NSW Government submission

Inquiry into Gene Patents
Senate Community Affairs Committee

Summary of NSW Government position

The NSW Government provides this submission with a view to balancing interests related to commercialisation and investment, research, and development, and health outcomes. The submission's recommendations are based on a widely held view that preservation of intellectual property protection for downstream applications will inhibit very few, if any, appropriate commercialisation opportunities in the field whilst not giving rise to the ethical and other health care related issues that have arisen because patents have been granted over gene sequences themselves.

Accordingly, the NSW Government is of the view that patents on gene sequences themselves should not be granted. The level of inventiveness in the acquisition of genetic information, most notably sequence data, is increasingly small and the potential negative impact of inappropriately awarded patents increasingly large. The negative impact of such patents is exemplified by those awarded for familial breast cancer genes (namely, BRCA1 & BRCA2).

Other downstream uses of sequence data should remain open to the possibility of patenting provided the use involves a significant level of inventiveness. Examples might include the generation of recombinant proteins for diagnostic or therapeutic use. Excluding such possibilities from patenting would almost certainly reduce the availability of such products as companies would not be prepared to cover the substantial development costs without patent protection.

Similar arguments can be made for genes from all other organisms including viruses. The direct use of sequence data for diagnostic, prognostic and predictive purposes should not be patentable. Inventive downstream uses of non-human sequence data should be potentially patentable for the same reasons given above.

Clarification of what can and cannot be patented should be clearly stated by the Patent Office in order to minimise confusion. Researchers should be given adequate support to help navigate through the patents granted, so that clarification is given if the research is infringing on approved patents. At the same time further training to those who grant patents would be beneficial to ensure appropriate guidelines are adhered to. It will also ensure that patents stand up to the test of utility, inventiveness and novelty.

Special provisions such as "Crown Use" and "Compulsory Licensing" need to be revisited and used when the Government feels it is necessary. Crown use is when the Commonwealth and State Governments may, in exceptional circumstances, require access to inventions and designs prior to the expiry of patent or design term. Compulsory licence is a licence granted pursuant to a court order requiring a patent holder to allow a third party to use a patented product or process, where the patent holder has failed to exploit it, or has exploited it on overly restrictive terms.

Existing law already provides for Crown Use for the purpose of promoting human health, and for compulsory licensing in the public interest, but these provisions are rarely used. Further, academic licensing should be defined within the patent to ease the concerns researchers have over rising cost of licensing fees and timeframes.

It is in the interests of both pharmaceutical industry and society that the patent system should operate to deliver strong protection without stifling or impeding research. Finding low-cost practical solutions for academia to deal with the kinds of issues that arise with gene patents is needed. These may or may not be provided by formal requirements for academic licensing of patents over downstream uses of gene sequence data.

1. Introduction

The NSW Government welcomes the opportunity to contribute to the Senate Community Affairs Committee's inquiry into Gene Patents. We recognise that the commercial exploitation of research findings benefits the economy through employment growth and national wealth generation. At the same time it is an essential step in the development of new diagnostics, treatments and preventative pharmaceuticals for the community.

Gene patents also present challenges to the health and medical research community. Exclusive licensing, licensing fees and infringement of patents have raised concerns within the health and research community. They are apprehensive that gene patents will retard the research process, prevent innovations from taking place and increase the cost of healthcare and research.

In preparing this submission, NSW Government agencies consulted with stakeholders in healthcare and medical research within NSW in regards to the effect gene patents will have on health care, medical research, and the health and wellbeing of the Australian people.

Major reports commissioned by governments and expert bodies all over the world have also been considered in the development of this submission, including:

- Australian Law Reform Commission Report on Gene Patenting and Human Health (2003, 2004).
- Australian Advisory Council on Intellectual Property, Consideration of Patents and Experimental Uses, 2005, and Review of Patentable Subject Matter, 2009.
- 2006 United States Congressional Research Service Report for Congress on Gene Patents: A brief overview of intellectual property issues.
- The 2007 Institute of Medicine Roundtable on Translating Genomic-Based Research for Health.
- OECD study on whether policies such as Myriad's are widespread in companies offering genetic tests and their effects, 2002.
- The 1970 European Patent Convention concluding that biological processes for the production of plant and animal varieties could not be patented but micro-biological processes could be.

- The Nuffield Council on Bioethics report, The Ethics of Patenting DNA, 2002, concludes that proper application of the criteria for inventive step (obviousness) would result in fewer gene patents being granted and recommends limiting patents to uses sufficiently described by the inventor.

- The 2005 European Commission Report to the European Parliament on the Development and Implications of Patent Law in the Field of Biotechnology and Genetic Engineering.

- The 1998 EU Directive on the Legal Protection of Biotechnological Inventions intended to harmonise European law.

