KATRINA HOWARD SC

28 April 2011

Ms Julie Dennett
The Committee Secretary
Senate Legal and Constitutional Committees

Dear Secretary

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

I wish to make the following brief submissions in relation to the Bill.

I first became aware of the issue of gene patenting in the early 1990s. At the time, I was junior counsel briefed on behalf of Murex in its challenge to the Chiron patent relating to the hepatitis C virus. The question of whether an isolated or purified gene is patentable subject matter was pleaded in that case, however, the issue was never ventilated, as the case settled before submissions. Around that time, there was also a proposal to amend the legislation (by Natasha Stott-Despoja).

Nearly 15 years later, it is somewhat surprising that the issue is still being debated in Australia, with yet another bill being introduced, when the technology in question has been available since the mid-1980s. In the meantime, industry, the Australian Patent Office and the patent profession have proceeded on the basis that gene patents are *prima facie* patentable, as is any other invention, provided that the requirements of the Patents Act, 1990, are met. There can be no doubt that if there is no patent protection for a particular technology in Australia (including isolated gene sequences), research and investment will be driven off-shore, to jurisdictions in which patent protection is provided.

In 1995, I presented a paper to the Intellectual Property Society Conference, in which I expressed my concern that isolated genes may not satisfy the requirements of the legislation (in terms of inventive step). Given this possibility, I proposed a *sui generis* sequencing right to protect isolated gene sequences. I **attach** a copy of my 1995 paper. If the proposed Bill were passed, it may be that such a right could provide a solution with respect to isolated gene sequences. Otherwise, it would be illogical if a plant variety, which comprises gene sequences, is capable of protection under the *Plant Varieties Act*, yet other gene sequences would have no protection at all.

The current Bill goes further than the previous bill, in seeking to exclude biological material as well as gene sequences. I commend to you the paper by Vaughan Barlow entitled *"Mumbo jumbo: The patentability of biological materials in Australia"*, which discusses the particular issues raised by the proposed bill, a copy of which is **attached**.

Finally, I raise for consideration whether the bill, if enacted, would be valid.

Section 18(2) excludes human beings from patentability, which are plainly outside the concept of "invention" as it was understood in 1900. But the proposed exclusions in the Bill go far beyond this, by seeking to exclude things that are plainly within the concept of "invention" as it was understood in 1900.

The relevant head of power in the Constitution is section 51(xviii), which empowers the Parliament, subject to the Constitution, to make laws for the peace, order and good government of the Commonwealth with respect to: "Copyrights, **patents of inventions** and designs, and trade marks".

The High Court considered this head of power in the Constitution in *Grain Pool of WA v Commonwealth* (2000) 202 CLR 202 CLR 479. I strongly recommend that the members of the Committee read this important unanimous decision of all members then sitting in the High Court. It is of fundamental importance in any debate on the patentability of genetic and biological material.

The High Court held that "there is no intrinsic impediment to the patentability of plant varieties" (at [46]). *A fortiori*, there is no intrinsic impediment to the patentability of gene sequences, or biological materials. Further, the High Court held that "a new plant variety" is an "invention in the constitutional sense" (at [75]). Gene sequences and biological materials (that are novel and inventive) are also "inventions in the constitutional sense".

The introduction of an impediment by the proposed Bill to patentability of gene sequences and biological material would be inconsistent with the purpose of the present legislation (enacted pursuant to the power provided in s 51(xviii) of the Constitution), to provide for patentability of inventions which fall within the concept of "patents for inventions" as provided in the Constitution.

Therefore, there may be an argument that to carve out from the meaning of

"invention" a particular technology that otherwise falls within the concept of "invention" as it was understood in 1900 is beyond the legislative power of the Commonwealth.

Yours sincerely

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