By email
legcon.sen@aph.gov.au

Our Ref: 510353

FB RICE & CO

25 February 2011

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

Submission to Senate Legal and Constitutional Committee Inquiry into the Patent Amendment (Human Genes and Biological Materials) Bill 2010

Dear Sir/Madam

We provide our comments in relation to the Patent Amendment (Human Genes and Biological Materials) Bill 2010. These comments are not only based on our experience in assisting our clients in the patenting of material of biological origin, but also on the experience of many of our staff who were research scientists in public institutions before they became patent attorneys.

The Bill proposes to amend the Australian Patents Act ("the Act") to exclude the following from patentable subject matter;

> *"biological materials including their components and derivatives, whether isolated or purified or not and however made, which are identical or substantially identical to such materials as they exist in nature".*

It is also proposed to amend the Act to define the term "biological materials" to include;

> *"DNA, RNA, proteins, cells and fluids".*

The scope of the Bill is unclear

Title

The title of the Bill is misleading. The title implies that the Bill relates to "human" biological material but the proposed amendments encompass biological material from any source. This inconsistency should be corrected.

Meaning of the terms "derivatives" and "substantially identical" are unclear

Most patent Examiners around the world, including Australian patent Examiners, typically reject a claim that reads;

> *"An isolated polynucleotide comprising sequence X, a polynucleotide substantially identical thereto or a derivative thereof".*

FB RICE & Co
Patent and Trade Mark Attorneys
ABN 53 487 267 594

Level 23, 200 Queen Street
Melbourne VIC 3000
GPO Box 1794 Melbourne
VIC 3001 Australia

tel +61 3 8618 4100
fax +61 3 8618 4199
partners@fbrice.com.au
www.fbrice.com.au

FB RICE & Co also has a Sydney Office
FB RICE & Co is associated with Computer Patent Annuities (CPA)

The reason for the rejection would be that the reader would not be able to determine the scope of the claim because the terms "derivatives" and "substantially identical" are unclear. Following the same logic, it is unreasonable to amend the Act using language which creates considerable doubt as to the scope of the excluded subject matter.

There are many different types of man made molecules which use the basic building blocks of DNA (nucleotides) and proteins (amino acids). For example, genetically engineered vectors and cells, humanized antibodies, diabodies and higher multimers, double-stranded RNA with a stem loop, PEGylated proteins, agonists/antagonists of peptides with non-naturally occurring amino acids and/or bonds, stem cells, fusion proteins such as antibodies conjugated to an imaging agent and many more. The Bill provides applicants for patents with no clarity as to whether such molecules are to be excluded from patentability.

Of concern is that much of the debate has focused on genes, but the Bill seems to encompass material such as therapeutic antibodies and stem cells. There are many Australian companies whose existence relies upon the patenting of biological materials such antibodies and stem cells. In our opinion, these companies can rightly feel aggrieved by their technology seemingly being encompassed by the Bill because until now the public debate has essentially been limited to human genes and genetic testing.

The term "biological materials" is unclear

The Bill provides a non-exhaustive list of examples of biological materials to be excluded from patentability. However, living organisms produce many types of materials beyond DNA, RNA, cells and fluids. For example, pyrethrum is a naturally occurring chemical compound produced by *Chrysanthemum sp*. Pyrethrum and many man made derivatives thereof are used as commercial insecticides.

Does the Bill include or exclude subject matter such as carbohydrates, lipids and other chemical compounds which do not comprise nucleotides or amino acids?

"Medicines" will still be patentable

The scope of the Bill is also unclear as to the extent to which the biological material can be manipulated in order for it to be considered patentable.

In a speech to the Senate on 24 November 2010, Senator Heffernan stated that "biotechnological inventions which make use of biological materials in such things as new and inventive diagnostics, medicines and treatments will continue to be afforded patent protection just as they are now" (emphasis added). We read this to mean that, for example, a human antibody cannot be patented because is it a biological material that exists in nature, but if you put the antibody in a solution that can be administered to a human (i.e. produce a medicine) it is patentable. Following the same logic, placing any biological material in a format suitable for a particular use would also render the biological material in that format patentable.

This may be why Senator Heffernan considers the Bill to be "very narrow", namely you do not have to do much to put the biological material in a form to be patentable. Nonetheless, it is currently unclear whether this is the case.

Is the Bill narrow?

As noted above, Senator Heffernan has stated on numerous occasions that the bill is "very narrow". We might be tempted to agree with him if biological materials in medicines or other compositions for medical, agricultural or industrial use are to remain patentable. However, we are hesitant to assume such subject matter will indeed still be patentable. Furthermore, if the Bill is intended to be narrow it is difficult to see what it actually achieves.

