SOUTH AUSTRALIAN GOVERNMENT SUBMISSION TO THE SENATE INQUIRY INTO GENE PATENTS

1. INTRODUCTION

The South Australian Government welcomes this opportunity to provide comments on the Senate Community Affairs Committee Inquiry into Gene Patents (the Senate Committee).

South Australia is committed to the provision of high quality, timely and responsive services to individuals and families in the community. South Australia creates opportunities for better healthcare and support, and supports research and innovation as integral elements of the healthcare continuum.

The content of this submission is partly drawn from South Australia's submission to the Australian Law Reform Commission's (ALRC) Inquiry Into Gene Patenting and Human Health[1], conducted from 2002–2004.

It is understood that since the completion of the report by the ALRC, there has not been significant progress in the implementation of the inquiry's recommendations.

The Senate Committee Inquiry is seeking information concerning the impact of granting monopolies over human and microbial genes and non-coding sequences, proteins and their derivatives, including those materials in an isolated form.

2. ADDRESSING THE QUESTIONS IN THE TERMS OF REFERENCE FOR THE INQUIRY

2.1 Whether the *Patents Act 1990* should be amended so as to expressly prohibit the grant of patent monopolies over human and microbial genes and non-coding sequences, including those materials in an isolated form

Current regulation of patents

Patents on human genes are regulated like any other patent under the Commonwealth *Patents Act 1990* (the Act). The aim of the Act is to encourage openness in developing new products and processes to foster further development and commercialisation.

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

Section 18 of the Act stipulates the following criteria when assessing patentability:

- manner of manufacture
- novel when compared to the prior art
- involves an innovative step
- is useful; and
- was not secretly used in the patent area before the priority date of that claim by, or on behalf of, or with the authority of, the patentee or nominated person or the patentee's or nominated person's predecessor in title to the invention.

The Act stipulates criteria of invention or innovation (not mere discovery), novelty (as measured against current knowledge at the time) and usefulness for the assessment of patent applications.

Novelty

The legal criteria for the application of 'novelty' causes difficultly when applied to human genes. Many argue that the process of isolating the gene from its natural state through biochemical processes is no longer novel, as it is already a common practice used by medical researchers and students of science and biotechnology. On this basis, patents should not be generated for isolated genes and should not have been granted since the early days of gene research.

Inventions and discoveries

The definition and application of the term 'invention' is also problematic in patent examination and assessment, because it hinges on the definition of 'manner of manufacture', which may be considered obscure and outdated. It provides very vague criteria that fails to provide an accurate test for inventiveness, particularly for technologies such as genetics. The debate as to whether genes are inventions or discoveries rests on this test.

South Australia notes that the Advisory Council on Intellectual Property (ACIP), an independent body appointed by the Australian Government, is currently undertaking a review of the appropriateness and adequacy of the 'manner of manufacture' test as the threshold requirement for patentable subject matter under Australian law.

Under the Act, for an Australian patent claim to have taken an inventive step, the invention being claimed must not be obvious to those skilled persons in the field. The field of gene technology employs highly skilled people of great intellect, and the threshold of obviousness is quite high. Thus when assessing the inventive step for a patent application in the field of gene technology, the threshold to meet this requirement should be high and considered carefully. However, in practice, the converse is often the case, because being able to assess what is obvious depends upon the extent of the

literature in the field. In relatively new fields like gene technology, the breadth of literature may be thin, especially in the more niche fields. There is an increasing tendency not to publish research findings, especially if commercial gain is anticipated. This may give the impression that even small advances in gene technology have taken an inventive step, when in reality they would be obvious to the skilled persons in this field.

Clearly, there is widespread concern about patents on genetic materials and the application of assessment criteria for patenting gene technologies.

Patentability of human genes

While the Act largely meets its aims, it has become obvious that there are some situations, particularly in gene patenting, where the objectives of patenting are not achieved.

Therefore, there is a widely held view that radical changes should be made to the Act to accommodate new ways of dealing with new technologies, such as genes.

This submission does not support a radical overhaul of the Act, because South Australia considers the Act should be generic and capable of application across all forms of technology. Gene patents should not be treated differently from other technologies because other technologies will emerge in the future and the law cannot be changed for every emerging area.

Section 18(2) of the Act provides that human beings and the biological processes for their generation are not patentable inventions. South Australia considers that if the Act is properly applied, genes should not be patentable and should be accessible to humanity.

The difference between patents on human genes and other biotechnology processes are the subject of much debate. These debates have come to the fore due to monopolies that have been claimed on genetic tests and restrictions on the ability of researchers to undertake research on human genes that are under a patent. This would not be a problem for healthcare and medical research if the natural gene itself (the biological material) was not patentable and was available to study for clinical diagnostic testing.

