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SUBMISSION 3

Wednesday, 25 May 2011

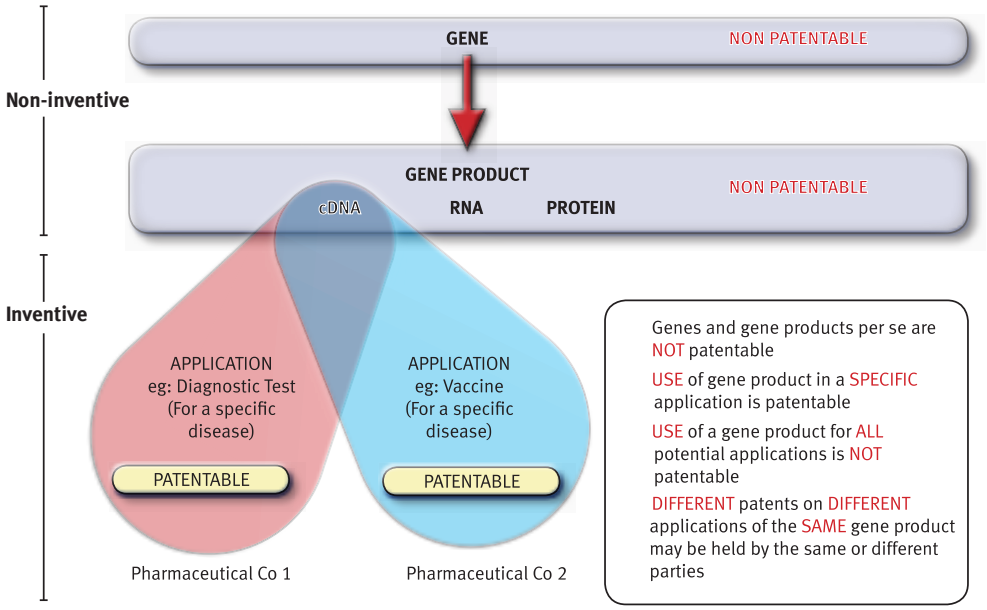
Ms Julie Dennett
Committee Secretary
Senate Standing Committee on Legal and Constitutional Affairs
Parliament House
CANBERRA 2600

Dear Ms Dennett

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

I am writing to provide the Committee with further information in response to matters raised during the public hearings held on August 28 and 29, 2011.

First, is Senator Crossin's concerns over this table (August 29, pages 21-22 Hansard):



This table shows that a human gene and its related products, such as DNA, RNA and protein, in an isolated form, are not patentable subject matter. However, the use of such biological materials, which are identical or substantially identical (i.e., immaterially different) to what exists in nature, in various applications, such as, biotechnological processes, diagnostic genetic tests and medicines e.g., vaccines, are patentable subject matter.

The table therefore shows how the Bill in section 18(2)(b) distinguishes between the biological materials per se (which are not invented) and the use of those materials, as components, in industrial processes or medical or scientific products. The former are excluded from patentability by section 18(2)(b). The latter are not.

Secondly, certain recently granted Australian patents have come to light which provide an answer to the concerns expressed in various submissions and in evidence to the Committee during the public hearings over the "broad" language of the Bill. These patents, some of which have already been referred to the Committee during the public hearings on August 28 and 29, have been granted since 2005 with the majority of them granted in 2008 and 2009.

They include the following:

1. **AU 2000035719** entitled "Schizophrenia associated genes, proteins and biallelic markers"; sealed 19/5/2005; expiring 30/3/2020.
2. **AU 2001017265** entitled "Full-length human cDNAs encoding potentially secreted proteins"; sealed 20/7/2006; expiring 12/7/2020.
3. **AU 2002343671** entitled "Type 2 cytokine receptor and nucleic acids encoding same"; sealed 18/6/2009; expiring 12 November 2022.
4. **AU 2003267943** entitled "Novel Flavivirus antigens"; sealed 7/5/2009; expiring 26/2/2026.
5. **AU 2004230485** entitled "The severe acute respiratory syndrome coronavirus"; sealed 7/5/2009; expiring 9/4/2024.

The range of expiry dates for these 5 patents is 30/3/2020 to 26/2/2026.

The claims, which defined the scope of the patent monopolies, include the following:

1. **AU 2000035719**: Claim 1: "An isolated, purified or recombinant polynucleotide or the complement thereof selected from the group consisting of: ... (d) an isolated polynucleotide comprising a polynucleotide have at least 70% identity with any of the polynucleotide sequences of SEQ ID No. 2 to 26; ...";
2. **AU 2001017265**: Claim 1: "An isolated polypeptide comprising: ... b) an amino acid sequence being at least 98% or 99% identical to SEQ ID NO: 399; c) an amino acid sequence being at least 98% or 99% identical to a polypeptide encoded by the clone insert of Clone 160-40-1-0-H4-Cs in ATCC accession number PTA-1218 ...";
3. **AU 2002343671**: Claim 1: "An isolated polypeptide consisting of an amino acid sequence at least 85% homolgous to amino acids 21-230 of SEQ ID NO: 2.";
4. **AU 2003267943**: Claim 1: "A recombinant or synthetic polypeptide comprising an amino acid sequence that has at least 90% amino acid sequence identity to at least one amino acid sequence selected from the group of SEQ ID NOS: 66, 69, 89, 93, 108, and 110."; and,
5. **AU 2004230485**: Claim 1: "An isolated polypeptide of the severe acute respiratory syndrome (SARS) virus, wherein the polypeptide comprises a SARS virus Spike (S) polypeptide or a functional fragment thereof;