Invention versus discovery

Regrettably, much of the discussion around the patenting of biological material has focused on a futile exercise in semantics as to whether such material in an isolated state is an invention or a discovery.

The ability to obtain a temporary monopoly to promote scientific endeavor whilst ensuring an early public disclosure of an "invention" useful to man kind (i.e. the patent system) is a man made concept. The term "manner of manufacture" was coined in 1623 with no knowledge of the areas of scientific endeavor that may be pursued centuries later.

All areas of science are bound by the laws of nature and pre-existing raw materials. It can be argued that any advances in the field of engineering are discoveries because it has been "discovered" by man that some naturally occurring entities (such as atoms, chemical elements, sound waves etc) can be manipulated in a certain way to produce an industrially useful effect. The term "discovery" and variations thereof (discovered etc) are often used to describe an invention in patent applications which do not relate to biological material. Two of a plethora of examples are; 1) US 20030150530 introduces a claimed invention relating to high purity aluminum alloy with controlled particulate size and distribution of mobile impurities by stating "[w]e have discovered that the formation of particulate inclusions at the surface of an aluminum alloy article, which inclusions interfere …" (emphasis added); and 2) US 20040134480 relating to an allegedly new connective system states that "[w]e have discovered a new technique for very low cost convective heat generation" (emphasis added) under the heading "discovery". In other words, the terms "invention" and "discovery" are widely used interchangeably in patent applications relating to many different technologies.

From our investigations the term "invention" is derived from the latin term "inventionem (nom. inventio) "a finding, **discovery**," from inventus, pp. of invenire "devise, **discover**, find,"" (see www.etymonline.com/index.php?search=invention&searchmode=none, as well as www.ichrusa.com/saintsalive/glossary.htm) (emphasis added). Thus, history shows that the terms invention and discovery are inextricably linked, and that any attempt by members of the Senate or others to suggest that are completely different concepts is without substance.

Government should be able to decide, at any given time, the subject matter for which there is a justification for granting a temporary monopoly without the need to play games with the terms "discovery" and "invention". Ideally, such decisions should also take into consideration our international obligations and be co-coordinated with our major trading partners to avoid inconsistencies. We urge the Senate Committee to focus on these issues rather than being distracted by the irrelevant "invention versus discovery" debate.

Investment into biotechnology research

The Department of Innovation, Industry, Science and Research estimated that in 2007 and 2008 venture capital and later stage equity alone invested over $1.2 billion dollars for research in the Australian "biotech, pharmaceuticals and health sectors". Furthermore, as at June 2008 the Department identified 487 Australian biotechnology companies both listed and private. Restricting patentable subject matter in the area of biotechnology research can only lead to less funding, a loss of jobs and logically a decrease in the rate of advancement in biotechnological sciences.

Research exemptions

In his speech to the Senate, Senator Heffernan implied that current laws stifle research, however, there are very few examples that suggest this is the case. In a presentation at the Ausbiotech conference in October 2010, Dr Julian Clark, the Head of Business Development at the Walter and Eliza Hall Institute of Medical Research, indicated that he was unaware of any patent rights which had hindered basic research at that Institute. As an example, Dr Clark pointed to the over 5,500 global scientific publications relating to the controversial BRCA1 gene (associated with breast and ovarian cancer). Such a massive number of publications clearly do not support Senator Heffernan's assertions that basic research is being hindered.

The focus on the patenting of "biological materials" allegedly inhibiting advances in relation to human health is perplexing. The reality is that many other technologies are also essential to medicine. There are large and expensive machines, such as those used in medical imaging, as well as medical devices, that rely on patented technologies in the fields of electrical and mechanical engineering. So too, there are patents to non-biologically derived compounds used for therapies or regeants for diagnostics.

It has been recognised for some time that current Australian laws regarding research exemptions need clarification (see Recommendation 13 of the Senate Committee into Gene Patents), and action on this issue seems to have dragged on for too long. If members of the Senate are truly concerned about basic research being stifled by patents, they should have presented proposed amendments focusing on the "broad research exemption" suggested by the Senate Committee into Gene Patents.

Stress of academic researchers

Recent studies have shown that at best there are only rare occasions where patents rights may have impeded basic research (www.sciencemag.org/cgi/content/summary/309/5743/2002). Furthermore, there are no examples in over a century of Australian Patent law of an academic researcher being sued for patent infringement.

