COUNTRY WOMEN'S ASSOCIATION OF NEW SOUTH WALES

SUBMISSION TO INQUIRY INTO GENE PATENTS

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INQUIRY INTO GENE PATENTS

The Social Issues Committee of the Country Women's Association of NSW wishes to thank the Senate Community Affairs Committee for the opportunity to contribute to this inquiry.

It would seem that medical science has been opened up to the corporate pursuit of profit. In November 2008, Genetic Technologies caused great concern by stating that it was going to enforce its proprietary rights over the human body's genetic code, and was insisting that testing of these products at public hospitals and laboratories should cease and all testing be performed at Genetic Technologies' own Melbourne laboratory at a cost of $2,100 per test. Up until November 2008 Genetics Technologies had not enforced its patent ownership, allowing public laboratories to conduct scans without charge, describing this as 'gift to the Australian people.'

After great concern and outrage was expressed by patients, doctors and researchers, and the Senate Inquiry into Gene Patenting was announced, Mr Mervyn Jacobsen, founder and 40% shareholder at the Melbourne Genetic Technologies, stated he would try to ensure that the company did not pursue its earlier demand for all testing to be done at the Melbourne laboratory and, at this time (March 2009) free testing is still being carried out at public laboratories **for now. 'For now'** is emphasized because Genetics Technologies is an Australian company with shareholders demanding profits. Everything depends on its performance on the stock market, where it is reported that there has been a decline in Genetic Technologies' performance, and it has been pointed out that the success of Genetics Technologies will depend on its ability to enforce its patent portfolio in the market. With the current global fiscal climate, one can only hope and pray that this firm will still be looking at public hospital and laboratory testing as 'a gift to the Australian people' for many years to come.

This threat highlights the dire consequences of allowing major international corporations to patent parts of the human genome. However, this gene patent monopoly problem should never have reached this stage - with public hospital and laboratory researchers being threatened with 'costly and time consuming litigation on public laboratories' past and prospective infringement on exclusive patent rights.'

Of concern here, were the rights for patents BRCA1 and BRCA2 genes which are closely linked to suspected cases of hereditary breast and ovarian cancer syndrome. These are not patents on <u>inventions</u>, but on parts of the <u>human body – genome.</u> An estimated 3 million gene-related patents have been issued in the United States alone. In 2003, Melbourne based Genetics Technologies obtained from the US firm Myriad Genetics the Australian and New Zealand rights to the two genes BRCA1 and BRCA2. Research was done from the 1980s with the United States, United Kingdom, France, Japan and Canada closely involved with researchers in the field brought together by the International Breast Cancer Linkage Group. In March 2000, when the genome was mapped, both President Clinton and Prime Minister Blair argued that raw data of this nature should be free. In spite of this recommendation, the US was allowed to take out patents for the sequence of the BRCA1 and BRCA2 genes. While the BRCA genes are now 'private property', their initial discovery was due to the efforts of publicly funded scientists collaborating on an international basis.

To the lay person, the word 'patent' evokes thoughts of inventions - is it innovative, is it novel, does it benefit mankind, does it save work, energy etc.? But, here we are talking about the human body. There is great concern about the legitimacy of awarding patents to those who isolate portions of the human DNA. So many eminent professionals are adamant in their opposition to the commercialisation of the genome.

Professor Guy Maddern, chairman of the Royal Australasian College of Surgeons, opposes the commercialisation of the genome, 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.' It is obvious that patent law, developed before the explosion of biological discoveries, is inadequate and should be re-visited.

Ms Terry Moore, Manager of the Office of the Director General of the Federal Government's intellectual property organisation IP Australia, defends the concept of patenting human DNA and wants more research into how well the patent system was working to promote and reward innovation, and whether it was meeting its remit of fostering public benefit while giving an appropriate incentive to people who come up with new discoveries. No-one quibbles at the owners of patented <u>inventions</u> reaping benefits for the specified time, but it is thought that there should be no restriction on research and investigation with human genes. Public hospital laboratories must be allowed access to all areas of human genes work to foster public benefit.

Professor Ian Frazer, the inventor of cervical cancer vaccine, has joined other cancer researchers calling for a revision of patent laws that allow private firms to claim ownership of human genes, as there was great concern that the laws could hinder public research and the development of new treatments. He went on to state that gene patenting had the potential to frustrate investigations into new cancer therapies and vaccines and that researchers needed to be able to proceed with their work without having to consult private companies that owned patents the work might infringe.

Graeme Suthers, the head of the familial cancer unit at the South Australian Clinical Genetics Service, said that while cancer was at the centre of the gene patenting debate because it was common and had a high public profile, people with rarer diseases stood to lose at least as much from company ownership of genes. The fact that few companies had sought to enforce gene patent rights was not reassuring, and he said that a core fundamental principle has been violated.

Luigi Palombi, an expert in patent law at the Australian National University, said the fact that human genes could be patented in Australia represented 'a big failure, a misuse of power.'

The threatened action by Genetics Technologies has shown what could happen with <u>any</u> gene patent monopoly. Allowing a monopoly on patents on human genes could, if the owners press ownership, increase costs for the clients, and seriously impact on budgets of Australian publicly funded facilities.

Research into these genes would be retarded as data from the gene scans would be available to only the monopoly's scientists. This would block all studies by public health officials and seriously impact on the training and accreditation of health workers in these areas. There must be an internationally coordinated approach involving the world's entire scientific community. Collaboration between world scientists is blocked by nationally based bio-technology firms, when the profit system takes control of potential advances.

The policy underlying the Australian public healthcare system is equitable access to healthcare for all Australians. There is great concern that a monopoly's licence terms for gene testing may threaten the ability of healthcare authorities in Australia to deliver high quality genetic testing.

A most important aspect of gene research in the public hospitals and laboratories (into familial genetic testing etc) is the wonderful counselling and 'one-on-one' discussions held. This is vital with public laboratories' genetic testing for women and men who, through family history, are regarded as candidates for early breast and ovarian cancers and prostate cancer. They can be advised on best procedures – advice such as 'have your family now, then think about having your ovaries removed' to defeat the onset of early ovarian cancer. This one-on-one friendly counselling would be lost if public hospitals lost their right to do testing on a privately patented gene and the entire nation's testing done through one commercial centre.

The Patents Act 1990, Section 18 is very definite that human beings and their biological processes are not patentable, and this committee firmly believes that these criteria should be retained and upheld. With regard to the BRCA1 and BRCA2 genes, the committee has learned that there are over 3 million gene-related patents issued to the US, and that the American firm Myriad had secured a total of nine patents giving it control of these two genes. Myriad then leased the Australian and New Zealand rights to the patents to Genetics Technologies.

To the lay person, it is surprising that a US patented gene - not on an invention, but on part of the human genome - could be accepted under the Commonwealth's Patents Act 1990. Was a rigorous series of testing done, inquiries made, checks done? Surely, the regulations/controls **must** be tightened.

This committee firmly believes that patenting of human genes should not be allowed, and that the Commonwealth's Patent Act must be strengthened to uphold this theory and that serious thought must be given to spread this theory globally. With the global environment and the acknowledged corporate pursuit of profit, it will be a hard road to hoe, but we have to try.

Mrs Joy Potts, Chair
Social Issues Committee
Country Women's Association of NSW