

Joint Submission – Six Universities within the Sydney Basin

University of Western Sydney  
University of Sydney  
University of New South Wales  
Macquarie University  
University of Wollongong  
Newcastle University

25 February 2011

Committee Secretary  
Senate Legal and Constitutional Affairs Committee  
PO Box 6100  
Parliament House  
Canberra ACT 2600

Dear Sir/Madam,

**Re: Patent Amendment (Human Genes and Biological Materials) Bill 2010**

Please find enclosed a joint submission from six universities within the Sydney Basin.

Thank you for the opportunity to provide comment on this proposed legislation. We would appreciate being kept informed as to the progress of this inquiry. We would also welcome the opportunity to address the committee if public hearings are scheduled.

Each of the universities who are signatories to this submission opposes the proposed *Patent Amendment (Human Genes and Biological Materials) Bill 2010*. We believe that the existing patent system encourages research funding and innovation, thereby providing ongoing patient access to new medicines, devices and diagnostics for the reasons set out in the attached submission.

Yours faithfully,

**Dr Fiona Cameron**  
Associate Director, Innovation  
UWS Innovation & Consulting

Submitted on behalf of six universities within the Sydney Basin

UWS Innovation & Consulting  
University of Western Sydney  
Locked Bag 1797 | Penrith NSW 2751

## **Gene Patent submission –Six Universities within the Sydney Basin**

Each of the six undersigned Australian universities within the Sydney Basin believes that all Australians should have access to world-class medical science.

Australian Universities are at the forefront of medical research and are immensely proud of their achievements. For example, the quality of life of Australians, and people around the world, has been improved by important inventions including Gardasil, the cervical cancer vaccine (University of Queensland; developed by CSL; marketed by Merck) and Neupogen, a cytokine used in various cancer treatments (Walter and Eliza Hall Institute of Medical Research; marketed by Amgen).

### **Link between research funding and patents**

Australian universities and associated research institutes are recipients of significant levels of public funding. This government funding supports a level of basic medical research.

It takes many millions of dollars to develop these ideas to the proof-of-concept stage, and then on to useful products thereby bringing medicines, devices and diagnostic technologies to market. This is well beyond the reach of university medical researchers on public funding.

Growth of university research is becoming increasingly reliant on external funding through partnerships with corporate and venture capital entities. The data universities generate from early phase research is used to attract the substantial investment needed to complete a new piece of biotechnology. These relationships provide the money and development capability to translate Australian university inventions from “bench to bedside”. These partners have the knowledge, skills and resources to take the risks to develop the university’s initial research to make available new medicines, devices and diagnostic technologies.

The cornerstone of a university’s ability to attract external commercial partnerships to increase research funding is providing tangible value through patents and related intellectual property rights. Patents are a pivotal element in the value proposition that investors study before making a decision to invest.

These external relationships are so vital that most Australian universities have established commercial arms to manage them, of which Sydnovate, NewSouth Innovations and UniQuest are prime examples.

Universities benefit from the intellectual property system because patents:

- inform and advance research programs through the associated searches;
- provide a vital platform for collaboration with industry;
- enable secure investment and income streams from technology licensing deals which provide growth in research and rewards for inventors;
- define rights and ownership over materials and inventions, enabling the attraction of funds and world class staff and students;
- support academic career progression; and
- underpin the translation of research innovation.

Thus patent rights are critical in attracting funding for early research through to the proof-of-concept stage and beyond.

Given that universities are recipients of public funds, we also believe that the community deserves to benefit from their important research. Translation of research into product through the patenting process is a critical pathway of achieving this.

Logically any reduction in corporate investment will correlate with a decrease in the number of innovative new drugs and diagnostic tests being developed. This will be to the detriment of the health and quality of life of Australians. A strong patent system is important to the advancement of medical research in our universities.

### **Genes as they exist in the human body are not patentable**

We acknowledge that human DNA sequences exist in nature and appropriately they are not considered inventions. Moreover the legislation specifically states that human beings, and biological processes for their generation, are expressly prohibited from patent protection. This makes it clear that the inclusion of human gene sequences in a patent has never and would never give the patent owner any rights or ownership in relation to the genes as they exist in the human body. This we strongly support.