In contrast, a 2002 survey into occupational stress in Australian universities (www.unisanet.unisa.edu.au/nuss/Detailed_stress_report.pdf) found that "this study corroborate previous research conducted in the US, UK, and New Zealand which reveals an alarming and increasing level of stress amongst university staff" (see page 95 of the report). The key causes of stress were identified as "(1) insufficient funding and resources; (2) work overload; (3) poor management practice; (4) job insecurity; and (5) insufficient recognition and reward". It was also recognised that reductions in funding "are taking their toll". No mention of patent infringement, but a heavy emphasis on lack of money. In our opinion, introducing the Bill will reduce funding into Australian research from commercial sources, and add to the stress of many Australian scientists.

The Bill adds to the cost of obtaining and enforcing patents

In our opinion, the ambiguity introduced by the proposed amendments will make the patent system more expensive, protracted and uncertain. In reality, the unfortunate consequence is that such costs will then be passed onto consumers.

First, phrases such as "derivatives" and "substantially identical" are unclear, meaning that there will be more costs at the patent prosecution stage arguing whether a non-naturally occurring biological material is patentable or not.

Second, in practical terms if the Bill is passed method claims will become more important because it may not be possible to obtain a product claim. A well known principle of the patent system is that product claims are easier to enforce than method claims. As a result, patentees may have to spend more time and money to prove that their rights are being infringed.

The Bill promotes companies to sue doctors and farmers

Generally, medium to large companies make biological products, and the consumer uses them. This means that product claims capture the manufacturer (e.g. drug companies) and method claims capture the end user (e.g. farmers and doctors). By excluding biological materials from patentability, the Bill promotes the enforcement of patent rights against those using the product (i.e., the person performing the claimed method).

As one example, company X spends US$30 million developing a new pyrethrum derivative with enhanced insecticidal activity. Under the Bill, company X cannot patent the compound *per se*, but can obtain a method claim to using the derivative to kill insects on a crop. Company Y recognizes the large market and also produces and sells the derivative. Who can company X sue? The farmer is the person directly infringing the patent so the Bill increases the chances that company X will sue the farmer when for many reasons company X would much rather be suing its competitor, namely company Y. Similar examples could easily be described for other molecules of biological origin including DNA, RNA, proteins, and cells.

Granted and pending patents

The Australian Government, through IP Australia, have been granting patents to isolated biological materials for decades. Logically, some businesses existence, and hence the jobs of their employees, rely on the current patent system. It seems particularly harsh for the Australian Government to "change the goal posts" without providing any suggestion of compensation to those who have filed patent applications under the current laws.

Genetic diagnostic methods

Even though, at least according to the speech to the Senate on 24 November 2010, diagnostics will continue to be afforded patent protection, there is nonetheless still a heavy emphasis on genetic diagnostics in the debate about the current Bill.

In our opinion, the debate on this issue has been very disappointing. The fact that genetic tests take considerable time and cost to develop to a state that someone else can copy seems to get ignored. There does not seem to have been any cost and/or turnaround time analysis of genetic services offered by innovators or their licensees compared to those offered by non-innovators. You would expect non-innovators costs to be much cheaper, but anecdotal evidence of which we are aware suggests this is not the case. The fact that a person only needs a particular genetic test once in their

lifetime (limiting an organizations opportunity to recover the costs of developing the test) has received little acknowledgement.

According to Davis et al. ("The microeconomics of personalized medicine: today's challenge and tomorrows promise (2009) Nature Reviews, 8:279-286), on average at a minimum a single molecular diagnostic test costs US$40 million to develop (see Figure 5). In the absence of patent protection for diagnostic tests, company X could spend US$40 million to develop a genetic diagnostic and Company Y (or hospital Y) can simply copy the test and owe nothing to company X. If genetic diagnostics are not afforded patent protection it is difficult to see who is going to bother developing them. In other words, we do not think it is being melodramatic to say – no patent protection for genetic tests then no (or few) new tests.

Most regrettable in the debate regarding genetic diagnostics is that much of it seems to be an "all or nothing" approach. Surely the Australian Government could look at regulating the industry to ensure that innovation is encouraged, subsidize tests where appropriate (especially tests for rare diseases where due to sample number costs will generally be higher), ensuring availability and accuracy of the test, and ensuring inventors are suitably compensated whilst not allowing them to "rort the system". Sadly, these simple concepts seem to be over-looked by many engaged in the present debate.

Summary

If the "Bill is very narrow", then what does it really achieve? The answer would seem to be nothing but to add extra expense to the Australian patent system, stifle investment into biotechnological research, contradict International agreements, and provide an inadequate solution to the issue of research exemptions which is relevant to all technologies, not just "gene patents".

Yours faithfully
F B RICE & CO

IAN ROURKE
Partner