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April 2, 2009

The Hon. Senator Claire Moore  
Chair  
Senate Community Affairs Committee  
Parliament House  
CANBERRA ACT 2600

Dear Senator Moore

### **Inquiry into Gene Patents**

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During the Committee's hearing on March 19, Senators Bilyk and Heffernan put questions to me with respect to which I was given leave to take on notice and to provide written answers. I now do so.

#### **Senator Bilyk**

At page 34 of the Hansard transcript I was asked this question by Senator Bilyk:

"I have a technical question. Are there definitions for innovation, discovery and speculative patents? Are there definitions within the patent process of those areas, do you know?"

There are no definitions of these words in the *Patents Act, 1990 (Cwth)*.

#### **'discovery'**

In patent law the word 'discovery' is understood to describe something that is not an 'invention'. Thus the discovery of a naturally occurring thing, something that occurs in nature, is not an 'invention'. The distinction between 'discovery' and 'invention' is fundamental because unless something is an 'invention' it cannot be the subject of a patent monopoly. This has been a policy of patent law from the very beginning which, for the purposes of Australian patent law, starts with the *Statute of Monopolies, 1623*. Similarly, patent law in the United States has been influenced by this same policy. In the landmark case of *Diamond v Chakrabarty* (1980) the US Supreme Court decided that a genetically modified bacterium which was capable of degrading crude oil was sufficiently different to the naturally occurring bacterium to be considered to be an 'invention'. What made the bacterium in that case sufficiently different to be considered an 'invention' was not merely that it had been subjected to human manipulation, namely, genetically modified, but that it performed a function which no naturally occurring bacterium could perform – it degraded crude oil.

In *Diamond v Chakrabarty*, the Chief Justice, the author of the decision, wrote:

The laws of nature, physical phenomena, and abstract ideas have been held not patentable. ... Thus, a new mineral discovered in the earth or a new plant found in the wild is not patentable subject matter. ... Such discoveries are "manifestations of . . . nature, free to all men and reserved exclusively to none." ... Judged in this light, respondent's micro-organism plainly qualifies as patentable subject matter. His claim is not to a hitherto unknown natural phenomenon, but to a *nonnaturally occurring* manufacture or *composition of matter* -- a product of human ingenuity "*having a distinctive name, character [and] use.*"

In the context of this Inquiry, the act of isolation (of a naturally occurring biological material, whether it be a human gene or the genetic material of a virus, plant or animal or some other naturally occurring substance) is not the kind of human intervention that can turn a naturally occurring biological material sufficiently into something that can be regarded to be an 'invention'. There are three reasons for this. First, merely isolating something from its natural environment does not change what it is. It only changes the state that it's in. Secondly, the functionality of the isolated biological material is not changed. It remains the same. It performs the same function as it does in nature. Thirdly, unlike a bacterium, which is a complete organism that is capable of functioning independently, genetic materials such as a human gene, are carriers of information (the genetic code) that will be processed by the human body to synthesise a protein. Not only are genes unable to function independently, but they can serve no other function other than to carry the specific information that nature designed them to carry.

#### 'innovation'

It must be understood that not everything that is capable of being considered to be an 'invention', for instance, something like a light bulb, a telephone, a microscope etc, is a 'patentable invention'.

There is a distinction in patent law between an 'invention' on the one hand and a 'patentable invention' on the other. That distinction implies that not every invention displays a sufficient level of 'innovation' to satisfy the thresholds in the *Patents Act, 1990*, namely, novelty, inventive step and industrial applicability. Therefore unless the 'invention' is also new, inventive and useful in a practical way (and these thresholds are defined in the legislation), it is not innovative enough to be the subject of a patent monopoly.

#### 'speculative patents'

The social contract which exists between the State and an inventor requires the inventor to make a full disclosure of what the invention is as well as defining the invention, which also defines the legal boundaries of the patent monopoly, in such a way as to not overreach. In other words, it is tantamount to fraud for an inventor to seek a patent monopoly from the State for an invention that does not work across the full breadth of the scope of that monopoly.

The public policy is clear. To the extent that an inventor is entitled to a patent monopoly, it is incumbent upon the inventor not to seek a patent monopoly for more than he or she has invented.

For example, for an inventor to claim to have invented a vaccine that is capable of preventing a human from hepatitis C virus infection, means that the patent should disclose sufficient information that would enable a person of ordinary skill in the relevant technology to make the invention without the need for undue experimentation.

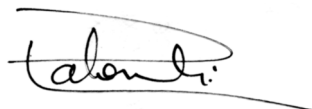
Thus a patent granted over an 'invention' such as a HCV vaccine is 'speculative' in the sense that the vaccine does not work, has not been made or is incapable of being made on the basis of the disclosure in the patent document.

In the context of this Inquiry, it is common place for patents to claim isolated biological materials as inventions. These patents will also claim the use of these materials in various applications, such as diagnostics, medicines, treatments and cures, as separate inventions. The assumption is, that knowledge of the biological material is all that a person of ordinary skill in the relevant technology needs to know in order to make the inventions that fall within the scope of the patent monopoly. This is, unfortunately, not always the case. The example that I give of Chiron claiming to have invented a HCV vaccine shows how easy it is for patents to be granted when there is, indeed, no such invention. In fact, even today there is no HCV vaccine.

### **Senator Heffernan**

At page 37 of the Hansard transcript there is a reference to Senator Heffernan providing me with 'a number of other questions'. I have not received these questions. If you or the Committee Secretariat could be so kind as to provide these questions to me I will endeavour to answer them.

Yours sincerely,

A handwritten signature in black ink, appearing to read 'Luigi Palombi', with a long horizontal flourish extending to the right.

Luigi Palombi LL.B, B.Ec (Adel), Ph.D (UNSW)