### **Clear examination guidelines and laws**

IP Australia has recently strengthened its "gene patent" patent examination guidelines. The thresholds of patentability are met provided that:

- the gene or gene fragment is artificially-generated or isolated from its naturally-occurring environment;
- the gene function is known and described in detail; and
- the requirements of novelty, inventive step and usefulness are demonstrated and clearly documented (i.e. isolated genes on their own, with no known utility, are not sufficient for a patent to be granted).

We believe that there is no reason for change. The current guidelines attain the correct balance between the rights of the public and monopolistic rights as a reward for innovation. Australian universities will benefit from clear guidelines and laws as to the patenting of biological material as they strive to innovate and attract research funding.

### **Public access to information and inventions**

The publicity surrounding the Myriad Genetics BRCA diagnostic breast cancer patents has caused confusion. The proposed "gene patent" amendments would not, as it is claimed, improve public access to the BRCA diagnostic test as it is the test itself, and not the gene sequence, which remains the subject of valid patent claims.

Public access to patented inventions is safeguarded in a number of ways. Firstly, the *Patents Act 1990* currently includes built-in provisions including Crown Use and Compulsory Licensing which allows the government or third

parties to exploit another party's patent in certain circumstances. These provisions exist to protect the Australian community from the hypothetically unethical behaviours of patent owners including those in the biotechnology industry.

Secondly, IP Australia is working towards enacting a formal Experimental Use exemption for researchers. This is to clarify the rights of researchers and the public with regard to exemptions from patent monopolies for research purposes.

We also refer to a recent survey<sup>1</sup> by the Intellectual Property Research Institute of Australia of some 3350 individual Australian academic researchers, where few reported instances when access to patented research tools and/or materials was denied.

We are concerned that restricting the patenting of biological materials as proposed will adversely affect the free dissemination of information that the patent system so readily provides. Potentially worse, should researchers be unable to demonstrate value in their research to investors through patents then there would be a disincentive to continue research in these areas.

### **Unintended consequences**

We are concerned that the proposed amendment to ban the patenting of human-derived biological material will have unintended consequences. The gene patenting ban will likely have ramifications beyond human health and will affect biotechnological innovation in general. This will adversely impact on a university's external funding for innovative efforts directed at improving the health and productivity of plants and other animals, in turn impacting on innovation in agriculture and sustainability.

### **Clarity of the issues**

We support a broad and inclusive consultation to examine the current legislation and report on areas where relevant areas of the Patents Act might be clarified or strengthened where necessary. Obtaining clarity and certainty as to the patentability of genes and related biological materials will assist universities with investment opportunities. Importantly it will also assist in addressing public misconceptions about patents on genes isolated from the human body and related biological materials.

### **Conclusion**

The issues raised in this debate are important. We believe that the revised examination guidelines for gene patenting strike the right balance between the rights of the public and the monopolies granted as a reward for innovation. We believe that the patent system provides for ongoing patient access to new medicines, devices and diagnostics which is intrinsically linked with the sustainability of Australian university innovation.

It is likely that the potential for university research funding from external partners will significantly decrease as a result of any decision to ban "gene patents" and biological materials. The flow on effect and unintended

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<sup>1</sup> [http://www.ipria.org/publications/wp/Working%20Paper%205\\_2010.pdf](http://www.ipria.org/publications/wp/Working%20Paper%205_2010.pdf)

consequence of these proposed changes is that new medicines and diagnostics will simply fail to be developed, benefiting no one.

Accordingly, we oppose the proposed *Patent Amendment (Human Genes and Biological Materials) Bill 2010* in the interests of advancing medical and scientific research and the diagnosis, treatment and cure of human illness and disease by encouraging research funding and innovation through the existing patent system.

Signatories

**University of Western Sydney**

Professor John Ingleson,  
Deputy Vice Chancellor (International and Development)

**University of Sydney**

Dr Anders Hallgren  
Director Sydnovate

**University of New South Wales**

Professor Les Field  
Deputy Vice Chancellor (Research)

**Macquarie University**

Professor Jim Piper  
Deputy Vice Chancellor (Research)

**University of Wollongong**

Professor Judy Raper  
Deputy Vice Chancellor (Research)

**Newcastle University**

Dr Brent Jenkins  
CEO Newcastle Innovations