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The Secretary
Senate Community Affairs Committee
PO Box 6100
Parliament House
Canberra ACT 2600

20 August 2009

Re: Inquiry into Gene Patents

Thank you for the opportunity to make a submission to this important inquiry. I note the many interesting and informative submissions already before the Committee.

Cases prompting concern

Genetic Technologies¹

My concern about this issue initially arose from last year's incident involving a Melbourne company, Genetic Technologies, ordering Australian hospital laboratories to stop testing for breast cancer, as it claimed such testing infringed the licence it had obtained from the US company, Myriad Genetics, in relation to the breast cancer gene. The company only backed down from its threats to Australian hospitals as a result of the public outcry.

Myriad Genetics²

I note further that the US Patents Office's decision to grant a patent on breast and ovarian cancer genes to Myriad Genetics is being challenged in the United States. The plaintiff, Ms Genae Girard, supported by the American Council of Civil Liberties and others, is taking the action because she was not able to get a second opinion on a positive genetic test for ovarian cancer as there is only one test and one company, Myriad Genetics, which owns the rights to the relevant tests, for which Myriad charges US\$3,000 per test.

Bionomics – Genetic Technologies

As noted by Dr Luigi Palombi in part two of his detailed submission to the inquiry³, the company Bionomics was granted a wide-ranging patent over the epilepsy gene when most of the research leading to the patent application had been carried out in publicly funded institutions such as the University of Melbourne and the University of Adelaide's Department of Paediatrics at the Women and Children's Hospital, and when the company had also received a federal R&D grant to identify

1 <http://www.smh.com.au/text/articles/2009/05/13/1241894047270.html>

2 <http://www.smh.com.au/text/articles/2009/05/13/1241894047270.html>

3 pp 47-51

- Attadale
- Atwell
- Aubin Grove
- Banjup
- Beaconsfield
- Beeliam
- Bibra Lake
- Bicton
- Cockburn Central
- Coogee
- Coolbellup
- East Fremantle
- Fremantle
- Hamilton Hill
- Hammond Park
- Henderson
- Hilton
- Jandakot
- Kardinya
- Munster
- North Coogee
- North Fremantle
- North Lake
- O'Connor
- Palmyra
- Rottneest Island
- Samson
- South Fremantle
- South Lake
- Spearwood
- Success
- Wattleup
- White Gum Valley
- Willagee
- Yangebup

the gene. Bionomics' patent was then exclusively licensed to Genetic Technologies. A story last November by the *Sydney Morning Herald's* medical editor Julie Robotham entitled 'Sick babies denied treatment in DNA row' quoted the head of neurology at Sydney's Westmead Hospital stating that, "he would test at least 50 percent more infants for the SCN1A gene – which would diagnose the disabling Dravet syndrome – if the hospital could conduct the test in-house." The article went on to note that "rights to the gene are controlled by the Melbourne-based Genetic Technologies, which has already threatened to stop public hospitals testing for breast cancer gene mutations, and the hospital will not risk a similar problem. Specialists are sending blood samples to Scotland, and only babies whose seizure patterns closely resemble Dravet syndrome are tested. This means children with slightly different symptoms may be treated with the wrong medicines for months, potentially retarding their development."⁴

Comment

These cases indicate a creeping and inappropriate privatisation of knowledge about the human body, and its chilling effect on research and testing for cancers and other diseases. By 2005 more than 20% of human genes had been patented in the US.⁵ I do not know what the figure is now but I surmise that it will not be long before knowledge about every part of the human body is controlled by corporations.

In my view the practice of granting patents over human genes is wrong both in law and as a matter of public policy for the following reasons.

1. A patent can only be granted over an invention: s18 Patents Act 1990.

Genes are not inventions and should therefore not be patentable under the *Patents Act*. Genes are biological material occurring as natural phenomena in the human body. A gene does not constitute an invention simply because it is discovered and isolated. No-one invents a gene or a gene mutation.

The excellent submission by the CWA of NSW to this inquiry notes Professor Guy Maddern of the Royal Australasian College of Surgeons' opposition to the granting of patents over human genes and quotes him stating, "it is not an invention worthy of a patent but a discovery [...] no worthier of a patent than a recently discovered species of animal or plant."⁶

Similarly, in Dr Palombi's answers to questions on notice from Senator the Hon Bill Heffernan following the gene patent inquiry hearing on 19 March 2009, Dr Palombi refers to a decision of the UK Court of Appeal in the 1989 *Genentech's Patent case*, where the court held that the claims to isolated biological materials were not inventions. Mustill LJ said in his decision: "... the success of Genentech lay, not in the invention of a new substance – for protein molecules with the amino-acid sequences shown in figure 5 and the functional characteristics set out in the specification have existed since far into the distant past – but in the accomplishment for the first time of a method of creating that substance."⁷

