Ms Julie Dennett
Committee Secretary
Senate Standing Committee on Legal and Constitutional Affairs
PO Box 6100
Parliament House
Canberra ACT 2600
Australia

25 February 2011

Dear Ms Dennett

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

We wish to provide this submission to the Senate Standing Committee on Legal and Constitutional Affairs (***Committee***) in its inquiry on the Bill. This submission is made on behalf of both Griffith Hack and Griffith Hack Lawyers.

Griffith Hack is one of Australia's largest IP firms, comprising patent and trade marks attorneys, IP lawyers, information services, and IP & portfolio management consultants. We provide a full range of comprehensive IP services to many of the world's leading companies and research organisations across many industry sectors, including many clients that are involved in the patenting and commercialisation of inventions in biotechnology, pharmaceuticals and chemicals.

The Bill proposes:

(i) to replace the current manner of manufacture test of patentability in s.18(1)(a) and s.18(1A)(a) of the Patents Act 1990 with the words:

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

We oppose this amendment. The current wording in s.18(1)(a) and s.18(1A)(a) of the Patents Act has been the subject of substantial judicial consideration in Australia (including by the High Court). The amended wording proposed will only serve to create further uncertainty and the necessity for costly legal debate about the effect of the amended wording.

(ii) to exclude the patenting of the following under Australian law:

'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.'[1]

'Biological materials' are proposed to be defined as follows:

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

For the following reasons, we submit that the Bill should not be passed:

1. The Bill purports to be for the purpose of advancing '*medical and scientific research and the diagnosis, treatment and cure of human illness and disease by enabling doctors, clinicians and medical 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.*'[2] In his second reading speech, Senator Heffernan made reference to the often quoted example of the patents granted to Myriad Genetics Inc., in relation to the human genes BRCA 1 and BRCA 2, including diagnostic tests for these genes. It is clear that the motivation behind the Bill is to ensure that there is free and unfettered access to inventions for doctors, patients and medical researchers. We applaud this motivation. However, the Bill is misconceived in that it will not, if passed, achieve what its proponents intend. The Bill may well extend so far as to prevent the patenting of genes and other biological materials *per se* (not just human genetic material), but it will not prevent the patenting of diagnostic or treatment methods relating to such materials.[3] As an example, claims in Myriad Genetics' patent which relate to the methods of diagnosis of the BRCA 1 and BRCA 2 genes would still be patentable (assuming that all other criteria of patentability have been met).
2. Despite the title of the Bill purporting to be for '*human* genes and biological materials', nowhere within the Bill is there any limitation on the exclusion of patentability to biological materials derived from humans. On a plain reading, the proposed exclusion from patentability is capable of extending to biological material derived from any living organism, including humans, plants and animals – essentially *any* organic materials that fall within the definition of 'biological materials' could be excluded.
3. Senator Heffernan referred to the Bill as 'very narrow' and only seeking 'to clarify and apply existing patent law.'[4] With respect, the Bill is far reaching, not narrow. By way of example, the definition of biological materials is inclusive and could apply to more than the items listed in the definition. It could, for example, extend to organic

[1] New proposed subsection 18(2)(b) in Schedule 1 of the *Patent Amendment (Human Genes and Biological Materials) Bill 2010*.
[2] Draft Explanatory Memorandum for the Bill, page 2.
[3] This was also acknowledged by Senator Heffernan in his second reading speech; see Senate Hansard 24 November 2010, page 60.
[4] Senator Bill Heffernan, second reading speech, 24 November 2010, Senate Hansard, page 60.

chemicals of biological origin, such as secondary metabolites (including antibiotics) and carbohydrates.

4. The Bill is vague and unclear and of indeterminate scope. For example, what does the phrase '*identical or substantially identical*' mean? What is a component? What is a derivative? There is no guidance to the interpretation of these terms and phrase provided in the draft explanatory memorandum or the second reading speech. Further, there is no existing Australian legal authority which would assist in defining such terminology in a patent context. If the Bill were to be passed in its current form, it would likely lead to the necessity for costly litigation to be undertaken which may not result in clarity of the application of the statute (should it become law) for many years.

5. There has already been significant review and discussion of issues relating to the patentability of genes under Australian patent law or the effect of patenting on research and access to inventions. None of these reviews or reports recommended the banning of gene patents, nor of the broader concept of banning the patenting of biological materials.[5] Even the Australian Council on Intellectual Property's (***ACIP***) most recent report[6] recommended the retention of the existing exclusion in the Patents Act (preventing the patenting of human beings and the biological processes for their generation) but did not recommend any additional exclusions.

6. Amending the Patents Act as proposed will place Australia out of step with other jurisdictions, including important trade partners, such as Europe and the United States of America. It may also result in Australia being in breach of its obligations under certain international trade agreements.[7]

7. There are alternatives to the proposed Bill, using technology-neutral language, which will provide the outcomes desired by doctors, patients, medical researchers and others involved in research and development generally. These include the introduction of a provision to exempt patent infringement for experimental use of patented technology and clarification of the Crown use and compulsory licensing provisions of the Patents Act.[8]

Many proponents of the Bill will believe that, as patent attorneys and IP lawyers working in this field, our views are biased and that we are only interested in maintaining our clients' ability to obtain patent protection over inventions that those proponents believe should <u>*not*</u> be patentable.

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[5] See Australian Law Reform Commission's report '*Genes & ingenuity: gene patenting and human health*', June 2004; ACIP Report '*Crown use provisions for patents and designs*' November 2005; ACIP Report '*Consideration of patents and experimental use*', October 2005; Senate Community Affairs References Committee '*Gene Patents*', November 2010.

[6] Patentable Subject Matter, ACIP, 16 February 2011

[7] The Agreement on Trade-Related Aspects of Intellectual Property Rights 1994 (TRIPS) & Australia-US Free Trade Agreement 2004

[8] See the recommendations of the ALRC 2004 report and the Senate Committee 2010 report.

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On the contrary, we are of the view that it is in the interests of all parties seeking protection under the Australian Patents Act for there to be a clear understanding of what is and is not patentable. The proposed exclusion of biological materials from patentability, as proposed in the Bill, is not clear. If the exclusion were to be introduced, there will be many millions of dollars wasted on patent attorney and lawyers' fees debating the interpretation of the exclusion, money that would be better spent on research and commercialisation.

Yours faithfully
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