**Industry and Investment NSW Response**
**to the Senate Legal and Constitutional Affairs Committee Inquiry into**
**the *Patent Amendment (Human Genes and Biological Materials) Bill 2010***

## Introduction

Industry and Investment NSW (I&I NSW) welcomes the opportunity to contribute a submission to the Senate Legal and Constitutional Affairs Committee in relation to the *Patent Amendment (Human Genes and Biological Materials) Bill 2010* (the Bill).

The NSW Government previously provided a submission to the Senate Community Affairs Committee (SCAC) Inquiry into gene patents that commenced in 2008. That submission was provided after significant consultation with stakeholders in healthcare and medical research within NSW. The major points from the submission included:

- Gene sequences are 'discoveries' and not 'inventions' and therefore should not be patentable.
- Downstream uses of sequence data, that is, the products of genes, should remain open to patenting, provided the use involves a significant level of inventiveness.
- Clarification is required for what can and cannot be patented.
- Training of Patent Officers is required to ensure that patents guidelines are adhered to and that patents will stand up to the test of utility, inventiveness and novelty.
- There is a need to revisit the issues of Crown Use and Compulsory Licensing to allow use in the public interest when necessary.
- Academic licensing should be defined for patents to ease the concerns of researchers over the rising costs of licensing fees.

## Industry and Investment NSW Position

The Bill aims to amend the *Patents Act 1990* to prevent the patenting of human genes and biological materials, their components and derivatives as existing in nature.

The issues that the Bill seeks to address are complex owing to advances in genetics, the complexity of IP protection systems, and the challenge of balancing individual rights and interests with those of governments and private companies. Owing to their social and economic implications these issues are of national and international interest and are subject to major litigation in the United States.

Further to this, the Bill poses significant issues regarding:

1. *Scope and its implications.* The Bill goes beyond excluding gene sequences from being patented and include products of genes that should be open to patentability provided they stand up to the standard test of utility, inventiveness and novelty. The limitations envisaged by the Bill have serious implications for industry, research and the provision of world class healthcare in Australia, as well as other unforeseen implications. There is also a need for a cost benefit analysis to be conducted to determine the impacts of the Bill.
2. *Process.* The Bill pre-empts consideration of the recommendations provided in the reports provided by the Senate Community Affairs Committee (SCAC) and the Advisory Council on Intellectual Property (ACIP) review of patentable subject matter.
3. *International Agreements.* The broad scope of the Bill is inconsistent with international trade agreements (TRIPS) and may raise issues with Australia's international IP and trade obligations.
4. *Legal Developments.* The Bill pre-empts outcomes of internationally significant litigation currently before the US courts regarding patenting of genetic materials.

These matters are addressed in more detail on the following pages.

I&I NSW is cognisant of legislation under development by IP Australia and suggests it as a more appropriate basis for a legislative framework going forward.

## 1. Scope and implications

The Bill goes beyond excluding gene sequences from being patented and aims to exclude all biological material including DNA, RNA, proteins, cells and fluids. This covers a considerable range of products that have uses for human and animal healthcare (medicines, vaccines, diagnostic techniques, biological therapeutics) and in other industries (genetically modified crops, enzymes and bacteria used in waste management) that are currently available or in development.

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.

The breadth of the scope envisaged by the Bill therefore has serious implications for both industry and the provision of world class healthcare in Australia. This breadth also poses other unforeseen implications as science develops.

- *Impact on industry in Australia.*

Patents provide the mechanism by which industry can create a return on investments into research and development. The inability to patent biological materials could impact investment into research and development in multiple sectors including health (diagnostics, medicines), environment, agriculture, manufacturing and waste management. Companies that cannot patent inventions in Australia may move off-shore where they are afforded patent protection. This could result in the loss of jobs, investment and export opportunities as well as the introduction of new products into the Australian market.

- *Impact on translation of research.*

Industry investment into research in Australian Universities, Hospitals and Medical Research Institutes is required to translate results and discoveries into new and innovative products for the market. This is especially true for clinical trials for new medicines and therapeutics. This loss of investment could result in a reduction in the availability of innovative products based on biological products in Australia. This loss of investment could also force many leading researchers to move to other jurisdictions internationally where they can receive industry funding for their research programs – reducing skills and the innovative capacity of Australian institutions.

