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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 (*Bill*)

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

We ask the Committee to consider our submission in the context of the effects that the Bill (if passed in its current form) would have on our company's business, and on the Australian biotechnology and pharmaceutical industries more generally.

The Bill proposes 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.'*

In our view, the effects of this ban on the patenting of biological materials would be extremely broad, and may have some serious consequences for our company's continued research and development and other operations in Australia, as outlined in more detail below.

Biomedical Consulting Services – background and technology

Biomedical Consulting Services (BCS) specialises in expert IP, commercialisation, and technology licensing services to industry as well as publicly-funded research institutions, Area Health Services, universities, etc...
With more than 17 years as a scientist having worked in the USA, Australia, and Venezuela, Dr Alfredo Martinez-Coll (Director of BCS) has particular expertise around patent issues related to stem cells and genetic technologies, vaccines, and medical devices.

BCS's current patent position

Our company has advised and managed IP for several clients in the Life Sciences sector, some with several granted Australian patents and at least 20 Australian patent applications containing claims which could potentially fall within the broad wording of the proposed ban on patentability outlined in the Bill.

Specifically, our client's patents and patent applications include claims in relation to genetic biomarkers for risk factors for obesity and diabetes and associated therapeutic targets, genetic screening methods for gene amplification, gene clusters for cytotoxic cyanobacteria engineered cell lines for various types of cancer, induced pluripotent stem cell lines for Alzheimer's Disease, viral polypeptides for HIV, potential peptide-based diagnostics and vaccines for inflammation, polypeptide fragments for H pylori, antibodies to regulate gene expression, polymerases, proteins, novel interferon stimulated gene therapies for hepatitis C virus, YY1 gene therapy for the prevention of restenosis, DNAzymes targeting c-Jun for basal cell carcinoma, rheumatoid arthritis, age-related macular degeneration, diabetic retinopathy, and cell therapies for ocular regeneration, methods for producing secondary metabolites through engineered repeat modules of various non ribosomal peptide synthetases (NRPS), genetic determinants of actuate sickness response to infection, diagnostic biomarker for motor neuron disease, gene-mediated production of clean renewable biodiesel from yeast and algae, etc...

Potential effect of Bill on BCS

If passed in its current form, the Bill may have serious consequences for the operation of BCS's business.

Patents are key assets to manage for BCS, and if prevented from seeking and obtaining protection for its research by way of a patent, this could potentially have the following consequences:

- inability to attract and retain investors with significant impact on the ability to spin off technology companies from the university
- inability to continue research in the area due to lack of funding and inability to protect the results of research
- potential loss of international collaborators
- potential loss of ARC Linkage grant revenue due to inability to protect Project IP
- loss of key revenue from licensing of patented technology
- significant impact on the ability to "transfer" technology out of the

university
- § significant impact on the further development of technologies arising out of the Faculty of Medicine its associated Research Institutes, Centres, and Hospitals
- § inability to attract and retain high-quality scientists to universities who are interested in solving real-world problems

Submission

For the reasons outlined above, we strongly urge the Committee to reject the proposed amendment to the *Patents Act 1990.*

As an alternative, we urge the Committee to review and consider the recommendations of the Australian Law Reform Commission's report on gene patenting and human health from 2004.

Yours faithfully

Dr Alfredo Martinez-Coll
Director, Biomedical Consulting Services