Australian biotechnology company enforces cancer gene patent, restricting medical scanning

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Australian biotechnology firm Genetic Technologies last month moved to enforce its patent over two critical genes implicated in the development of breast and ovarian cancer. As a result, genetic scanning on potential cancer victims has stopped in all publicly funded laboratories, potentially placing many women's lives at risk.

The incident highlights the destructive consequences of allowing major international corporations to patent parts of the human genome. Medical science, like virtually every aspect of contemporary society, has been opened up to the corporate pursuit of profit. Even the very "building blocks" of human life have been effectively privatised and converted into the property of major biotechnology firms. As a result, the rational utilisation of the most advanced medical technologies is impossible and doctors and scientists are prevented from providing the highest possible standard of treatment to patients.

An estimated three million gene related patents have been issued in the United States alone. The gene is a segment of genetic material in the cell nucleus that codes for a protein or is involved in the regulation of the genome. Firms can take out patents on genes, variations on the genes known as mutations, and on any resulting therapeutic procedures—enabling them to charge researchers licence fees to investigate the genes' functions.

Melbourne-based Genetic Technologies obtained the Australian and New Zealand rights to two genes, known as BRCA1 and BRCA2, in 2003 from the US firm Myriad Genetics.

Women who carry mutations in the two genes are known to have a high risk of breast and ovarian cancer, as the mutant genes are unable to repair damaged DNA. Women with the mutant form of the BRCA genes, which are implicated in up to 10 percent of breast cancers, usually develop the disease at an early age. Inherited mutations can reportedly increase a woman's risk of breast cancer from 9 percent to up to 80 percent, and the risk of ovarian cancer from 1 percent to up to 65 percent.

Early detection is crucial to save lives. Doctors can scan women with a family history of the relevant cancers for the mutant genes; anyone found to have faulty copies of the gene can then be regularly screened to detect the onset of any cancers as soon as possible.

Until now, Genetic Technologies has not enforced its patents, allowing public laboratories to conduct scans without charge. But the company is now charging $2,100 per scan. The public health insurance scheme Medicare covers the cost only for women with a family history of breast cancer, but other concerned women who fail to qualify will either have to pay the fee or, if they cannot afford it, go without.

Even those who qualify for Medicare coverage are likely to experience delays. As a result of Genetic Technologies' legal threats, just one laboratory (the company's new facility in Melbourne) is now able to conduct work that was previously done in 10 different labs. Cancer research also may be retarded, as data from the gene scans will only be available to Genetic Technologies scientists. This may block epidemiological studies by public health officials.

Cancer patient advocate groups and medical professionals have expressed outrage at the enforcement of the patent.

Professor Guy Maddern, chairman of the Royal Australasian College of Surgeons, opposed the commercialisation of the genome: "It is not an invention worthy of a patent, but a discovery. While this discovery certainly constitutes the basis of scientific and clinical understanding and might serve as the starting point for future, and patentable, medical research, it should in itself be no worthier of a patent than a recently discovered species of animal or plant."

Cancer Council Australia chief executive Ian Olver noted that the price charged for screening increased by between 200 and 300 percent in Canada when a different company took similar steps several years ago to enforce its patent rights over the BRCA genes. In the US, the price is about $4,000, or twice the current Australian charge.

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The development of breast cancer genetics

Mankind's increasing knowledge of the human genome and the extraordinarily complex workings of different genes has the potential to resolve many diseases afflicting millions of people around the world—such as diabetes, asthma, cancer, mental illness, alcoholism, Parkinson's disease, quadriplegia, and many others. Yet potential genetic medical advances have been stymied at every turn by the profit system.

Significant research data on the human genome is now held by corporate patent holders, excluding publicly funded laboratories from accessing information crucial to their own research. What is required is an internationally coordinated approach involving the world's entire scientific community. But much of the work is confined to nationally based biotechnology firms, which serves to stifle collaboration between scientists.

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.

Breast cancer genetics was first developed in the 1980s with research groups based in the US, UK, France, Japan and Canada. In 1988, the International Breast Cancer Linkage Group (BCLG) was formed to bring together researchers in the field. In 1990, researchers at the University of California, Berkeley announced the discovery of the BRCA1 gene and indicated its association with breast cancer. The BCLG then conducted tests with 214 families to prove the hereditary character of the condition.

At the same time, a team based at the University of Utah's Centre of Genetic Epidemiology was also working on the identification of cancer genes. Scientists used a genealogical database of 200,000 Mormon families that was checked against Utah's cancer registry.

The research team founded the firm Myriad Genetics and used its exclusive access to the Utah and Mormon databases to attract investment from the giant US pharmaceutical company Eli Lilly. Myriad published its findings in 1994, and in 1995 obtained a patent for the sequence of the BRCA1 gene and methods of detecting its mutations.

Also in 1994, researchers from the University of Utah and Britain identified the existence of a second gene, BRCA2. The sequence for the gene was published in 1995 by the British group in collaboration with 40 scientists in six different countries. Myriad then published its own sequence a few months later, claiming the published sequence from the British team was incomplete. By 2000, it had obtained the patents to the second gene. Myriad secured a total of nine patents, giving it control of BRCA1 and 2, including any diagnostic tests based on the genes.

Myriad has ruthlessly pursued its patent around the world. The company has fought protracted legal battles in the European Union courts to have its "property" recognised.

The Australian and New Zealand rights to the patents were leased to Genetic Technologies in 2003; the company initially said it would not enforce its legal claim over the gene, describing this as a "gift to the Australian people".

It appears as though the change in policy has been driven by the company's worsening performance on the stock market. It was down 15 percent in 2006, 57 percent in 2007, and has lost a further 63 percent so far this year. Valuetech, a firm that estimates the value of corporate intellectual property, concluded recently that the "success of Genetic Technologies will depend on its ability to enforce its patent portfolio in the market".

The Labor government's health minister Nicola Roxon issued a short statement last month after Genetic Technologies announced it would enforce the patent. She said she recognised the "legitimate concerns held by members of the community about these actions" and was in talks with company executives aimed at deferring the company's declared deadline for the patent's enforcement. This deadline, November 6, has already passed, but there has been no further public statement from the government.

Neither Roxon nor any other Labor minister suggested they would look at altering Australia's patent laws, which permit the effective privatisation of the human genome.

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