IVD AUSTRALIA

Submission to

Senate Standing Committees on Legal and Constitutional Affairs

regarding the Patent Amendment (Human Genes and Biological Materials) Bill 2010

February 2011

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Recommendations

IVD Australia believes that the proposed Bill will do incalculable damage to Australia's biotechnology and IVD sectors, and that it will have far reaching and unintended consequences for patient access to diagnostic tests into the future. We believe that the Bill has a number of flaws. Specifically;

- It is too broadly scoped and ill-defined;
- It is opposed in practice to current patent law;
- It could be applied to existing patents;
- There is no need for the Bill as the current Act generates no adverse effects;
- It is opposed to the Australian Law Reform Commission conclusions in its 2004 Report, *Genes and ingenuity;*
- It will actually discourage investment in R & D for IVDs;
- It conflicts with Australia's existing international obligations; and
- It ignores the use of compulsory licensing and Crown Use provisions that would provide an alternative to the proposed amendments

IVD Australia therefore makes the following recommendations regarding the *Patent Amendment (Human Genes and Biological Materials) Bill 2010*;

Recommendation 1

IVD Australia strongly recommends that the Bill be rejected.

Recommendation 2

IVD Australia recommend that the Government adopt Recommendations 11 - 13 of the Senate Inquiry into Gene Patents, released on 26th November 2010, in respect of Crown use, compulsory licensing and research exemptions.

Who is IVD Australia?

IVD Australia is pleased to provide our submission to the Senate Standing Committees on Legal and Constitutional Affairs as part of its deliberations on the *Patent Amendment (Human Genes and Biological Materials) Bill 2010*.

IVD Australia is the Industry Association representing Australian sponsors and manufacturers of *in vitro* diagnostics (IVDs).

In vitro, literally "*in glass*" diagnostics (IVD's) comprises the instruments and reagents that are used to perform pathology tests requested by General Practioners or specialist Physicians. These are generally performed in accredited Public and Private pathology laboratories across Australia, but IVD's also include over-the-counter tests such as blood glucose meters for diabetes testing and home pregnancy test kits. Supply of these products is regulated for the Government by the Therapeutic Goods Administration.

These tests influence over 70% of the medical decisions taken in respect of a patient's health and often comprise over 75% of a patient's health record.

IVD Australia was formed in July 2009 and currently represents 60 multinational companies, local distributors and Australian manufacturers of IVDs. Our members supply products valued at over $800,000,000 representing in excess of 90% of all IVDs sold in Australia. They employ over 2000 people across Australia.

Almost all of the IVDs used in Australia are imported and conversely, a large percentage of the IVDs manufactured in Australia are exported. However the Australian market for IVDs (as well as medical devices in general) represents less than 2% of the world market for these products. Thus it is critically important that regulation impacting IVDs in Australia is light-touch, consistent with overseas practice and not financially burdensome on sponsors and manufacturers.

Clearly the *Patent Amendment (Human Genes and Biological Materials) Bill 2010* will have a major impact on IVD Australia members. Many of the IVDs sold in Australia are covered by patents obtained in Australia and elsewhere, and members often rely on these patents to protect their commercial interests.

IVD Australia thanks the Legal and Constitutional Affairs Committees of the Australia Senate for the opportunity to participate in the review process of the *Patent Amendment (Human Genes and Biological Materials) Bill 2010*. We look forward to the ongoing discussions foreshadowed in the referral. We assure the Committee of our willingness to participate as necessary to achieve a workable outcome.

Introduction

The *Patent Amendment (Human Genes and Biological Materials) Bill 2010* (**Bill**) seeks to amend Section 18 of the Patents Act 1990 (**Act**);

> *"(1) Subject to subsection (2), an invention is a patentable invention for the purposes of a standard patent if the invention, so far as claimed in any claim:*
>
> *(a) is a manner of manufacture within the **full** meaning**, including the proviso**, of section 6 of the Statute of Monopolies; and*
>
> *(b) when compared with the prior art base as it existed before the priority date of that claim:*
>
> *(i) is novel; and*
>
> *(ii) involves an inventive step; ...*
>
> *(2) **The following are not patentable inventions:***
>
> ***(a)** human beings, and the biological processes for their generation, are not patentable inventions**; and***
>
> ***(b) biological materials including their components and derivatives, whether isolated or purified and however made, which are identical or substantially identical to such material as they exist in nature."***

The purpose of the Bill is to amend the Act so as to prevent the patenting of genes and other biological material that exists in nature.

