enforce these rights, a decision which the company subsequently retracted. The BRCA1 patent is currently the subject of a Supreme Court case in Australia which is yet to be decided.

While there are only limited Australia data comparing the costs of genetic testing based on broad versus exclusive licensing, several US studies have found that there is "little evidence" to support the view that exclusive licensing leads to more expensive genetic testing than broad licensing[1]. However, what is evident is the importance of patient and broader community engagement in developing license agreements, because without it, mistrust, controversy and litigation are more common[3].

In the US, the National Institutes of Health (NIH) guidelines on intellectual property encourage, but do not mandate, nonexclusive licensing of genetic tests. NIH has taken this approach because of the potential for exclusive licensing to limit access to tests derived from publicly funded research. In Australia the National Principles of Intellectual Property Management for Publicly Funded Research[4] (the Principles) acknowledge that there is no 'single best' approach for commercialising intellectual property and that it should be determined on a case-by-case basis. The Principles are over ten years old and are currently being reviewed.

Non-voluntary access to patents - Compulsory licensing provisions in the Patents Act

NHMRC's view that the compulsory licensing provisions are an important and necessary component of the *Patents Act 1990*, especially when there is a public health imperative and an existing key patent is not being utilised. Nonetheless, Australia's compulsory licensing provisions have received very little use and in NHMRC's opinion there are two issues that have contributed to this. The first is that the circumstances under which the compulsory licensing provisions can be used are ambiguous and the second is that the broad nature of many patents means that the compulsory licensing provisions, if invoked, could have implications for downstream research and development.

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[1] Evans JP (2010) Putting patients before patents. *Genetics in Medicine* **12** (Supplement): S3-S4.

[2] Secretary's Advisory Committee on Genetics, Health and Society (2010) Gene patents and licensing practices and their impact on patient access to genetic tests. *US Department of Health and Human Services* (http://oba.od.nih.gov/oba/sacghs/reports/sacghs_patents_report_2010.pdf)

[3] Colaianni A (2010) Impact of gene patents and licensing practices on access to genetic testing and carrier screening for Tay-Sachs and Canavan disease. *Genetics in Medicine* **12** (Supplement): S5-S14.

[4] The National Principles of Intellectual Property Management for Publicly Funded Research were developed by a Working Party comprising: the Australia Research Council (ARC), the Australian Tertiary Institutions Commercial Companies Association (ATICCA), the Australian Vice-Chancellors' Committee (AVCC), the then Department of Education, Science and Training (DEST), the then Department of Industry, Science and Resources (DISR), IP Australia and the National Health and Medical Research Council (NHMRC).

While a number of parties have claimed the current provisions act as a deterrent to restrictive or non-licensing practices by bringing parties together to negotiate, others[5] contend that the effect is minimal given the low utilisation of the compulsory licensing provisions in Australia and the differences in bargaining power that are common between the patent holder and the licensee. Irrespective of these different points of view, in NHMRC's opinion the licensing provisions could be significantly improved by amending the grounds for invoking compulsory licensing so they are more comprehensive and less ambiguous.

NHMRC agrees with the recommendation by the Australian Law Reform Commission[6] and others that the best way to achieve this would be through the provision of guidelines on what constitutes anti-competitive behaviour in relation to the use of intellectual property. While NHMRC is aware that the Australian Competition and Consumer Commission (ACCC) has agreed to develop guidance following of amendment to s 51(3) of the *Competition and Consumer Act 2010*, which is yet to occur, NHMRC suggests that the interim guidance could be developed now.

NHMRC also agrees that better guidance should be developed on the criteria used by the Federal Court to determine the terms of compulsory licensing, including pricing. While NHMRC suggests that this be done on an industry by industry basis, NHMRC also recognises the inherent difficulties given the diverse range of patents and license arrangements that could be under consideration. In particular, NHMRC would like to see criteria to address the importance of a particular patent to further research, for example access to an upstream genetic invention to develop a downstream diagnostic test.

NHMRC supports the need to raise awareness of the compulsory licensing provisions amongst sectors that are likely to be affected by their use, especially the Federal Government, State and Territory Governments and the research sector (including universities, research institutes and the CSIRO). Such awareness raising would be best done by IP Australia.

'Raising the Bar' reforms - Research exemption

NHMRC supported the Intellectual Property Laws Amendment (Raising the Bar) Bill to the Patents Act, which passed into law on 15 April 2012. In particular, the introduction of free access to patented inventions for research (known as a "research exemption") provides a level of certainty to health and medical research in Australia.

The medical research pipeline is expensive and not all health and medical research leads to a patentable (commercial) outcome or an outcome that improves health (dead-end research). The recent shelving of the drug Bapineuzumab to treat Alzheimer's disease after it failed in two late-stage clinical trials is one such example. The two international

[5] Including the Centre for Law and Genetics

[6] Genes and Ingenuity: Gene patenting and human health (2004), Australian Law Reform Commission (ALRC) Report 99.

pharmaceutical companies involved spent hundreds of millions of dollars US to develop Bapineuzumab prior to shelving.