- *Impact on healthcare standards.*

The inability to patent certain innovations based on biological materials, such as vaccines and biological therapeutics, may provide a disincentive to companies to provide their new products to the Australian market. This may have an impact on the cost and availability of new medicines. The loss of these newly developed products may lead to a reduction of healthcare standards, and in turn, reduce economic productivity and capacity associated with advances in human health.

## 2. Process

The Bill pre-empts consideration of the recommendations provided in the reports provided by the Senate Community Affairs Committee (SCAC) and the Advisory Council on Intellectual Property (ACIP) on patentable subject matter. Both of these reports recommend amendments to the *Patents Act 1990* that provide suitable alternatives to the Bill that require consideration. The amendments recommended in the reports address many of the concerns that the senators' Bill aims to address by improving, patent quality; the suitable operation of the patent system; and by allowing for exemptions for research to continue. It should be noted that the two reports concluded that a specific prohibition on the patenting of human genes and genetic products and any other specific exclusion could not be supported at this time for a number of reasons such as conflicting evidence

on whether such legislation would be effective, and its potential unforeseen effects on other fields of technology.

## 3. International Agreements

The World Trade Organisation Agreement on Trade–Related Aspects of Intellectual Property Rights (TRIPS) agreement captures many important trade related aspects of IP. The Agreement requires signatory countries to adhere to its criteria for patents. Article 27.3 of TRIPS, provides a general exclusion of the patentability of diagnostic, therapeutic and surgical methods for the treatment of humans and animals (27.3(a)); and plants and animals other than micro-organisms and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes (27.3(b)). The TRIPS agreement does not currently include broad exclusions on biological materials, their components, and derivatives as set out in the Bill.

The broad scope of the Bill is inconsistent with international trade agreements and may raise issues with Australia's international IP and trade obligations.

## 4. Legal developments

The Bill pre-empts the outcomes of internationally significant litigation currently before the US courts regarding the patenting of genetic materials. Specifically, the case of Myriad Genetics, who own the patents for the breast cancer genes (BRCA1 and BRCA2), in which a US Distinct court concluded in March 2010 that gene sequences were discoveries and therefore not patentable material. An appeal by Myriad Genetics has been made to the US Federal Court.

Further to this the, US Department of Justice filed an amicus brief in this case in October 2010. The US Department of Justice supported the decision made in the US District court: i.e. that genomic DNA that has merely been isolated from the human body, without any further manipulation, is not patent eligible. Further to this, the brief discussed that altered DNA products (e.g. cDNAs, vectors, recombinant plasmids and chimeric proteins), as well as countless industrial products (such as vaccines and genetically modified crops), created with such molecules, are in every meaningful sense the fruits of human ingenuity and thus qualify as 'human made inventions'. This position mirrors the NSW Government position provided to the SCAC inquiry in 2009.

The results of future ligation regarding gene patents should be monitored closely. Whether the decision is upheld or overturned this will have implications for the international community, and the provision of healthcare in regards to the availability and control of diagnostic methods.

## Alternatives to the Bill

It is understood that IP Australia has drafted legislation that would bring changes to a range of Commonwealth Acts to systematically address issues raised in the Commonwealth review reports and the SCAC report recommendations. This includes simplifying systems; raising the quality of granted patents; allowing free access to patented inventions for research regulatory activities; reducing delays in resolving patent and trademark applications; and improving mechanisms for trade mark and copyright enforcement.

The IP Australia draft legislation provides a sound approach to addressing the concerns that prompted the Bill, but avoids many of the problems raised by the Bill. The value of the IP Australia approach is that it does not seek to protect rights by specifying patent restrictions on a particular item or technology, but focuses on more clearly defining what a discovery is or is not, and therefore provides an "umbrella' as to what can, or cannot be patented. This approach protects individual rights and accommodates unforeseen developments, while enabling research to continue.