REGULATORY INSTITUTIONS NETWORK (RegNet)
Director: Professor Peter Drahos
Centre for Governance of Knowledge and Development
College of Asia Pacific
Coombs Extension Building #8, Cnr Fellows & Garran Roads
The Australian National University
Canberra ACT 0200
AUSTRALIA

http://regnet.anu.edu.au

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Ms Julie Dennett
Committee Secretary
Senate Standing Committee on Legal and
Constitutional Affairs
Parliament House
CANBERRA 2600

Dear Ms Denett

Inquiry into Patent Amendment (Human Genes and Biological Materials) Bill 2010

I refer to your letter of 9 December 2010 inviting me to make a written submission to the abovementioned inquiry.

My submission takes the form of answers to key questions concerning the enactment of the Bill.

1. Would the Bill, if enacted, place Australia in breach of its treaty obligations?

The short answer is that it would not. The two principal conventions in this field, the Paris Convention for the Protection of Industrial Property and the Agreement on Trade-Related Aspects of Intellectual Property Rights do not define invention. The same is true of the intellectual property chapter in the US-Australia free trade agreement. The international framework allows states to exclude subject matter from the meaning of invention. All states take advantage of the open meaning of invention in this framework.

2. Would Australia be out of step with other countries in enacting the Bill?

No, it would not. Patent quality in key technology sectors has become a major issue in both developed and developing countries. The biotechnology sector is one of the greatest areas of concern. Below are some brief examples of what other countries have done.

> Brazil excludes isolated biological materials from patentability. In the case of pharmaceutical inventions the Brazilian drug registration authority has the final say on the grant of the patent.
>
> Andean Community countries have excluded isolated biological materials from patentability.
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> India has reformed its patent law over the last several years. It has both pre-grant and post-grant opposition procedures. In addition it excludes from the meaning of invention variations of known substances that do not lead to significant gains in efficacy.

China has recently strengthened its compulsory licensing law. It also has the political will to use this law.

The position of the US is currently evolving through the courts. The Department of Justice in a brief as *amicus curiae* in the Association for Molecular Pathology case has indicated that the US has re-evaluated its views on patents granted over isolated and unaltered genetic material. The position of the US Administration on the correct principle of patentability for naturally occurring biological material is clear. Merely isolating and purifying a biological material found in nature does not turn that substance into an invention.

In Europe countries are constrained by the language of the Biotechnology Directive, but the German Patent Office is leading an initiative by a group of patent offices to find ways to improve patent quality.

3. Would enacting the Bill adversely affect investment in the Australian biotech sector?

No, it would not. Australia represents less than 2% of the global pharmaceutical market. Investment decisions by pharmaceutical multinationals are driven by three markets – the US, the EU and Japan. China and India have an increasing influence on those decisions. Australia's patent law does affect the access rights of Australian consumers and researchers, but it does not affect global investment decisions because of the small size of the Australian pharmaceutical market.

4. Would it be better to rely on a research exemption or crown use/compulsory licences to deal with access issues?

The answer is no in both cases. Patent research exemptions have been restrictively interpreted in all the jurisdictions of the world. The US case of Madey v Duke University is emblematic of this restrictive approach. There the Court of Appeals for the Federal Circuit restricted experimental use "for amusement, to satisfy curiosity, or for strictly philosophical inquiry". Consideration might be given to designing a broad statutory research exemption, but this should be done in addition to and not in place of the Bill.

Relying on crown use/compulsory licensing provisions is not a politically feasible strategy. The US has been a great critic of the use of these provisions and has brought trade pressure to bear on countries that have gone down this path (eg Thailand). It is true that China and Brazil have been prepared to confront the US in the WTO over trade disputes concerning intellectual property, but one wonders whether Australian political leaders would be prepared to tread this same confrontational path. By enacting the Bill, Australia would be taking an option that is supported by the US administration. It follows that it would also minimize the risks of a trade confrontation with the US over the patenting of biological materials.

5. Is the language of the Bill too broad?

No, it is not. Every country that has gone down the path of excluding isolated biological materials from the category of invention has used general language such as 'biological materials'. To refer to some subset of biological materials such as genes sets up the dangerous inference that other naturally occurring materials that have been isolated are patentable inventions.

The Bill relies on the concept of 'substantially identical'. This concept is used in other areas of intellectual property such as copyright law and trade mark law. Introducing this concept is important because it prevents the purpose of the Bill being defeated by an applicant who introduces a minor but functionally unimportant variation to a biological material in order to obtain a patent over it.

The Committee will no doubt receive submissions claiming that the concept of 'substantially identical' is too uncertain or imprecise. However, judges have learnt to work with the concept in other parts of intellectual property. In any case there is no choice here as it would be impossible to prohibit through individual rules every possible minor variation in biological materials.

There are different drafting strategies that one might employ depending on how much guidance one wishes to give a patent office or court. For example, one could omit the reference to "substantially identical" from the proposed paragraph 18(2)(b) and introduce a clarifying subsection along the following lines:

> (2A) For the purpose of determining identical in paragraph 18(2)(b) minor variations in biological materials from those as they occur in nature shall be disregarded unless it can be shown by the patent applicant that those variations lead those materials to perform significantly differently to those that occur in nature.

I am not pushing this as an alternative draft, but simply pointing out to the Committee that depending on the level of concern expressed in other submissions received by the Committee there are drafting options to accommodate those concerns.

Summing up I see no reason why the Bill should not be passed by the Parliament. It serves Australia's goal of equity in access to medicines and would assist researchers by providing a legislative guarantee of access to the foundational materials of biological research. In my view it would make the biotech market in Australia more competitive. More researchers would have access to essential biological materials and their ability to make product claims over inventions flowing from those materials would not affected by the Bill.

Yours sincerely

Professor Peter Drahos
Australian National University and Chair in Intellectual Property, Queen Mary, University of London