Inclusion of 'Objects' in the *Patents Act 1990*

South Australia's submission to the ALRC recommended that an 'Objects' section be included in the Act, providing principles for the consideration of ethical and social dimensions of gene patenting.

It was proposed that the 'Objects' section include the following principles:

- patents exist to encourage research, innovation and commercialisation

- patents that are granted must be genuine inventions, not mere discoveries

- the criteria of novelty, inventiveness/innovation must be stringently applied, regardless of whether an equivalent patent has already been issued overseas

- the scope of the granted claims must be consistent with the scope of the invention being disclosed to the public.

It is recommended that these principles should govern the issuing of patents, with due regard to ethical and social issues.

An 'Objects' section in the Act which emphasised social and ethical issues, would serve as a guide to patent examiners, prompting them to give due attention to those issues when assessing patent applications.

Separate legislation for addressing social and ethical issues

Another avenue for addressing social and ethical issues in gene patenting is through the introduction of separate legislation. In terms of human embryo research, this has occurred through the Commonwealth's *Research Involving Human Embryos Act 2002,* which regulates what research can be undertaken using human embryos and recognises the social and ethical issues associated with stem cell research. Similarly, separate legislation regulating genetic research could recognise the community concerns about the social and ethical implications of genetic patents for research and diagnostic services by regulating access to human genes.

2.2 Identifying measures that would ameliorate any adverse impacts arising from the granting of patents on human genes

While this submission recognises the importance of maintaining the legal integrity of the Act, South Australia believes that there are opportunities for improvement in patent practice, with a significant role for Intellectual Property (IP) Australia to lead the reform.

Potential role of IP Australia

IP Australia, the Australian Government agency responsible for administering patents, could be commissioned and funded to develop patent examination guidelines, and provide examiners with continuing education in emerging areas of technology, such as genetics.

It would be useful to have a searchable online database comprising patents and published patent applications. Currently, patent data in Australia is difficult to search because the database is not user friendly and is not indexed and classified by gene, investigator or state. Lack of knowledge about

existing patents is an impediment for the public to initiate objections to the grant of a patent at each stage of the patenting process.

With an easily accessible database, users, particularly those with an interest in the ethical and social dimensions of gene patents, would be able to gather information about patent applications at an early stage. This way, they could voice their opposition at various stages of the patent examination process, particularly during the period immediately after the publication of a patent application.

It is also important that IP Australia consults with other government bodies when assessing the impact of gene patenting on healthcare and research. A panel of experts could be established to assist with the assessment of novelty, obviousness and utility of gene applications. Ethics advice could also be provided by the panel. Certainly South Australia, through SA Health, would be interested in contributing ethics advice on gene patents, as it has done through the Australian Health Ministers' Advisory Council (AHMAC) Advisory Group on Human Gene Patents and Genetic Testing.

Government and non-Government bodies

There is also a role for Government and non-Government bodies, such as IP Australia, the Australian Competition and Consumer Commission, the Australian Research Council, the National Health and Medical Research Council and AHMAC in the patent system. It is suggested that the Senate Committee consult these bodies about providing advice and encouraging good practice in patenting. Collaboration between these bodies may also be useful to assist in the assessment of the impact of gene patenting on healthcare and research.

Challenging patents

The Act provides a mechanism to oppose patents, but health systems do not have the resources for legal costs associated with the lodgement of opposition, re-examination and revocation proceedings. It is understood that there is a low incidence of challenges against patents granted in Australia and this is probably attributable to the high costs involved and the complexity of the legal processes. In addition, patent insurance is available to patent holders to cover the patent holder's costs of defending a challenge to a patent's validity. This is a significant disincentive for those who intend to challenge the validity of a patent. This possibly explains why many gene patents continue unopposed, even if these are not novel, do not involve an inventive step, or the 'invention' relates to human beings or biological processes for their generation, which is a recognised exclusion under the Act.

International trends

The discussion above highlights the complexities of the intellectual property system and its inability to confront the realities of the Australian health system. The current intellectual property system is perceived as having many limitations because it tends to foster competition, instead of cooperation. Sharing of information between researchers is slowed down, instead of being encouraged. With an increasing number of technologies protected through intellectual property, there is also a slower advancement in healthcare to the needy populations of the world.

