Australian court upholds patent for breast cancer gene

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Australia's Federal Court has handed down a ruling supporting a patent on a breast cancer gene. The February 15 decision serves to entrench the rights of biotech companies as they scramble to obtain, enforce and profit from patents on genetic material.

Justice John Nicholas found against advocacy group, Cancer Voices Australia, and a breast cancer victim Yvonne D'Arcy, and upheld the patent for the cancer gene BRCA1 claimed by Genetic Technologies and Myriad Genetics. Genetic Technologies holds the patent in Australia under licence from US firm Myriad Genetics.

The judgment represents the first legal finding in Australia on the patentability of genetic sequences and has far-reaching ramifications both in Australia and internationally, where the case has been closely followed.

The development of relatively cheap genetic scanning and the identification of small genetic variations responsible for various human conditions are making possible new medical treatments and the early monitoring of diseases. The patenting of genetic material is a mechanism used by biotechnology and pharmaceutical firms to monopolise and commercially exploit entire areas of genetic research.

Women who carry certain mutations of the BRCA1 gene are known to be more susceptible to breast and ovarian cancer. Early screening for the BRCA1 mutations in women with a family history of cancer is an important tool to set in place regular checks for tumours and to thus enable early detection.

In their suit, Cancer Voices Australia and D'Arcy argued that the BRCA1 gene sequence should not be patentable as it occurred in nature and was no different to the genetic material found in cells. Therefore nothing had been invented or manufactured.

Nicholas, however, ruled that the act of isolating the genetic sequence constituted manufacture and could be patented. "[E]ven if the physical properties of the material have not changed, the removal of the material from its environment and its separation from other cellular components may still give rise to what might reasonably be described as an artificial state of affairs," he stated. The decision was in line with a recent US court case upholding Myriad's patent.

Cancer Voices Australia lawyer Rebecca Gilsenan told the media that the group was very disappointed with the outcome and would consider appealing. "One of the reasons that we agreed to bring this case was because of a concern about access to research, development of treatments and cures for genetically transmitted diseases," Gilsenan said.

Doctors and medical scientists strongly opposed the ruling. Australian Medical Association president Steve Hambleton said: "[O]ur position is the holding of a patent must not prevent the diagnosing and treatment of a disease; there is a balance here, but we don't want to see barriers."

Patent law expert Luigi Palombi, an opponent of gene patenting, described the decision as "contradictory and absurd." Writing on the Australian ABC's *Drum O pinion* website, he said the ruling meant that as soon as genetic material was removed from the human body, the patent holder had an exclusive right of exploitation. "It is akin to giving someone the private right to impose a tax on human genes," he wrote.

In 2008, Genetic Technologies provoked a public outcry when it threatened legal action against the renowned Peter MacCallum Cancer Institute in Melbourne unless it stopped performing the diagnostic test for BRCA1 and BRCA2. The company backed down, but in the wake of the latest ruling could attempt

to again enforce its patent. In the US, Myriad uses its patent to ensure that scans are performed only in its laboratories, at a cost of $3,000 each.

The BRCA gene patent became the focus for opposition to the patenting of human genetic material in general. The Australian Senate carried out two inquiries into gene patents beginning in 2009, but ruled out any amendment to the Patent Act to halt gene patents despite their impact on scientific research and the cost of medical procedures.

A Peter MacCallum Cancer Centre submission called for the Senate to "expressly prohibit the grant of patent monopolies." It explained that the centre's research into breast and ovarian cancer had been delayed by two years and their costs tripled because Genetic Technologies refused permission to use the patented breast cancer genes.

In its submission, the Cancer Council Australia pointed out that "the actions of Genetic Technologies Ltd (to reverse the imposition of a fee in 2008) in our view averted a significant public health problem in Australia." But, it added, that decision was purely voluntary and "there is nothing in law to prevent a potential monopolisation of genetic testing under these circumstances."

Two private members' bills were introduced in the Australian parliament to ban human gene patents. Liberal Senator Bill Heffernan moved the first in 2010 and Labor parliamentarian Melissa Parke the second in 2012.

Parke was critical of the Gillard Labor government's own Raising the Bar bill, that supposedly protected cancer researchers wanting to access genetic material under patent. She explained that the bill did not address the issue of what was patentable subject matter and did not cover gene patents.

Significantly, Justice Nicholas noted that his finding was in line with the Australian government's recent decisions on patent law. The Labor government, which has been seeking to encourage the biotech industry, did not back either of the private member bills to ban gene patenting.

According to Johns Hopkins University medicine professor Steven Salzberg, an individual's genome can now be sequenced in a few days for less than $5,000. Numerous companies offer tests for cheaper microarrays that scan for single base changes (the smallest unit of information in the genetic code) that are thought to be implicated in human diseases. These scientific advances, rather than providing more improved medical services, are seen as a financial boon for the biotechnology companies. More than 4,000 human genes, or about 20 percent of the human genome, are the subject of patents.

Scientific research is based on the free exchange of information, but the patenting of human genes works in the opposite direction. Discoveries and new techniques are treated as highly profitable, commercial secrets.