We believe it is largely a reaction reaction to recent publicity surrounding the enforcement by the Australian company Genetic Technologies Ltd (Myriad Genetics' exclusive Australian licensee) of the BRCA 1 and BRCA 2 patents against public laboratories testing for genetic breast and ovarian cancer.

However IVD Australia believes that there are a number of serious issues with the Bill that mean that it should be rejected by the Senate. We do not believe that it is possible to redraft the Bill as it currently stands to address many of the issues that we raise.

Issues

Issue # 1 - the Bill is too broadly scoped and ill defined

IVD Australia believes the scope of the Bill is far too broad and ill-defined and based on a false premise.

Currently, section 18(2) of the Act states that human beings, and the biological processes for their generation, are not patentable inventions. It is accepted that DNA sequences of humans exist without any intervention of man or without the necessity for an inventive process. The mere identification of a gene sequence is not sufficient to obtain a patent in Australia or indeed elsewhere.

Therefore it is not possible at present in Australia to patent a gene *per se*, and hence the Bill is based on the false premise that genes themselves are patentable. This concern is often expressed as "someone will own my DNA". This is not correct and thus one of the major arguments for the Bill is not sustainable.

IVD Australia also submits that the Bill is far too broadly written. Within the Bill, "Biological materials" is defined to "*include... DNA, RNA, proteins, cells and fluids*." In short, the Bill proposes to extend the current prohibition on patenting human beings, and the biological processes for their generation, to prohibiting the patenting of most, if not all, biological materials.

Under the Bill, patents for biological materials, which are "*identical or substantially identical to such material as they exist in nature*" will no longer be valid. The following issues with this approach should be noted:

- The parameters a Court may ascribe to biological materials which are "*substantially identical to such material as they exist in nature*" is entirely unclear in view of the inclusive definition of "biological materials", and uncertainty as to what is meant by "components and derivatives" of biological materials.

- Specifically, the scope of the prohibition is much broader than simply for patents for isolated DNA, RNA or proteins. It extends to all biological materials and their derivatives. "Derivatives" is not defined, but potentially includes isolated substances produced by cells, monoclonal antibodies, antibiotics, enzymes, hormones, immunoglobulins, recombinant therapeutics.....

- The degree to which the material sought to be patented must differ from that in nature is also unclear. Small changes in DNA sequences can lead to significant differences in biological activity.

- Similarly, changes in DNA sequences may lead to significant changes in proteins that they transcribe. It is unclear whether the test of "substantially identical" is focused on the sequence or structure of the biological material on the one hand or its function on the other.

The exclusion of biological materials from patent protection will however not address one of the main concerns of the Bill's proponents; that of the inability of Australian health consumers to access diagnostic tests, such as the BCRA1 and BCRA2 tests, due to patent exclusivity. Patents for diagnostic tests are often based on the novelty of the detection system or the application of the marker to the disease state. The patentability of the BCRA1 and BCRA2 diagnostic tests would still remain under the proposed Bill as the Myriad patents are based on the valid and patentable application genes to the diagnosis of breast cancer, and not on the sequences themselves.

The Bill's provisions are themselves ambiguous. This will mean that if the Bill is passed that the courts will be called upon to determine what can and what cannot be patented. Instead of bringing "clarity" to the issue of biological patents, this Bill will bring more uncertainty and litigation. This will add substantially to the costs of development of new and novel IVDs which will certainly not benefit the Australian health consumer.

