GROUP OF EIGHT

The Group of Eight Limited
ACN 089 687 990

PO Box 6229
O'Connor ACT 2602

Level 2, Group of Eight House
101 Northbourne Avenue
Turner ACT 2612

Tel +61 (0)2 6239 5488
Fax +61 (0)2 6239 5808

www.go8.edu.au

24 February 2011

Secretary
Legal and Constitutional Affairs Legislation Committee
Parliament House
CANBERRA ACT 2600

Dear Secretary

Re: Inquiry into Patent Amendment (Human Genes and Biological Materials) Bill 2010

The Group of Eight universities strongly support the distinction between discovery and invention and accept that discoveries, whether of the laws of nature or natural substances, are not patentable. They believe that this distinction is clear from the current wording of the Patents Act 1990 and believe that the Patent Amendment (Human Genes and Biological Materials) Bill 2010 is unnecessary.

The current Patents Act 1990 specifies that a patentable invention has to be: a manner of manufacture, novel, involve an inventive step and useful. While the requirement to be a manner of manufacture within the meaning of section 6 of the Statute of Monopolies 1623 can be open to a wide interpretation, the requirement for an inventive step should be sufficient to ensure that discoveries cannot be the subject of granted patents. Identifying the DNA sequence of a particular gene no longer involves an inventive step and such a sequence is, by itself, without a use. We believe that separately proposed amendments to the Patent Act (currently the subject of stakeholder consultation) and which will require the disclosure of a specific, substantial and credible use for the invention will reinforce this position.

The amendments proposed in the Bill extend beyond a more explicit prohibition on patenting discoveries to prohibit certain classes of inventions. This is because the proposed amendments to the Patents Act expressly exclude from patentability "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". Designing and creating derivatives of biological materials can involve significant research and major inventive steps. Tweaking natural materials in this way can lead to critical advances in medicine as the derivative compounds can be more efficacious than the natural compounds.

Particularly in the case of designer drugs, it is not sufficient to be able to patent the process that produces the derivative compound. The major intellectual contribution may have been in understanding the basis of its functionality and working out how to improve this, with the production process involving standard techniques. Moreover, the investment necessary to carry the compound through the regulatory system relates to the material itself, not to the process that produced it; and as the benefits arise from the compound, not from its production

process, an inability to patent the material opens up the possibility of others inventing around the process to benefit from the design work on the compound.

If it becomes impossible to patent such derivatives because of their similarity to a naturally occurring substance, then the research aimed at producing such improvements is likely to stop, especially given the frequently high cost of such research and the cost of seeking regulatory approvals. Attracting funding from industry for medical research would become much more difficult if the Patents Act did not provide the incentive of being able to achieve a time-limited monopoly on the use of that research.

As a separate case, it is not inconceivable that research aimed at designing a drug to interfere within a particular physiological process might independently create a compound that is later found to be naturally occurring. Invention can also lead to the development of novel uses of biological materials which go beyond the uses that one might anticipate from their natural functions. Again, the inability to seek a patent for these materials would have the potential to stifle inventive activity and decrease innovation.

More generally, the scope of the 'biological materials' definition in the proposed amendments is unclear and extremely broad. Adopting such a definition would lead to uncertainty about the law in Australia that would itself discourage investment.

Any move to change the patent legislation to make it more restrictive than that of other countries could disadvantage Australian universities compared to their overseas counterparts. Such a move would also inhibit biotechnology and pharmaceutical companies from performing research in Australia and potentially lead to them moving offshore.

There is no evidence that the amendments proposed by the Bill would achieve its stated objectives of advancing medical research or the diagnosis, treatment and cure of disease. Patenting is a form of publication which can itself promote research by making what otherwise might be proprietary. A robust research exemption provision in the Patents Act would facilitate the free conduct of research much more effectively than making it impossible to patent certain categories of invention.

We also note that on 16 February 2011, ACIP released its report on patentable subject matter, which supports the position we present in this submission. In particular, ACIP has recommended the government maintain the current exclusion from patentability of human beings and biological processes for their generation – but not introduce any further specific exclusions. Other relevant recommendations are that the government codify the established principles of patentability – so that an invention must be an artificially created state of affairs in the field of economic endeavour; and introduce a general exclusion from patentability of inventions whose commercial exploitation would be wholly offensive to the Australian public. (ACIP expect that the use of such an exclusion would be extremely rare.)

For these reasons the Group of Eight believe that the proposed amendments are unnecessary and have the potential to harm the effective operation of Australia's national innovation system.

Kind regards

Michael Gallagher
Executive Director