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**SUBMISSION TO SENATE INQUIRY:**

***PATENT AMENDMENT (HUMAN GENES AND BIOLOGICAL MATERIALS) BILL 2010***

**Summary**

It is my belief that the Senate should not support passage of the *Patent Amendment (Human Genes and Biological Materials) Bill 2010* ('Bill').

More particularly, it is my opinion that:

1. the amendments to the *Patents Act 1990* proposed by this Bill are not in the interests of stakeholders in the patent system, including inventors, medical and scientific researchers, public and industrial research institutions, and members of the general public;

2. enactment of the Bill would result in an increase in obscurity and uncertainty, compared to the present situation;

3. the proposed amendments may have unintended adverse consequences; and

4. the Bill seeks to address a 'problem' that is either substantially nonexistent or, in the alternative, is better dealt with by strengthening other aspects of the patent system.

My more detailed reasons for holding these opinions are set out below.

**Purpose of the Bill**

According to the Explanatory Memorandum, the purpose of the *Patent Amendment (Human Genes and Biological Materials) Bill 2010* is:

> *…to advance medical and scientific research and the diagnosis, treatment and cure of human illness and disease by enabling doctors, clinicians and medical and scientific researchers to gain free and unfettered access to biological materials, however made, that are identical or substantially identical to such materials as they exist in nature.*

The report of the Australian Senate Community Affairs Committee Inquiry into Gene Patents ('Senate Committee'), which was released on 25 November 2010, indicated that the Committee had heard of a number of instances where the provision of healthcare or the conduct of medical research in Australia has been impeded. However, the Senate Committee ultimately determined that the evidence did not support a conclusion that gene patents are a systematic cause of adverse impacts in these areas. While this was partly due to a lack of comprehensive, systematic and accessible data in relation to gene patents, it seems reasonable to conclude that if there were a genuine problem in this regard it would have become apparent through the extensive consultation and submissions received to the inquiry. On the contrary, the Committee heard conflicting evidence as to whether a

prohibition on the patenting of genes and other biological materials would be effective, or whether it would lead to unforeseen consequences in other fields of technology, particularly biotechnology research and development.

In this context, there is no evidence to support a need for any legislative change meeting the stated purpose of this Bill. Indeed, there is some evidence to suggest that it may have unintended adverse consequences.

**Proposed Amendments to the *Patents Act 1990***

The Bill proposes amendments to subsections 18(1)(a) and 18(1A)(a) of the *Patents Act 1990*, which define patentable subject mater by reference to a 'manner of manufacture within the meaning of Section 6 of the Statute of Monopolies', as well as subsection 18(2), which defines express exclusions to patentability, and adds a definition of 'biological materials' in subsection 18(5).

It is my opinion that all of the amendments proposed in the Bill are substantially lacking in merit, have the potential to cause unforeseen adverse consequences, and would represent a retrograde step in the development of the Australian patent law.

Firstly, the Bill proposes to require than an invention be:

> *a manner of manufacture within the full meaning, including the proviso, of section 6 of the Statute of Monopolies.*

The 'proviso' in question is the original (1623) exclusion for subject matter that is 'contrary to Law', 'mischievous to the State, by raising Prices of Commodities at home', or 'Hurt of Trade', or 'generally inconvenient'.

However, with the possible exception of 'general inconvenience,' these exclusions have either been deliberately dropped from the modern patent law, or have been covered in specific provisions of the Act. Reintroducing these outdated concepts is, without doubt, a retrograde step.

In the Final Report on its review of Patentable Subject Matter, the Australian Government's Advisory Council on Intellectual Property (ACIP) concluded that:

> *[t]he current test for patentable subject matter as applied by the courts in Australia is the best one available to us.*

Nonetheless, ACIP considers that there is scope for legislative improvement because:

> *[f]irstly, the legislative language is obscure. It does not match the principles developed by the courts to determine inherent patentability. Secondly, the manner of manufacture requirement overlaps with other tests for patentability. Thirdly, the wording of the Patents Act 1990 is confusing. Finally, there is uncertainty about the residual exclusions covered by the 'general inconvenience' proviso.*

While I do not, as it happens, agree with ACIP's specific proposal to address these concerns, I am in complete agreement with ACIP that any amendment to the legislation relating to the 'manner of manufacture' test should represent a step forward in modernising the Australian patent law.