Issue # 2 - the Bill is opposed in practice to current patent law

The orthodox approach in patent law, including with respect to small molecules, in determining patentability in the light of pre-existing material is to ask whether the invention is novel or includes an inventive (non-obvious) step. It is unclear why the Bill proposes that a different approach should be adopted for biological material.

As indicated previously, it may be that a small change in the structure or function of material that is inventive would not be patentable under this Bill on the basis of substantial identity to that which occurs in nature. Many of these small changes in conformation, glycosylation, or other chemical modifications produce dramatic changes in the activity and usefulness of an antibody or enzyme. However these molecules may be determined to be "substantially identical" to those existing in nature and hence will not be patentable under the proposed amendment.

The Patent Act is also quite clear that the mere discovery of a gene, or any other biological material, is not sufficient grounds to obtain a patent. The existing law requires that a patent contain an inventive step and that applicants provide substantive evidence about their technology in support of its novelty, utility and inventiveness.

Many of the gene sequences that this Bill seeks to prevent being patented are in fact now in the public domain. The Human Genome Project has made freely available the vast majority of human gene sequences and so it is unlikely now that a patent for a native sequence itself would be issued.

Issue # 3 - the Bill could be applied to existing patents

IVD Australia submits that the Bill could apply to existing patents that presently have effect in Australia, and lead to the withdrawal of products from the Australian market. IVD Australia is concerned that this issue does not seem to have been considered in the drafting of the Bill.

As currently drafted, the Bill will potentially apply to all relevant Australian patents, regardless of when they were granted. There are no transitional provisions in the Bill that would limit its application only to patents applied for after the Bill becomes law (if it does).

Thus existing patent owners would lose any revenue stream that currently funds their research and development activities. This would apply to all patent holders, not just those who are commercial organisations, but also to medical research institutes who rely on the royalty stream for funding. The loss of sales revenue may also lead to removal of products from the Australian marketplace and hence may deprive the Australian health community of access to critical pathology tests.

There is also a potential concern that this Bill, if it became law, would be unconstitutional. Patents are personal property and the retrospective invalidation of a patent could constitute the acquisition of property. The Commonwealth only has the power to acquire property "on just terms", which is a constitutional guarantee of just compensation. There are currently proceedings before the High Court to determine whether a reduction in the scope of intellectual property rights, in particular copyright, may be unconstitutional.

Issue # 4 - the Bill is unnecessary to allow research access to gene technology

The Senate Community Affairs References Committee's report on Gene Patents which issued a few weeks ago states that "*the evidence did not show that gene patents are systematically leading to adverse impacts in [the areas of healthcare or the conduct of medical research in Australia]*." (at xi). This appears to be at odds with the policy behind the Bill.

There is little evidence to support claims that gene patents restrict research or that Australian scientists lack free access to biological materials because of issues with pre-existing patents. Australian researchers for example have published hundreds of papers over the past 10 years with respect to the BCRA1 gene without major patent infringement issues. This patent is in fact due to expire with a year or so and hence it will become available for anyone to use at that time.

The existence of a patent means that all information regarding an invention must be disclosed and hence the details of the research on which the patent is based are available for anyone to duplicate. The existence of a patent also means that the knowledge contained within the patent is preserved and available for future generations. The alternative to patents is “trade secrets” which restrict the flow of information and constrain research, and could inhibit the access of the general public to the benefits of the innovation.

Australian scientists are amongst the world’s best medical researchers and our medical research institutes are world leading. Numerous developments such as the Gardasil vaccine for cervical cancer, the cochlear implant, novel TD diagnostics etc have been developed in Australia. These have all been developed with the protection of patents that have enabled recoupment of some of the extensive investment made by these medical research institutes.

Issue # 5 - the Bill is opposed to Law Reform Commission conclusions

The policy positions taken in this Bill depart materially from those set out in the report of the Australian Law Reform Commission (ALRC) delivered in June 2004 (**ALRC 2004 Report**) which was also a response to the Myriad/GTG BRCA1 and BRCA2 issue.

In preparing its recommendations, the ALRC consulted widely within the health sector and the research community, released two major consultative documents and conducted 73 meetings. It can hardly be said that its work was anything but thorough.

