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

24 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* (The Bill)

I wish to provide this submission to the Senate Standing Committee on Legal and Constitutional Affairs (The Committee) in its inquiry on the Bill.

I ask the Committee to consider this submission in the context of the effects that the Bill (if passed in its current form) would have on the Australian biotechnology and pharmaceutical industries.

The Bill proposes to exclude under Australian law the patenting of:

> "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."

The text of the bill bans biological materials *per se*; the word "including" and the materials listed thereafter merely provide examples of biological materials, but in no way is limited to those examples.

In my view, the effects of this ban on the patenting of biological materials would be extremely broad, and may have some serious consequences for continued research and development and other operations in Australia.

Much of the argument in support of the Bill has focussed on improved access to healthcare. Fundamentally, the argument is flawed because it is based on hindsight. In other words, the argument is based in the present with the knowledge that a medicament or diagnostic exists. However, if the Bill passes, developers of medicaments and diagnostics, many of which are based on biological materials, will not be able to seek and obtain patent protection for their research. Without a patent, a developer of medicaments and diagnostics will not be able to attract and retain investment for both basic research and commercialisation activities. As such, it is likely that new medicaments and diagnostics will never come into existence in Australia. Similarly, if new medicaments and diagnostics are developed elsewhere, it is unlikely that they will be marketed in Australia, because there will be no means for protecting the developer's investment. Consequently, the effect on access to healthcare will actually be detrimental, rather than beneficial.

Medicaments and diagnostics often cost hundreds of millions of dollars to bring to market. Without patent protection for biological materials, the Government will need to pay for research and development, or it will need to pay to manufacture medicaments and diagnostics that have been developed elsewhere and are not marketed in Australia. The Government of all stakeholders must understand that this is the role of the biotechnology and pharmaceutical industries; it is not the role of the Government.

Therefore, it is not in the national interest to preclude patent protection for biological materials.

In addition, I consider that it is inappropriate to amend the *Patents Act 1990* (the Act) with specific reference to one technology. Any amendment to improve the Act (which the Bill does not do) should be technology-neutral. Technology-neutral recommendations have been made by the Australian Law Reform Commission, *Genes and Ingenuity: Gene Patenting and Human Health*, Report No 99 (2004) (the ALRC Report) and the Advisory Council on Intellectual Property, Patentable Subject Matter, Final Report (2010) (the ACIP Report).

In particular, the ACIP Report recommends that ethical considerations be dealt with by amending the Act to exclude from patentability any invention, the commercial exploitation of which would be wholly offensive to the ordinary reasonable and fully informed member of the Australian public. In my opinion, discussion of the Bill has been surrounded by misinformation and emotion, not by facts and reason. I consider that the ordinary reasonable and fully informed member of the Australian public would not be wholly offended by the commercial exploitation of biological materials. As a trite example, this member of the Australian public would not be offended by laundry detergent – laundry detergent commonly incorporates enzymes, which are biological materials and would be excluded from patentability if the Bill is passed.

Submission
For the reasons outlined above, I strongly urge the Committee to reject the proposed amendment to the *Patents Act 1990* as provided by the Bill.

As an alternative, I urge the Committee to review and consider the recommendations of the ALRC Report and the ACIP Report.

Yours faithfully

Dr Malcolm Lyons
Patent Attorney