Committee Secretary
Senate Legal and Constitutional Committee
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Parliament House
Canberra ACT 2600
Australia

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

Dear Senate Committee,

Thank you for the opportunity to comment on the Bill.

Synopsis

1. The *Patent Amendment (Human Genes and Biological Materials) Bill 2010* (the Bill) should be slightly amended to ensure that it explicitly includes methods of diagnostic testing, and then passed.
2. In the alternative, the Bill should be passed in its current form.

Rationale

1. Manipulated or non-manipulated genes, DNA, RNA, proteins and other biological materials are not inventions as they do not meet the test for 'methods of manufacture' within the meaning of section 6 of the *Statute of Monopolies* as required by Section 18 of the *Patents Act 1990 (Cth).*
2. The proposed Bill does not conflict with Australia's international obligations.

The case of *National Research Development Corporation v Commissioner of Patents* (1959) 102 CLR 252 (NRDC) is the leading decision in Australia for the test of whether an invention satisfies the manner of manufacture test within the meaning of section 6 of the *Statute of Monopolies*.[1] The High Court of Australia held that the

[1] Section 6 of the *Statute of Monopolies* provides that the declarations of invalidity contained in the preceding provisions of the Act "shall not extend to any letters patents and graunts of privilege…hereafter to be made of the sole working or makinge of any manner of new manufactures

meaning of Section 6 requires that the alleged invention satisfy a threshold requirement of inventiveness by being more than a mere new use of an old substance. In addition, the alleged invention is, or needs to achieve, an artificially created state of affairs of utility in a field of economic endeavour.

Although the Court in the NRDC case warned against taking a narrow interpretation of Section 6,[2] the court nevertheless agreed and quoted the following proposition:

"The statement was that fruit and other growing crops, although the assistance of man may be invoked for their planting and cultivation, do not result from a process which is a "manner of manufacture". This may be agreed. However advantageously man may alter the conditions of growth, the fruit is still not produced by his action."[3]

The court also expressed doubt, quoting the case of *Maeder v. Busch* (1938) 59 CLR that methods of surgery and other processes for treating diseases of the human body could come within the meaning of an invention.[4]

Based on the above statements of the court in the NRDC case, humans, plants and animals and their genetic material are not intended to come within the definition of an invention under Section 6 of the *Statute of Monopolies*.

Similar sentiments were expressed by the majority of the court in the *President & Fellows of Harvard College* v. *Canada (Commissioner of Patents)*, [2002] SCC 76 (the Harvard Mouse case). The Canadian Supreme Court held that higher life forms were not contemplated by the Canadian *Patent Act,* and provide a radical departure from the traditional patent regime. The majority also held that merely because an invention may be unanticipated and unforeseeable does not mean that it is necessarily patentable, and that the patenting of higher life forms raises serious practical, ethical and environmental concerns.[5] The minority tried to liken the oncogenic "cancer"

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within this realme, to the true and first inventor and inventors of such manufactures, which others at the tyme of makinge such letters patents and graunts shall not use, soe as alsoe they be not contrary to the lawe or mischievous to the state by raisinge prices of comodities at home, or hurt of trade, or generallie inconvenient": Halsbury's Statutes of England, 2nd ed. vol. 17 (1950), p. 619.

[2] *National Research Development Corporation v Commissioner of Patents* (1959) 102 CLR 252 at paragraph 15 http://www.austlii.edu.au/au/cases/cth/HCA/1959/67.html

[3] Ibid at para. 26.

[4] Ibid at paras. 15, 22.

[5] *President & Fellows of Harvard College* v. *Canada (Commissioner of Patents)*, [2002] SCC 76, pp. 5,6. http://scc.lexum.umontreal.ca/en/2002/2002scc76/2002scc76.html

mouse with moon rockets, antibiotics, telephones, e-mail or hand-held computers to claim that the mouse did fall within the meaning of the Canadian *Patent Act*.[6]

With respect, such reasoning is fallacious. Biological entities and their component parts, no matter how altered, were not invented by human beings. While all matter is ultimately perishable, the component parts of a rocket or a telephone, unlike a mouse or a palm tree, do not die. Rockets and telephones degenerate rather than perish. Indeed, it is the biological aspect of elements such as genes in biological entities that make such entities attractive for study and manipulation in the first place. A discovery, such as gene manipulation, combined with a separate discovery of gene manipulation in a particular entity such as a mouse or cancerous cells, do not alone nor together create an invention nor a method of manufacture. Equating perishable genes with the steam engine or a computer under the term "invention" is to give section 6 of the *Statute of Monopolies* too broad a meaning. Such a wide interpretation threatens to render the Section 18 of the *Patents Act 1990 (Cth)* uncertain or even meaningless. Passing the Bill will fill this lacuna.

In the alternative, I draw the Committee's attention to the 'markedly different' test from *Diamond, Commissioner of Patents and Trademarks v. Chakrabarty* 447 U.S. 303 (1980)[7] which was applied in the *Association For Molecular Pathology, Et Al., v. United States Patent And Trademark Office, Et Al*, (AMP v USPTO).

In *AMP v USPTO,* Justice Sweet held that isolated gene sequences are not markedly different from gene sequences as they exist in a human being. The unique quality of DNA is the physical embodiment of information and is preserved whether it is in or extracted from the human body.[8]

[6] Ibid, p.9.
[7] *Diamond, Commissioner of Patents and Trademarks v. Chakrabarty* 447 U.S. 303 (1980), p.310, http://digital-law-online.info/cases/206PQ193.htm.
[8] *Association For Molecular Pathology, Et Al., v. United States Patent And Trademark Office, Et Al,* No. 09 Civ. 4515 (RWS) ECF Case, pp.107,121,127 per Sweet J.

Australia's International Obligations

The proposed amendment to the Patents Act will not be in conflict with Australia's obligations under the World Trade Organisation Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).

- **Article 27.2:** Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.
- **Article 27.3:** Members may also exclude from patentability:
  diagnostic, therapeutic and surgical methods for the treatment of humans or animals; plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes.

Australia-United States Free Trade Agreement (AUSFTA) states:

Article 1.1 : General

2. The Parties affirm their existing rights and obligations with respect to each other under existing bilateral and multilateral agreements to which both Parties are party, including the WTO Agreement.[9]

Guide to the Agreement

17. Intellectual Property Rights

3. Further to Article 1.1.2 (General), the Parties affirm their rights and obligations with respect to each other under the TRIPS Agreement.[10]

[9] http://www.dfat.gov.au/fta/ausfta/final-text/chapter_1.html
[10] http://www.dfat.gov.au/fta/ausfta/final-text/chapter_17.html

Conclusion

Patent law is complex and perhaps in need of wide scale reform. Compared to the pace of law reform, biotechnology is moving quickly. As biotechnology has potentially many economic, social, environmental and health consequences, the best course of action would be for the Parliament to pass this current amendment as a safeguard against ad hoc developments by the courts. Passing this amendment will provide clarity for the law and encourage cooperation between researchers to reward scientific endeavour whilst ensuring public access to publically owned biological materials.