It is of course right that new methods, processes and treatments meeting the criteria of an invention should be patentable. What should not be patentable is the underlying genetic material, since that material self-evidently exists in nature and has not been invented. As noted by the Australian Medical Association in its submission to the inquiry, "the holding of patents should not infringe the principle that the human genome is the common heritage of humanity."⁸

4 <http://www.smh.com.au/news/national/sick-babies-denied-treatment-in-dna-row/2008/11/28/1227491827171.html>

5 http://news.nationalgeographic.com/news/2005/10/1013_051013_gene_patent.html

6 http://www.aph.gov.au/senate/committee/clac_ctte/gene_patents/submissions/sub35.pdf

7 Dr Palombi Answer to Question 2, p3

http://www.aph.gov.au/senate/committee/clac_ctte/gene_patents/submissions/sub04c.pdf

8 http://aph.gov.au/senate/committee/clac_ctte/gene_patents/submissions/sub07.pdf

2. Gene patents limit rather than promote research and development.

It is suggested by some that gene patents encourage private investment in research and development by providing some secure reward for that effort. However, the Bionomics case set out above is an illustration of the point that many of the greatest leaps forward have been achieved through publicly funded research programs. It is also worth noting, as Dr Palombi has done in his recently published book *Gene Cartels: Biotech Patents in the Age of Free Trade*⁹, that the most significant discoveries in research and medical history were not achieved in pursuit of a patent. For instance, Pasteur's work with bacteria and vaccines, Lister's work on sterilisation, Fleming's discovery of penicillin, Florey's development of penicillin as a medicine and Watson and Crick's development model of the molecular structure of DNA.

Of course, scientists and researchers must be encouraged to develop new diagnostic processes, treatments and cures — for which patents may legitimately and deservedly be granted. However, the granting of patents over the underlying genetic material has the effect of preventing researchers pursuing such innovative processes and treatments because they are blocked from using the genetic information they need for research — unless they pay large sums of money to the patent holder.

Dr Ian Frazer's view

I think the matter is best summed up in an article published in *The Australian* on 8 August 2009 entitled 'Sharing genes is patently obvious: gene patent inquiry' by Dr Ian Frazer, the inventor of the Gardasil vaccine for the prevention of cervical cancer:

"As a scientist and patent holder I can understand why clinical researchers seek to have their inventions patented.

Individuals or corporations whose talent and hard work result in a useful invention ought to benefit from a system that protects their investment of time and effort — and their willingness to make the invention public — by ensuring their labour and creativity are rewarded.

Patent law was developed in the 17th century as an incentive to ingenuity, to help make the benefits of invention widely available and to further develop novel uses for the invention. However, patenting of a naturally occurring gene sequence and claiming the right to benefit from the use of that gene sequence by others fails on both counts.

First, there is no more invention in isolating and characterising biological material that exists in our bodies, using existing research techniques, than in collecting and arranging a set of postage stamps. Second, claiming a monopoly on the use of a particular gene sequence in an already existing diagnostic test method can lead to restricted public access to vital diagnostic services.

Gene patent owners have told a Senate committee that awarding gene patents is necessary to encourage investment in biotechnology research. The reality, however, is that a gene patent can also be a licence to monopolise its use, eliminating the competitiveness and information sharing essential to the development of genetic therapies whose invention should be rewarded by a patent.

Restricting the research use of a gene sequence could delay the development and testing of truly inventive and practical uses of the gene and its protein product for diagnosis and therapy. This would be to the detriment not only of the wider community, but also of the biotechnology industry itself ..."¹⁰

9 Luigi Palombi (Edward Elgar, UK 2009), preface x-xi
10 <http://www.theaustralian.news.com.au/story/0,25197,25896728-23289,00.html>

Organisations that oppose gene patents

I note the large number of submissions to this inquiry from organisations opposed to the granting of patents over human genes, such as the Breast Cancer Network Australia, the Peter MacCallum Cancer Centre, the Breast Cancer Action Group NSW, the Human Genetics Society of Australasia, the Country Women's Association of NSW, the National Coalition of Public Pathology, Cancer Voices NSW, the Royal College of Pathologists of Australasia, the Cancer Council Australia and the NSW Government.

Recommendation

I submit that section 18 of the Patents Act 1990 should be amended to expressly prohibit the grant of patent monopolies over human gene sequences, proteins and their derivatives including those materials in an isolated form.

I thank the Committee for its consideration of these matters and look forward to its report and recommendations.

Yours sincerely,

A handwritten signature in black ink, appearing to read 'Melissa Parke', written in a cursive style.

Melissa Parke MP

Federal Member for Fremantle