While there is a tendency from some sectors to downplay the significance of patents to the economy, it is important not to underestimate the value of a single large success. For example, sales of the vaccine Gardasil which provides protection against the human papillomavirus (HPV) peaked at US $1.5 billion for the year ending December 2007[7]. Gardasil is manufactured by the CSL Group and its inventors, Dr Ian Frazer and the late Dr Jian Zhou, filed a provisional Australian patent application on their research into the vaccine in 1991.

Future developments

NHMRC considers it relevant to note that the focus of attention in Australia to date has been on affordable access to single-gene tests (e.g. BRCA1 and BRCA2). It is now evident that many diseases and conditions require multiple gene expression analysis and that these are starting to impact on health care (e.g. microarray analysis of cancer tissue). As the costs of whole genome sequencing decrease rapidly, the goal of the "$1,000 whole genome sequence" will likely be realised in the near future[8]. This will allow patients to be assessed for a range of conditions instead of conducting expensive tests for each condition separately and will lay the groundwork for the much publicised era of "personalised medicine".

It is also now evident that complex genetic disorders require a new level of sophistication which is becoming possible through *omics* which describes approaches to characterise the many molecules within a cell, tissue or organism[9]. While *genomics* was the focus of the Human Genome Project, we now appreciate that other *omics*, particularly *transcriptomics* (the study of all RNA transcripts), *metabolomics* (the study of metabolites), *proteomics* (the study of proteins), and *epigenomics* (the epigenetic profile), are all important In understanding and treating complex diseases.

As they become part of routine use, these rapid advancements in sequencing technology will present new challenges for the patent system. The implications of gene patenting and licensing practices should be considered in an environment that will continue to change rapidly, particularly given the time required to amend legislation that is found to be outdated or problematic.

In addition, new strategies to share access to gene sequence information from publicly funded medical research are emerging, for example, the International Cancer Genome Consortium (ICGC) to which NHMRC is contributing $27.5 M over 5 years. To maximize the public benefit from ICGC member research, all consortium participants have agreed to make their data publicly available and not to file any patent applications or make other intellectual property claims on primary data from ICGC projects. Similar approaches have

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[7] http://www.ipaustralia.gov.au/get-the-right-ip/patents/patent-casestudies/power-of-patents/?doc=cervical-cancer&view=Detail

[8] However, it should be noted that this does not include the cost of analysing the data generated.

[9] Trent RJ (2012) Molecular Medicine: Genomics to personalized healthcare 4th ed, *Elsevier - Academic Press*

been adopted by other international consortia, including ENCODE[10] and the 1000 Genomes Project[11].

NHMRC has joined other international health research funding bodies, such as NIH and the Wellcome Trust, in requiring that publications and data from funded research, be placed in public repositories[12]. NHMRC remains committed to supporting Australia's scientific culture and driving innovation by funding the best and most relevant research. Genomics and Frontier Technologies is a current Strategic Plan (2009-2012) priority for NHMRC and in 2011 NHMRC committed over $175 million for research on this topic.

Through the expertise of its Human Genetics Advisory Committee (HGAC), NHMRC is able to provide advice on high-level technical and strategic issues in human genetics, and on the social, ethical and legal implications of human genetics, genomics and related technologies. Details of HGAC's functions and membership are provided at Attachment A for your information.

In summary, research into the human genome is already benefitting health care and health outcomes and the potential for future gains is immense. A balance between access to equitable, affordable, appropriate and high quality healthcare, and the need to support, maintain and nurture biomedical research and innovation is necessary. NHMRC's view is that while the compulsory licensing provisions are an important component of the Patents Act, amendments are needed to ensure that the grounds for invoking compulsory licensing are more comprehensive and less ambiguous, and hence are more likely to be utilised.

NHMRC commends the establishment of the Inquiry and trusts that this submission will assist the Commission in its work.

Yours sincerely

Professor Warwick Anderson AM
Chief Executive Officer

22 October 2012

[10] http://www.genome.gov/10005107
[11] http://www.1000genomes.org/
[12] https://www.nhmrc.gov.au/_files_nhmrc/file/grants/apply/projects/project_grants_funding_rules_2012.pdf

Attachment A

Functions and Membership of HGAC's Human Genetics Advisory Committee

Functions:

(a) Advise the CEO of the NHMRC, through Council, on current and emerging issues in human genetics and related technologies, particularly the expected impacts on human health and healthcare; and

(b) Advise the CEO, through Council, on the ethical, legal and social implications arising from developments in human genetics and related technologies; and

(c) Such other functions as the Minister from time to time determines in writing after consulting the CEO; and

(d) Any other functions conferred on the Committee by the NHMRC Act 1992, the regulations or any other law.

Membership:

Professor Robyn Ward (Chair)
Professor Andrew Biankin
Professor Jim Bishop
Professor Ngiare Brown
Professor Leslie Burnett
Professor John Christodoulou AM
Associate Professor Clara Gaff
Professor Christopher Goodnow
Professor David Mackey
Ms Mary Murnane PSM
Mrs Lesley Murphy
Mrs Dianne Petrie OAM
Professor Andrew Sinclair
Dr Vanessa Tyrrell
Professor Emma Whitelaw
Professor Ingrid Winship
Professor Margaret Otlowski