The amendment proposed in this Bill is clearly retrograde, in that it seeks to reintroduce the full meaning of the original 1623 definition of 'manner of manufacture'. This would exacerbate the concerns expressed in ACIP's report. Specifically:

- the obscurity of the language is enhanced by reference to 'full meaning', and a 'proviso', neither of which are comprehensible within the terms of the current Australian *Patents Act*;
- the reintroduction of the 'proviso' moves the language further from the principles now applied by the courts to determine inherent patentability;
- the reintroduction, through the 'proviso', of exclusions (such as 'contrary to law') that have since been codified in other specific provisions of the *Patents Act* increases the overlap between different requirements of the Act; and
- the amendment would do nothing to address concerns about the residual exclusions covered by the 'general inconvenience' proviso.

The Bill further seeks to add an exclusion from patentability, in subsection (2), for:

> *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.*

A new subsection (5) is a 'deeming provision' specifying that:

> *biological materials, in section 18, includes DNA, RNA, proteins, cells and fluids.*

These proposed provisions are unclear in their scope, and I particularly note that the deeming provision is non-limiting, and therefore potentially includes (perhaps unintentionally) much more besides the biological materials actually listed.

In its Report, ACIP agreed with the Senate Committee that:

> *…no persuasive case has been made to introduce a specific exclusion to prevent the patenting of human genes and genetic products. In its review of Gene Patents, the Senate Committee stated that an express exclusion should be introduced only if there is a very clear case, and significant social and political consensus, on the need for such a change.*

I agree with ACIP that no such consensus exists, and I am further opposed to the exclusions proposed in this Bill on the basis that the potential breadth of scope of 'biological materials' may lead to unintended adverse consequences. It is possible, for example, that had such a broad exclusion existed in the past, it may have impacted upon many of the important developments which may not have come about without the incentive of a patent monopoly, including the development of pharmaceutical therapies such as taxol, insulin, heparin, erythropoietin, and vaccines for influenza, tetanus, diphtheria, and pertussis.

**Alternative Solutions to the Gene Patent 'Problem'**

Assuming that there is some problem with the current approach to the patenting of biological materials, I do not believe that it is best addressed by the introduction of express exclusions having potential unintended and adverse consequences.

In its Report, the Senate Committee noted:

> *…a strong consensus among opponents of an express prohibition on gene patents that the concerns which formed the basis of the Committee's inquiry can be more effectively addressed through a range of responses directed not at gene patents per se but at improving the operation of the patent system more generally.*

The responses advocated by persons appearing before the Committee, including representatives of IP Australia, include a strengthening of the patent laws around obviousness, written description, enablement, utility, prior art,

common general knowledge, and so forth, as well as changes to compulsory licensing provisions and creating a research exemption to infringement. Indeed, it is my understanding that all of these issues are addressed as part of IP Australia's current reform agenda, and that an exposure draft of legislation that would amend the *Patents Act* to implement this agenda is currently being circulated for comment.

It would therefore be premature, and inconsistent with IP Australia's more expansive agenda (which has involved a long period of consultation with a range of key stakeholders) to amend the *Patents Act* in the manner proposed by this Bill.

**Conclusion**

It is my considered opinion that the amendments to the *Patents Act 1990* proposed by this Bill are not in the interests of stakeholders in the patent system, including inventors, medical and scientific researchers, public and industrial research institutions, and members of the general public.

Enactment of the Bill would result in a *Patents Act* that is more obscure and uncertain than is presently the case. It could result in unintended adverse consequences in respect of the important incentive to invest in research and innovation that is provided by the patent monopoly. Finally, it seeks to address a 'problem', the existence of which is not supported by substantive and credible evidence and which, if it does exist, is better dealt with by strengthening other aspects of the patent system, such as the tests of novelty and inventive step.

I urge the inquiry to recommend that the Senate not support the passage of this Bill.

Mark Summerfield

25 February 2011