   Claim 9: "An isolated or purified or recombinant nucleic acid encoding the polypeptide of any one of claims 1 to 8;

   Claim 11: "A polynucleotide comprising a nucleotide sequences having greater than 80% sequence identity to the nucleic acid of claim 9 or claim 10."

The point being that each of these claims define the respective biological materials, not by sequence to the *identical* natural biological material, but by homology ranging from as low as 70% to as high as 99%. In other words, the claims are to biological materials that are "substantially identical" to what exist in nature.

Consequently, if the language of the Bill deletes reference to "substantially identical" these claims will not be caught by the prohibition and will continue to be granted by IP Australia.

More troubling, however, is the recent discovery that IP Australia has granted a patent to Amgen over a biological materials which is a research tool vital to any medical or scientific research directed to the study of osteoporosis and its potential treatment.

Details of this Australian patent are:

AU 2003203661 entitled "Mammals Lacking Expression of Osteoprotegerin"; sealed 3/5/2007; expiring 23/9/2018.

This patent claims, as an invention, the following:

Claim 1: “A non-human mammal comprising the gene encoding OPG wherein one allele of the gene has been disrupted by insertion of a marker sequence".

OPG means the protein osteoprotegerin, a naturally occurring biological material.

This is a claim to *all* non-human mammals which have been genetically modified so that they do not express the protein osteoprotegerin. This is a claim to a genetically modified organism. The organism can be a mouse, rat, hamster, cat, dog, primate etc etc. The only difference between these animals and a normal animal is the inactivation of the gene which permits the animal to express this protein. Therefore, it is a claim to a biological material (in its broadest sense) but which is not identical to what exists in nature.

This raises a moral issue. Should a genetically modified animal, such as a dog, be patented under Australian patent law? To my mind the idea is absurd and is offensive in that human beings are also mammals. The point being how and where does one draw the line between mammals?

Regardless, patents like this one are a problem because they prevent use of the patented biological materials by others that may wish to make an alternative medicine to Amgen’s Prolia[1] or that may wish to develop an alternative process for the manufacture of Prolia or an alternative to it. Additionally, the patents on the research tools themselves create a further barrier to fair competitive behaviour in that they prohibit the use of these biological materials in a research environment.

These kinds of patents are more like land mines surround the patent over Prolia or its ingredients.

They pose a serious threat to innovation in the field of medicine and undermine one of objectives of the patent system which is to require disclosure so as to enable third parties to use that disclosure for the purposes of inventing around the patented invention. Innovation happens because the disclosure is supposed to spurs others onto developing product improvements or cheaper and more efficient processes to manufacture the same or improved product. And patents prevent this happening they stifle, not encourage, innovation.

The relevant question in terms of the impact of the Bill is this: Are these underlying biological materials identical (or immaterially different) to what exists in nature?

If they are, the Bill, if passed, will prevent their patenting but only in the future (as there is no retrospective effect). If they are not, however, the Bill will not prevent their patenting. This then raises the further issue of what to do about these kinds of patents. Clearly, if the relevant biological materials are modified and have a practical application then the are likely to meet the patentable subject matter threshold. Yet, they are clearly problematic for the reasons already given.

Accordingly, there is a further need to look at reforming other aspects of the patent system, but short of banning these kinds of patents there presently appears no obvious workable solution. We know that compulsory licensing and Crown Use are very rarely, if at all, used in Australia. We also know that the proposed research exemption is narrow and will not immunise commercially directed research from the threat of patent infringement. Moreover, both TRIPS and the AUSFTA restrict the ability of an Australian government to use compulsory licensing and/or Crown Use as policy instruments.

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[1]Prolia has been registered in Australia: http://www.health.gov.au/internet/main/publishing.nsf/Content/pbac-psd-Denosumab-july10

Declaration of Interest

I wish to declare to the Committee that I have no interest, direct or indirect, financial or otherwise, in the subject of this Inquiry or in its results. Neither I, nor any member of my direct family, nor any corporate vehicle in which my direct family owns or controls, has any shares in any biotechnology company or has any interest in any organisation that may directly or indirectly benefit from patents of the kind which may be impacted by the Bill (should it become law). I am not a member of a patent attorney firm nor do I have any interest, actual or contingent, of any kind in such firms. Indeed, I have nothing to fear nor favour from the Bill nor the outcome of this Inquiry.

Yours sincerely,

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