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Myriad gene patenting suit ends on a win-win note

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In the legal case of Myriad Genetics vs Association for Molecular Pathology, the US Supreme Court's verdict unanimously struck down patents on isolated, natural human genes, in June. Patents on synthesized DNA were however held to be valid. Commercially important patents on cDNA (segments of DNA synthesized using an RNA template) too are included in this category. Even as all the sides claimed victory in the case, Myriad's patents on the BRCA1 and BRCA2 gene were held invalid.

For the last four years, this case was debating whether human DNA can be claimed as intellectual property, sealing the fate of the life sciences industry in unimaginable ways and that of the treatment of a disease that kills one in every eight affected women across the world. Above all, the lawsuit was being looked upon as the most defining chapter in how the world would take forward human genomic and the progress that can be achieved in breast and ovarian cancer treatment - for better or for worse.

The case of Myriad Genetics vs Association for Molecular Pathology has, in recent times, had become an argument between the former and the world. Even as the US Supreme Court examined various aspects of the case since November last year, all the stakeholders in the case made their perceptions publicly clear.

The long drawn legal battle heard every argument including, turning the ethical spotlight on the issue of patenting, the alleged 'forced monopoly' on testing, the apparent impact patenting was said to be having on scientific research, and even the future of the 100,000 or so genetic patents already awarded.

Some had called Myriad Genetics' BRCA gene patent tangle, a move towards blatant corporatization of breast cancer treatment in the US, while others argued that patenting is a way to pay for the investments made by the company in developing the test.

How the case unfolded

In 2009, the American Civil Liberties Union (ACLU) and the Public Patent Foundation challenged seven patents held by Myriad Genetics on two human genes associated with breast and ovarian cancer. The patents were then held invalid in a federal court. The verdict was later overruled in an appeals court and has since moved to the US Supreme Court. Over 150,000 geneticists, pathologists, laboratory professions, researchers, genetic counselors, breast cancer support groups, cancer survivors, presented their arguments against gene patenting, asking the court to invalidate two of Myriad's patents on BRCA1 and BRCA2 (Breast Cancer) genes.

The Utah-based company had unequivocally argued that it deserved the patents as it required human ingenuity and judgment to become the first to isolate BRCA1 and BRCA2 genes. Everyone opposing the reasoning stated that genes cannot be patented because they are found in nature. Even, the global life sciences industry, to which Myriad belongs, had come out in arms against the company. Patenting genes stifles the ability of other scientists to study genes and slows the lifesaving research, the industry had claimed.

The medical fraternity argued that patents force people in the US to undergo tests that are inferior as well as costlier than those available in other countries. However, the groups representing biotech, pharmaceutical and agriculture companies supported Myriad in the global debate.

The debate reached its peak when a leading scientific journal interviewed double-helix co-discoverer Mr James Watson, who outrightly rejected the need to patent genes. The Nobel laureate, 85-year-old, Mr Watson, who is currently researching the link between cancer and genes, had also filed a brief in the case to argue against patenting genes. "Scientists should be permitted to experiment on human genes free from any threat of patent infringement. Life's instructions ought not be controlled by legal monopolies created at the whim of Congress or the courts," he boldly stated in his brief at the court.

The propagators of this thought in the scientific community even brought out a long forgotten interview of American medical researcher, Mr Jonas Salk, who become the man behind the world's first successful polio vaccine. 'Could you patent the sun?' Mr Salk had questioned in the interview.

Myriad argued that its patents are not on the genes as they exist in the human body, but on isolated, modified versions that have been snipped from the genome and chemically altered to make them useful in a laboratory. This, the company argued makes them human inventions and therefore eligible to be patented.

Supporters of Myriad, like Biotechnology Industry Organisation (BIO) and the Animal Health Institute, believe that if gene patenting is ruled invalid then companies would stop investing in genetics research as there would be no probability of profit from discoveries.

Questioning the monopolies created by companies that own patents to such human genes, Mr David Koepsell, author of*Who Owns You: The Corporate Gold Rush to Patent Your Genes* had defined patents as 'government-sponsored monopolies.' "Biotech companies and other corporations need to be made to compete with the actual values of their products. Even setting this radical argument aside, gene patents are not the most economically efficient way to exploit publicly funded science, nor necessary to spur useful innovation in drugs."

