Copy of a speech by Ms Melissa Parke, Member for Fremantle, in the Australian Parliament on Monday 24 June 2013. Civil Liberties Australia is mentioned (see bold, underlined):

Ms PARKE (Fremantle—Parliamentary Secretary For Homelessness and Social Housing and Parliamentary Secretary for Mental Health) (18:47): I welcome the **Intellectual Property Laws Amendment Bill 2013** and thank the Minister for Industry and Innovation, Greg Combet, and Parliamentary Secretary Yvette D'Ath for bringing forward these reforms which represent an important step towards improving the current patent system.

Some of the flaws in the system were highlighted a number of years ago through the unacceptable behaviour of a patent holder. In July 2008 an Australian company, Genetic Technologies, which had acquired the exclusive patent rights to a number of Australian patents granted by IP Australia to Myriad Genetics of the breast and ovarian cancer genes, or BRCA genes, wrote to all of Australia's publicly funded clinical laboratories demanding that they immediately cease providing Australian women with BRCA genetic testing or they would be sued for patent infringement. No government at the state or federal level or the regulator, IP Australia, stepped in to challenge the conduct of this patent holder. It was only a public outcry that forced Genetic Technologies to back down on its threats.

Crown use is an important safeguard in the Patents Act that allows governments to access patented inventions without the consent of the patent owner. However, despite the fact that Crown use provisions have been in the Patents Act since 1903, they have rarely been used in this country. The Productivity Commission, in its recent report into compulsory licensing of patents, found there was uncertainty around the scope of the Crown use provisions. This bill seeks to clarify the operation of the Crown use provisions so that governments are not impeded by patents which are in effect Crown grants, from acting in the public interest.

Crown use can be exercised when a government has the primary responsibility for providing or funding the provision of the service. This means that governments can intervene to address unreasonable patent holder conduct that could result in patients being denied reasonable access to health care, such as occurred with Genetic Technologies unreasonably refusing to allow Australian laboratories to test for breast cancer.

I hope that it would also deal with a situation that was highlighted in the Senate Community Affairs References Committee inquiry into gene patents. During that inquiry the Peter MacCallum Cancer Centre gave evidence that its research into breast and ovarian cancer had been delayed by two years and ended up costing three times as much because gene or patent holders Myriad and Genetic Technologies refused to grant it permission to use the genes in its research. To the extent that there may have been uncertainty in the operation and scope of the Crown use provisions in the Patents Act, with this amendment there will now be no impediment to governments in Australia, state and federal, taking action in the public interest to prevent despicable behaviour by corporations like Genetic Technologies and Myriad that have demonstrated repeatedly that they are motivated only by greed and self-interest.

Another aspect of the bill will be very important in assisting developing countries to access vital medicines. Much of the world's population is suffering from treatable diseases including HIV AIDS, tuberculosis and malaria and yet developing countries are often unable to make essential medicines

themselves and cannot afford to buy them at normal market prices. A 2010 study commissioned by the World Health Organisation and Health Action International shows that the continuing high price of medicines is having catastrophic effects on the world's poorest people. The WHO has stated that the availability of generic products is a major contributor to reducing the cost of medicines. Of course we have seen that here in Australia with the cost to the PBS being dramatically reduced whenever drugs come off patent and are able to be produced generically.

The TRIPS protocol—that is, the World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights Protocol, agreed by the General Council for TRIPS in 2005 and accepted by Australia in 2007—enables pharmaceuticals to be exported under compulsory licence. As noted in the bill's explanatory memorandum, the aim of the protocol is to encourage patent owners to either practise price differentiation and provide medicines to least-developed and developing countries in need at affordable prices, or to issue voluntary licences to generic manufacturers to provide medicines at affordable prices. If the patent owner is unwilling to do this, then the protocol provides a mechanism to force the patent owner to issue a compulsory licence. This bill will implement the TRIPS protocol in Australia by amending the Patents Act to enable the Federal Court to grant compulsory licences to generic pharmaceutical manufacturers to make an export a patented pharmaceutical product. Patent holders will receive adequate compensation for the use of their patent.

Another welcome aspect of the bill is the amendment of the Plant Breeder's Rights Act to extend the jurisdiction of the Federal Circuit Court to include plant breeders' rights, thereby avoiding the need for expensive actions to be commenced in the Federal Court. In addition, the bill allows for a single trans-Tasman patent attorney regime and examination process for Australia and New Zealand, which has been agreed as part of the trans-Tasman single economic market agenda and which will reduce duplication and costs.

Finally, I would note that the amendments in the bill are a welcome first step along the path of greater and long overdue reforms of a flawed patent system. The patent system is a notable exception to the principle of competition that is supposed to underpin the Australian economy. Patents are monopolies sanctioned by law as a way of encouraging inventive contributions.

The government principle on which the patent system is based is that there must be an invention; however, currently, the Australian patent system allows the patenting of things that no-one invented: things that are natural, things that make us who and what we are—our genes. The practice of IP Australia over the past more than two decades has been to grant patents over human genes where such genes have been isolated from the human body and to grant patents over diagnostic tests that consist only of mere comparisons of genetic sequences. Therefore corporations can patent genetic materials that they did not invent and, by patenting simple genetic tests, they can exclude pathologists from looking at patients' DNA sequences to assess the risk for disease. In these ways, corporations gain legal monopolies over genetic materials to the exclusion of scientific and health researchers and practitioners. This is not some theoretical issue but has very real ramifications for scientific and health research as well as clinical practice and, ultimately, is detrimental to patients.