Specifically, the ALRC 2004 Report concluded (at p. 13) as follows:

"*One frequent concern was that claims over genetic sequences - being naturally occurring - are 'discoveries', not inventions. Whatever the merits of that argument, the Inquiry was faced with the fact that since the 1980s - in Australia and internationally - large numbers of patents have been granted on genetic sequences, provided they have been isolated from their natural state and otherwise satisfied the statutory requirements for patentability.''*

The Inquiry ultimately concluded that if there had been a time to recommend that gene sequences should not be patentable, that time had long since passed. Rather, it was preferable to focus on reforms that would make the system work better."

IVD Australia believes that, whilst there have been a number of patents issued for gene sequences in the past, this issue has been dealt with by both Australian and overseas patent authorities. It is not possible in future for "native" gene sequences to be patented and hence one of the major arguments in favour of the Bill is negated.

Issue # 6 - the Bill will actually discourage R&D investment in IVDs

Proponents of the Bill have argued that the current situation which allows patenting of biological materials, subject to an inventive step, inhibits research and development activity as scientists are unwell to be found in breach of patent provisions and hence do not undertake research in areas that may be of concern in this regards.

It can be argued that the proposed Bill will in fact have this effect and will discourage investment in R & D if any biological product that is developed can be copied by all and sundry. While the cost of accessing otherwise patented biological materials would be removed, the Bill could actually destroy incentive for development of discoveries.

In addition, patents provide the framework on which the whole of R&D commercialization is based. Patents provide much of the value proposition that allows public and private investors to commit funds to up and coming research. Removal of the protection that patents afford will mean that investors will be much less inclined to advance the necessary capital to permit discoveries to progress to a commercial product. This lack of investment will translate to fewer IVDs being developed in Australia, rather than more .

Issue # 7 - the Bill creates conflicts with international obligations

Article 17.9.2 of the Australia-United States Free Trade Agreement provides that, in general, patents will be available for all inventions. The text also includes the flexibility to exclude from patentability inventions that fall within the terms of Articles 27.2 and 27.3(a) of the TRIPS Agreement, that is:

- methods of treatment - diagnostic, therapeutic and surgical methods for the treatment of humans or animals;
- inventions which should not be allowed on moral grounds - where necessary to protect public order or morality, including human, animal or plant life or health or to avoid serious injury to the environment.

Thus if this Bill is enacted Australia will be in breach of our International Treaty obligations. In addition we will be seriously out of step with all other Western jurisdictions, none of whom have moved to ban the patenting of "biological materials".

Issue # 8 - the Bill ignores Crown Use and compulsory licensing

There are a number of safeguards built into the current Patent system that allow the Government or third parties to exploit a patent under certain circumstances. This include Crown Use provisions and compulsory licensing provisions. These have not previously been invoked in Australia in respect of healthcare related patents.

IVD Australia recommends that the Commonwealth take up Recommendations 11, 12 and 13 of Senate Inquiry into Gene Patents which was released on 26th November 2010.

Specifically these were;

- *Recommendation 11 - The committee recommends that the **Patents Act 1990** be amended to clarify the circumstances in which the Crown use provisions may be employed; and that the Government develop clear policies for the use of the Crown use provisions. The Committee recommends that the Government adopt the ALRC recommendations from its 2004 Report, Genes and Ingenuity.*
- *Recommendation 12 - The committee recommends that the Government amend the **Patents Act 1990** to clarify the scope of the 'reasonable requirements of the public' test taking into account the recommendation of the ALRC's recommendations….; The Committee recommends that the Government review the operation of the competition based test for the grant of a compulsory license….*
- *Recommendation 13 - The Committee recommends that the **Patents Act 1990** be amended to include a broad research exemption.*

Adoption and enactment of these recommendations would mean that diagnostic test of public health concern could be made available to the Australian community despite the existence of patent protection on the tests. This would go a long way to achieving the aims of the Bill's proponents without the need for a blanket prohibition on the patenting of biological materials.