- British Department of Trade and Industry report published in May 2004 on Patents for Genetic Sequences.

The NSW Government has communicated with stakeholders within NSW including medical researchers and clinicians and found consistent views across the terms of reference of the inquiry. As a result, the NSW Government makes the following proposals to the Senate Community Affairs Committee inquiry:

- New patents on gene sequences themselves should not be granted.

- Downstream uses of sequence data should remain open to the possibility of patenting.

- Clarification of what can and cannot be patented should be clearly stated by the Patent Office to minimise confusion.

- The Patent Office should provide adequate training of patent officers to ensure that these downstream patents are appropriately narrowly defined.

- There is a need to revisit the issues of Crown Use and Compulsory Licensing to allow the utilisation when necessary.

2. Overview of Gene Patents

The patent system has been designed to create incentives for invention and has unquestionably contributed to significant advances in medical research and the biotechnology and pharmaceutical industries.

Recently, intellectual property rules negotiated under the World Trade Organisation's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) have provided an important underpinning for national patent law regimens, including Australia's. Biological-related patents have been an important consideration as TRIPS has been implemented around the world.

Under TRIPS, Articles 27.2 and 27.3 provide a general exclusion of patentability on diagnostic, therapeutic and surgical methods for the treatment of humans or animals. Therefore whilst it is open for the Australian patent regime to permit the patenting of gene sequences as is currently the case, adopting the proposals in this submission will not *prima facie* be inconsistent with obligations under TRIPS.

In the fields of biotechnology, patents have been granted for novel gene sequences, new functions of known DNA sequences, and for mutations to DNA sequences involved in disease. As the art moves on, fewer novel genes will be found and patents will instead relate to the application of known sequences such as diagnostic testing kits, therapies, and improvements.

Currently genetically engineered plants and animals can be patented as long as the inventor can specify a use for them. Genes and DNA sequences are considered patentable once isolated from their natural environment and are regarded as equivalent to any other chemical compound. In order to patent the gene, the test of at least one specific, substantial and credible utility must be met. In Australia, gene patents are currently authorised under the *Patents Act 1990*.

In regards to patents of DNA sequences, debate has centred on whether these claims can meet the legal requirements for patentability. For example, many consider that the identification of genes and their function are discoveries (and thereby excluded from patentability) and that many claimed DNA sequences result from mere routine use of the technology, particularly computerised techniques, making it more difficult to demonstrate any inventive step by the researcher.

3. Impact of Granting Gene Patents

(i) Provision and costs of healthcare

Gene patenting has been a source of contention between some commercial organisations and healthcare providers in recent years and has come under the media spotlight, for example, the recent case of licence of patents over the breast cancer genes, BRCA1 and BRCA 2.

BRCA 1 & 2 genes are implicated in about 5 to 10% of breast/ovarian cancers. These mutations, if present, increase susceptibility to, or development of, breast and ovarian cancer. The vast majority of genetic tests, including BRCA1 and 2, are not funded by Medicare but are funded through public hospital laboratories.

In NSW, access to most genetic testing, including BRCA1 and 2, is through specialised genetics or cancer genetics clinics in public hospitals. Access is based on clinical need and within clinical priority guidelines and is free of charge to the patient. Testing of BRCA1 and 2 genes is conducted in three public hospital laboratories. It is understood that nationally testing is offered through nine public sector facilities.

Gene patents granted to Myriad (UT, USA) for BRCA1 and BRCA 2, caused considerable worldwide concern over cost and terms of access. Since the company has pursued exclusivity and royalties, research institutes and hospitals are facing litigation for infringement of patent because they carry out tests for mutations of BRCA 1 and 2.

In Australia, the exclusive licence on these patents is held by Genetic Technologies. On 11 July 2008, this company made a commercial decision to enforce the rights granted to it to perform diagnostic testing of BRCA1 and BRCA2 genes in Australia and New Zealand. Under significant public pressure, Genetic Technologies announced in December 2008 its decision to revert immediately to its original approach to allow other laboratories in Australia to freely perform BRCA testing.

Genetic Technologies also holds patent rights to the SCN1A gene used to diagnose Dravet syndrome, a form of epilepsy which causes severe seizures that can cause brain damage. Standard childhood epilepsy medications are ineffective with Dravets and may worsen it. Media coverage on SCN1A testing raised concerns that the gene patents held by Genetic Technologies will stop public hospitals from being able to test this gene in-house and tests will need to be sent overseas or face high fees.

These cases highlight a number of key issues:

(1) A positive result from genetic tests will indicate risk but will not indicate if and when symptoms will develop. It may also impact on a person's ability to obtain life insurance or employment and will have implications for their health decisions. A negative result from genetic testing reduces the risk of said disease but still leaves the person with a residual risk for other related diseases. It is vital that supportive clinical processes, including provision of information and counselling, are provided to assist individuals with informed decision-making.