There is now a widespread movement for the introduction of a new era in intellectual property, which "involves not only balancing patents with other ways of encouraging creativity, but also facilitating cooperation and collaboration among creators and among users of innovation".[2] In this new intellectual approach to property proposed by the International Expert Group on Biotechnology Innovation and Intellectual Property, some of the themes suggested include:

- trust and relationship building is essential among all the players involved in intellectual property. Governments, industry, researchers and the public should manage intellectual property together
- industry, Governments and universities should develop new models to mobilise the innovation system to produce better results. Examples include public-private partnerships;
- new ways of communicating between parties with an interest in intellectual property should be introduced
- more attention needs to be paid to understanding how intellectual property contributes to the overall function of the innovation system rather than dealing with it in isolation
- more information should be generated as to whether intellectual property increases level of investment in research and development, and whether it fosters or hinders the dissemination of new products and services
- action should be taken by Governments, patent offices, universities and the research community to improve intellectual property systems.

The Senate Committee is urged to consider the key themes of the proposed 'new intellectual property' when considering measures that would ameliorate adverse impacts of gene patents.

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[2] *Toward a New Era of Intellectual Property: From Confrontation to Negotiation: a Report by the International expert Group On Biotechnology, Innovation and Intellectual Property*, Montreal, Canada, September 2008; http://ssrn.com/abstract

2.3 Impact of the granting of patents in Australia over human and microbial genes and non-coding sequences, proteins, and their derivatives

The provision and costs of healthcare and the health and wellbeing of the Australian people

Gene patents have a significant impact on healthcare. Since patent laws tend to create monopolies for genetic testing, patents therefore have the capacity to considerably raise the cost of genetic testing.

Most genetic testing in South Australia is conducted at near cost within State-funded public health laboratories and patients do not pay directly for the tests. Only a small number of the tests are covered by the Medical Benefits Scheme and it does not provide a generous reimbursement that would allow the absorption of licence fees or royalties charged by patent owners on tests currently conducted or new tests coming on line. Any actions to grant or enforce patents would lead to increased costs and would have to be funded. These costs would be met by:-

- increased State funding to cover royalties and licences, by redirecting funding from some other areas of healthcare
- reduced funding to maintain laboratory costs within budget, by redirecting funds currently used for provision of testing services to families towards licence fees for patent holders; or
- charging families affected by genetic abnormalities an amount to cover the licence fees.

In addition, patent monopolies on genes are likely to become far more complicated as single gene tests are about to make way for panels of gene tests for cancers and other diseases. In such cases, the genes in the panel are likely to be covered by different patent holders, making licence negotiations very complicated.

Australia will face the ultimate challenge when next generation sequencing allows whole genome sequencing to be applied to an individual. In essence, all the human genes will be examined simultaneously. Such a situation is likely to happen within the next five years and certainly within 10 years. This will create an impossible environment for negotiating licences. In such a situation, it seems illogical that a patient will have to pay royalties to have their own genes analysed. Equity issues will be heightened as tests become more expensive, and there may be cases where patients will be required to pay for their own tests. Those who cannot afford to pay will certainly be disadvantaged.

Cytochrome P450 patents

The enforcement of a patent has had an impact on health provision in South Australia. In 2005, a company that claimed to be the exclusive licensee for the genetic tests for cytochrome P450 mutations wrote to the then Institute of Medical and Veterinary Science (now SA Pathology) and advised that they were imposing their exclusive right on their licence. The company sought payment of a one-off fee of UK £20 000 and five per cent of any fees for any tests performed. The likely consequence would have been an increase to the test cost of $1 000 per test (if the $50 000 licence fee was averaged over a five year period), taking the cost per test up to about $1 250 with a further five per cent required to be added. Such a situation was untenable, and as a consequence, the then Institute of Medical and Veterinary Science ceased performing the test.

Similar situations have occurred for other tests. In the United States of America, demands were made on laboratories to pay licence fees for using the haemocromatosis test, making it impractical for smaller laboratories servicing regional centres to continue with testing.

BRCA patents

The Senate Committee would be aware that Genetic Technologies Ltd (GTG) wrote to all testing laboratories in Australia in 2008 seeking to enforce its intellectual property rights with regard to the provision of genetic testing of the BRCA1 and BRCA2 genes for suspected cases of hereditary breast cancer in Australia.

The letter advised laboratories to cease testing and refer the performance of all BRCA1 and BRCA2 testing to GTG. SA Pathology also received a letter, which advised that legal action would be taken unless use of the patent ceased within seven days of the receipt of the letter. GTG withdrew its claim in October 2008, but there is a possibility that it could attempt to impose its monopoly again, as it did in 2002. These actions disrupt the operation of public testing laboratories and their capacity to retain and train staff to provide services in the long term.