ACLU had further argued that patents on BRCA1 and BRCA2 are harmful to patients and create barriers to medical and scientific advancement. "Gene patents also have a chilling effect on research. Researchers must either obtain permission from the patent holder, or run the risk of being sued. And by virtue of its patents, Myriad controls most of the data about the BRCA genes and has refused to share that information with the scientific community," ACLU presented in court.

To this Myriad questioned the future of 100,000 or so genetic patents already awarded by the US Patent and Trademark Office since 1982. So much so, that *Genome Medicine* journal stated, "Your doctor cannot look at about 41 percent of the human genome without the permission of a patent holder because, in effect, those genes aren't legally yours. This has profound implications for personalized medicine, in which doctors will prescribe individualized cures that could be vastly more effective because they target a person's makeup. Many researchers, doctors and medical organizations fear that the proliferation of gene patents will limit those treatments because patent holders have locked down genes in ways that discourage research and kill competition."

In 2012, geneticist Mr S L Salzberg, in his commentary on the case in Nature, called patenting of human genes absurdity. "By this argument, a blood sample or even an amputated limb is not 'naturally occurring' and is therefore patentable. Genes are not inventions. This simple fact, which no serious scientist would dispute, should be enough to rule them out as the subject of

patents," he wrote. He had also pointed out, "Given that there are well over 4,000 gene patents and 1,100 different claimants, it's extremely onerous for scientists to work on certain genes. It forces them to have to navigate through a costly and bureaucratic process of negotiating licenses and paying for these licenses. Consequently, many would rather spend their time and resources working on other genes - including less important ones. This is an indirect threat to human health."

Ahead of the Supreme Court's ruling, Myriad had issued a statement defending its patent on the company's official blog. "The diagnostic tools based on the company's patents have been used by more than one million women. Without adequate intellectual property protection, companies would face significant obstacles conducting pioneering research and bringing new products to market that save lives. We think it is right for a company to be able to own its discoveries, earn back its investment, and make a reasonable profit," Myriad officials wrote.

Human genetics researcher from Columbia University Medical Centre, Dr Wendy Chung argued through the case that allowing exclusive licenses on genes compromises the access to care and quality of care patients receive. "When genetic testing is performed by a single laboratory, the quality of the genetic testing and interpretation of results suffer and the price of the testing remains artificially elevated. Independent scientists could have studied not only whether a variant is dangerous or benign but also whether that risk is modified by the presence of other genes - crucial information when a woman is agonizing over whether to have her breasts removed," she had said.

Similarly, Dr Arupa Ganguly, Director of the University of Pennsylvania Genetic Diagnostic Laboratory, had stated that gene patents had a negative impact on scientific research. "Gene patents have allowed some companies to enforce monopolies and dictate the terms under which researchers may or may not perform their own tests on the genes they control. I and my fellow researchers are forced to constantly worry about violating patents, and as a result there are things we completely avoid. This ultimately takes its toll on the patients - the very people gene patent holders claim they are trying to help," she said in her brief to the court.

The company counters that gene patents, by rewarding research, helps patients. "Scientific research has not been hindered. These are among the most studied genes in the world," said Mr Mark Capone, president of Myriad's laboratory division at a press conference, citing 18,000 scientists who have published 10,000 papers on BRCA.

Dr Stephen T Warren, human geneticist had raised doubts on the ACLU website about the 'education of the next generation of laboratory medical geneticists' when patents are held by one firm.

Direct-to-confusion?

Apart from exerting strict monopoly over the BRCA test, Myriad had also set up a direct-to-consumer (DTC) marketing campaign. Genetic research scientist and director of Cancer Genetic Counseling at the Yale School of Medicine, Ellen T Matloff explained, "The company bills its DTC campaign as a 'public awareness campaign,' although it omits most of the information key to educating the public about BRCA1 and BRCA2 testing."

Further, her explanation to this that appeared first in *The American Journal of Bioethics* said that, "There are reports of an increase in the number of women whom have had BRCA testing without having genetic counseling by a qualified professional. Horror stories of age 20-something women being advised to find a man, get married, have children, and have their ovaries and breasts removed as soon as possible have been reported. Other women have been falsely told that their mutation was a normal result, that their normal result was a mutation, or that a variant of uncertain significance was disease-causing - all incorrect, all potentially leading a woman and her entire family to make drastic and perhaps life-threatening decisions based on a result misinterpretation. Myriad's DTC campaign shows that there is not much time remaining if those who might avail themselves of genetic testing are to be protected against commercial manipulation, masquerading as sound public health education."