(2) Whilst laboratory processes are relatively straightforward, the interpretation of the result is complex and is best managed through dialogue between laboratory scientists and specialist clinicians with expertise in the condition. There is concern that the outcome for patients may be less than desirable where tests are ordered outside this specialised process by medical practitioners with insufficient training in the genetics of the condition.
(3) The number of patients requiring or benefiting from genetic testing is rising and will continue to do so. As the vast majority of genetic tests are funded through state public hospital services, there is a significant concern that access to clinically appropriate testing may be reduced if prices exceed the currently available budgets.

(4) These cases show there is evidence that private intellectual property rights over genes are adversely affecting medical care. Many healthcare providers feel that gene patents will decrease further research into patented gene sequences, decrease the integrity of gene tests and increase the cost of conducting gene analysis.

Key Point: Gene patenting has been a source of contention between some commercial organisations and healthcare providers in recent years and raises a serious issue of private benefit versus public good.

(ii) Training and accreditation for healthcare professionals

Aspects of diagnostic testing in the molecular laboratory may be negatively affected by gene patents. The presence of gene patents already has a significant negative impact on the ability to develop and perform tests in public hospital laboratories. It has also been suggested that training and accreditation for healthcare professionals may be negatively impacted as in-house teaching and training will become limited. Removal of such testing from public hospital laboratories could lead to disenfranchisement of public hospital/research laboratories, and loss of trained staff and expertise to the private sector.

Limiting testing to a single laboratory is considered undesirable, as it may create a restricted knowledge base and lacks the benefits of a broader community of scientific collaboration. Currently, public laboratories share knowledge on gene variants on a shared database, leading to improved interpretation of variants and improved diagnosis and clinical management.

It is understood that the Royal College of Pathologists of Australia is making a submission to this inquiry that is anticipated to address issues related to laboratory training and accreditation in the healthcare setting.

Key Point: It is unclear how gene patenting licensing fees will impact on the training and accreditation of health care professionals. This issue needs further attention and investigation.

(iii) Progress in medical research

In the US, large numbers of gene patents have been granted and gene patent ownership is extremely important for the success and viability of biotechnology companies. Gene patenting has stimulated investment in the research, development and commercialisation of new biologics. Inventions that are not patented are much less likely to secure the required funding and might never become available to industry. Denying patent protection to research facilities would greatly undermine the incentive to invest in this field.

The patent system obliges the inventor to publish details of his or her invention, thus allowing academic scientists to study it. However, as soon as a researcher tries to make commercial use of developments based on original patent, the patent holder can stop them or oblige them to pay a license fee. Academic licensing can be made available at a fraction of the cost for commercial use licensing by companies such as Genetic Technologies. However, this is currently not a formal requirement under patent law. Equally, academic licensing may not provide the level of reassurance which researchers are seeking, as licensing fees can easily be raised and licensing timeframes may be short in duration compared to the number of years required for research.

Allowing academic licensing is considered more rather than less likely to enhance medical research activities in Australia and NSW without in any way impinging on private sector investment in medical research and development.

Key Point: Gene patenting has stimulated investment in the research, development and commercialisation of new biologics. Academic licensing needs to be reviewed as current academic licensing may not provide the level of reassurance which researchers are seeking and is currently not a formal requirement under patent law.

4. Measures that would ameliorate any adverse impacts

A report from the University of Sussex funded by a European Commission program ('The Patenting of Human DNA: Global Trends in Public and Private Sector Activity – the PatGen Project') provides some useful insights into current practice and activity in the European Patent Office, the Japanese Patent Office and the United States Patent and Trademark Office. In this regard it is worth noting a conclusion from this report:

> *Debates on the patenting of human DNA need to reflect the disparities between patenting activity in the US and elsewhere. Moreover with the number of patent applications in decline, more stringent examination procedures and the likely restriction of the scope of granted patents by case law, suggest that the negative impact of DNA patenting may turn out to be more limited than some had feared.*

Clarification of what can and cannot be patented should be clearly stated by the Australian Patent Office in order to minimise confusion. Researchers should be given adequate support to help navigate through the patents granted, so that clarification is given if the research is infringing on approved patents. At the same time further training to those who grant patents would be beneficial to ensure appropriate guidelines are adhered to. It will also ensure that patents that stand up to the test of utility, inventiveness and non-obviousness.

Academic licensing should be defined within the patent process to ease the concerns researchers have over the rising cost of licensing fees and timeframes.

Finally, the *Patents Act 1990* should be amended to specifically cover genetic materials. New patents on the gene sequence itself should not be granted, however the inventive downstream innovations that result or flow from such materials should be considered patentable.

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