28 February 2011

Committee Secretary
Senate Legal and Constitutional Committee
PO Box 6100
Parliament House
Canberra ACT 2600
Australia

Re Proposed Amendments to the Patents Act 1990

Dear Sir/Madam,

I write in response to requests for submissions relating to the private Senator's Bill (the bill) to amend Section 18 of the **Patents Act 1990 (Clth)**. I write as a clinician scientist whose public record comments on the issues surrounding the Myriad genetics patents on gene sequences relating to breast cancer have been used by others as a justification for the proposed amendments to the Patents Act 1990 that would follow if the bill were enacted.

In my opinion, the bill goes much further in intent than simply to prevent the issue I perceived with the Myriad genetics patents. This related to patenting of gene sequences already existing in nature in such a way that they could be tested for using existing methodology under patent protection, and therefore only with a licence from the patent holder, which seemed inconsistent with the current Patent Act.

The amended Bill is intended to prevent the patenting of human genes and biological materials, including DNA, RNA, protein, cells and fluid, which are identical or substantially identical to such material as they exist in nature. This intent is much broader that would be necessary to obviate my concerns with the Myriad genetics patents.

The explanatory memorandum to the Bill suggests that its purpose is to advance medical and scientific research and the diagnosis, treatment and cure of human illness and disease by expressly excluding from patentability biological materials which are identical or substantially identical to such materials as exist in nature, however made. I comment as an active participant in the biotechnology industry through two companies on which I sit as director and scientific advisor. The bill if enacted would actually prevent much development of novel products of biomedical research. It would remove much of the patent protection that currently can be granted to the inventor of a method of manufacture of a material that is "substantially identical" to something that exists in nature, but could not be manufactured without a novel and inventive method, and which once manufactured would be of potential utility in industry or in health care. By way of example, the papillomavirus vaccines currently in use are based on a material, virus like particles, which might easily be construed to be "substantially identical" to something that exists in nature, defective HPV virions. In consequence, the patents relating to method of manufacture held with me as named inventor would, so far as I can determine, not be grantable under the proposed legislation. A method of use patent might protect the product's use in Australia but would not

prevent manufacture in Australia, of the product using the methodology we developed, for use overseas, or manufacture of the same product by a different technology.

One consequences of the enactment of the bill would be to provide yet one more incentive for Australia's biomedical research talent, and biotech industry to move overseas.

Yours Sincerely

Ian Frazer