If GTG had been successful in imposing its monopoly on the BRCA breast cancer genes, the cost of testing for these genes in South Australia would have risen significantly, meaning additional cost to individuals, families and the South Australian Government. SA Pathology currently charges $1 000 each for the BRCA1 and BRCA2 tests, while it is understood that GTG charges not less than $2 000 for each test.

Other countries have mounted a challenge against Myriad Genetics Inc. In 2007, the Board of Appeal of the European Patent Office rejected Myriad Genetics Inc's assertion that it had sole monopoly of the isolated BRCA genes. The European Patent Office ruled that Myriad's patent on the BRCA1

gene in Europe was not valid because it lacked an inventive step. This led to the revocation in Europe of the patent on the BRCA gene and its applications.

Non-coding patents

Deoxyribonucleic acid (DNA) sequences that code for the active genes that translate into proteins comprise only 1.5 per cent of the total human genome. Until recently, 98.5 per cent of the genome was considered as 'junk' DNA. Recent discoveries have found that a large proportion of this 'junk' DNA plays a direct and major part in the regulation of the protein coding genes resulting in individuality and disease susceptibility. As such, mutation (variation) in this non-coding DNA can have significant impact on human disease.

GTG has claimed ownership of certain non-coding DNA, which has significant impact on researchers' ability to undertake further investigations into the non-coding genes.

If a laboratory uses any non-coding DNA to amplify a coding sequence using polymerase chain reaction (PCR), GTG could claim that the laboratory is in breach of their non-coding patent. The validity of this patent is widely disputed in the scientific community as its claims are considered to be 'prior art'. Nevertheless, USA and Australian patents were granted. GTG has negotiated licence agreements with many commercial companies including Myriad Genetics Inc in the USA, with GTG receiving the BRCA1/2 rights as part of the settlement.

In 2003, GTG served a claim on the Auckland District Health Board (ADHB) demanding a fee of NZD $2 000 000 for a licence for laboratories within the ADHB's jurisdiction to use any non-coding DNA as part of routine genetic testing. The claim was vigorously defended by ADHB, but the issue was settled out of court. If the claim by GTG had been successful, the cost of genetic tests in that area would likely have risen by a significant margin.

<u>Impact on progress in medical research</u>

In South Australia, genetic testing and research are closely linked, with many genetic tests developed in testing laboratories. Monopolies on patents have the potential to limit others' ability to research on a gene, and develop processes to advance genetic testing, diagnosis and therapy. This may slow progress in gene research.

Also if uncertain of the implications of undertaking research on a patented gene, some researchers will refrain from undertaking research on that particular gene, thus impeding progress and innovation in healthcare.

The patenting of a gene, particularly if the patent is broad, could potentially limit opportunities for research and development on that gene. Broad patents claim a wide scope of the technology, covering both current and potential uses, thus making it impossible for health and medical researchers to expand their investigation into a gene. Patent considerations prevent them from being

innovative, which defeats the objectives of research and development. Researchers are concerned that potential patent challenge could impact negatively on their research and their budgets.

Impact on the provision of training and accreditation of healthcare professionals

The patenting of human genes could adversely affect the provision of training and accreditation of healthcare professionals. Patent considerations could potentially discourage public laboratories from exploiting certain genes, thus limiting the development of knowledge on those genes. Training and accreditation could also be jeopardised.

Private sector research is published much less frequently than public sector research. If genetic testing becomes the monopoly of the private sector, there is risk of genetic data residing with this sector, making it difficult for staff within the public health system to access the data for population health studies. Advancement in knowledge would be stifled and training of genetics staff would be hindered.

3. SUMMARY

The aim of patenting has always been to encourage openness in developing new products and processes, to foster further development and commercialisation. It is suggested that this should also apply in relation to gene patenting. It is not the criteria for assessing patentability in the Act that are of concern, but the interpretation and application of those criteria which are the foundation for the many contentious issues arising in this field.

There is appeal for core principles to be substantiated in the law and underpinning practice guidelines specific to gene patents to reinforce the effectiveness of the Act. Thereby, requiring consideration of not just the law, but the ethical and social dimensions of patenting human genes.

IP Australia, along with expert panels and both Government and non-Government agencies, have an opportunity to transform our current intellectual property system into one that exceeds the international standards and sets a new benchmark for patenting; especially in emerging areas such as gene technology. If Australia falters in this area, the financial and non-financial implications will continue to grow in the future inhibiting innovation and critical research.

South Australia believes that the monopolisation of gene patents virtually guarantees the future cessation of medical advancements and progress in healthcare and stifles the training and knowledge of future generations for research. South Australia believes there is a need to balance the need for patents with other ways of encouraging creativity, facilitating cooperation and collaboration among creators and among users of innovation.