I referred earlier to the example of Genetic Technologies ordering public laboratories not to test for breast cancer and to their denying the Peter MacCallum Cancer Centre permission to use the breast cancer genes in their research into breast cancer. Another example was provided in the ABC *Four Corners* program *Body Corporate* in September 2010. That program highlighted the fact that doctors at Westmead Hospital were sending children's DNA samples to Scotland for epilepsy testing rather than paying the fees and royalties demand by Genetic Technologies, which holds the patent

right for the epilepsy gene and genetic test. This company holds these rights, despite the fact that most of the research to identify the epilepsy gene and to develop the genetic test for epilepsy was publicly funded.

I am happy to say that a significant development has recently occurred that will change the way that companies like Myriad and Genetic Technologies are able to operate in the future. Just over a week ago on 13 June, the US Supreme Court delivered a 9-0 unanimous decision finding that isolated genes are not patentable in the Myriad case. During the hearing of the case, Justice Sotomayor noted that she could bake a chocolate chip cookie from natural ingredients—salt, flour, eggs, butter—and that, if she combusted those ingredients in a totally new way, she could get a patent on that. But she could not imagine getting a patent on the basic items of salt, flour and eggs simply because she had created a new use or a new product from those ingredients.

Similarly, there is no objection to patents being granted over actual inventions such as medicines, vaccines, therapies and new methods for diagnosis that use genetic materials in them. The objection is to the patenting of the underlying genetic materials themselves, because

(a) no-one invented those materials—they are products of nature; and

(b) the patents prevent others accessing fundamental genetic information needed to diagnose disease and develop new health treatments.

This decision that isolated genes are not patentable is consistent with the previous unanimous 9-0 decision of the US Supreme Court in Prometheus v Mayo on 20 March 2012 where the court held that laws of nature, natural phenomena and abstract ideas are not patentable. It noted:

> *This Court has repeatedly emphasized a concern that patent law not inhibit future discovery by ... tying up the use of laws of nature and the like.*

The court made the further point that 'monopolization of natural phenomena through the grant of a patent might tend to impede innovation more than it would tend to promote it.' The US Supreme Court decision in the Myriad case regarding the nonpatentability of human genes will be strongly influential and will have serious implications for IP practice here in Australia.

The full Federal Court of Australia constituted by five judges, not the usual three, will hear the appeal of the decision of Justice Nicholas in the Myriad case in Sydney in August. This case too will be the subject of intense local and international scrutiny. It is certainly extremely unusual to have a situation where the same legal principle is being determined at almost the same time by appellate courts in both the US and Australia. In my view, this important issue should have been dealt with administratively or legislatively a long time ago and should not have been left to make its slow and expensive way through the court system here and in the US.

This action is only happening in a court system, one that is stacked in favour of corporations with deep pockets, because of the goodwill and persistence of organisations, including the American Council of Civil Liberties in the US and Cancer Voices Australia here in Australia; the assistance of dedicated lawyers acting pro bono in the public interest; and the courage of many cancer patients such as Yvonne D'Arcy here in Australia and their advocates, including the Cancer Council of Australia, the National Breast Cancer Foundation, **Civil Liberties Australia,** the Royal College of Pathologists, the Royal College of Surgeons, lawyers like Professor Luigi Palombi, David Catterns, Peter Cashman, Maurice Blackburn law firm and many others to stand up to big pharma.

The patenting of human genes is fundamentally flawed, because knowledge about human genes should not be private property but rather should belong to everyone. This is why when the human genome was decoded 13 years ago, US President Clinton and British Prime Minister Blair issued a joint statement which said:

> *To realize the full promise of this research, raw fundamental data on the human genome, including the human DNA sequence and its variations, should be made freely available to scientists everywhere. Unencumbered access to this information will promote discoveries that will reduce the burden of disease, improve health around the world, and enhance the quality of life for all humankind.*

A couple of weeks ago, here in Parliament House, I attended the 65 Roses event for Cystic Fibrosis Australia where it was noted that the identification of the cystic fibrosis gene was the genesis of the human genome project which has enabled the flourishing of genetics research and the development of personalised medicine.

Medicines are now being tailored to suit particular genetic profiles, thereby ensuring people get the exact treatment for their condition and preventing wasteful ineffective treatments. However, this transformative development in the health field will become more and more difficult, the more that knowledge about genes is privatised and the more that genes become the subject of private property rights in the form of patents, thus preventing scientists and health researchers from getting free access to genes.

I have long advocated for changes to the Australian patents system, in particular to prohibit the patenting of human genes. This bill does not do that but it does implement a number of measures that will improve the system in other ways. I welcome that. I also welcome the government's recent announcement that it would undertake a number of measures to further clarify the patents system and strengthen mechanisms for oversight, including appointing a patent audit committee to advise on patent policy settings and undertake audits of patent approvals for certain technology groups. Commencing consultations on a new objects clause for the Patents Act, and consulting on excluding certain inventions that would be offensive to the public.

This is a public policy debate that will continue until the imbalances and injustices of the present system are overcome. There are many members in this place and the other place of different political stripes who will ensure that this is so.

ENDS excerpt from parliamentary speech

For a background analysis of this important issue, see the article by Dr Matthew Rimmer, ARC Future Fellow and Associate Professor in Intellectual Property at Australian National University:

http://theconversation.com/a-crowning-glory-patent-law-and-public-health-15259

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