

THE DAILY RECORD

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IP FRONTIERS

Genetic screening dispute to be argued

National Breast Cancer Awareness Month celebrates its 26th anniversary this month.

At the same time, patenting genetic discoveries has never been more controversial. The National Human Genome Research Institute — a division of the National Institutes of Health — estimates there are now patents associated with about one quarter of the genes in the human genome.

Notably, Myriad Genetics and the University of Utah Research Foundation have received several patents directed to the BRCA-1 and BRCA-2 genes, used to perform breast cancer genetic screening tests.

Specifically, the Myriad patents claim isolated DNA containing human BRCA-1 and BRCA-2 gene sequences and methods for identifying mutations in the BRCA-1 and BRCA-2 gene sequences.

According to Myriad, BRCA-1 and BRCA-2 appear to be responsible for about 84 percent of early onset hereditary breast cancer and about 90 percent of hereditary ovarian cancer.

Since obtaining the BRCA patents, Myriad has licensed the rights to perform the BRCA-1 and BRCA-2 genetic screening tests to about a dozen laboratories in exchange for very high royalties for each test performed. Those licensing practices have caused significant controversy in the public health community. Opponents contend Myriad's restrictive licensing and high royalty rates significantly increase the cost of the genetic tests, effectively restricting the availability of testing and preventing patients from obtaining independent, second-opinion testing. There is additional concern that Myriad's aggressive patent approach is limiting the use of basic genetic information, which inhibits or limits future biomedical research.

Proponents maintain that gene patents are critical tools needed to encourage innovation. Gene patents provide the protection needed to allow those investing in genetic research the opportunity to recoup their investments and maximize profits needed to fund future research. Without the funding, according to proponents, future research and development of genetic testing would be stifled.

In May 2009, the American Civil Liberties Union and several other plaintiffs filed a lawsuit against Myriad, the U.S.

Patent and Trademark Office, and the University of Utah Research Foundation, challenging the constitutionality and validity of seven patents directed to the BRCA1 and BRCA2 genes.

In particular, the plaintiffs argue patents directed to isolated nucleic acid molecules violate “long established principles that prohibit the patenting of laws of nature, products of nature, and abstract ideas.” The case, *Association for Molecular Pathology, et al. v. U.S. Patent and Trademark Office, et al.*, was filed in the U.S. District Court for the Southern District of New York and assigned to Judge Robert W. Sweet (Civil Action No. 09-cv-4515).

The validity issue boils down to whether isolated genetic material constitutes patentable subject matter under Section 101 of the U.S. Patent Act, which defines as patentable “any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement.”

To the contrary, laws of nature, natural phenomena and abstract ideas are not patentable subject matter under Section 101. Based on those legal principles, the genes found in nature (i.e., within the cells of an organism) cannot be patented.

In the early 1990s, however, the U.S. Patent and Trademark Office began issuing patents directed to isolated DNA molecules whose sequences correspond to genes found in nature, taking the position that isolated DNA molecules are patentable because they do not exist in a purified, isolated form in nature. According to current Patent and Trademark Office guidelines pertaining to genetic discoveries, identification of a gene's sequence alone is not patentable, but a gene isolated from its natural state may be patentable if the isolated gene possesses “specific, substantial and credible utility.”

Shortly after commencement of the lawsuit, Myriad and the other defendants moved to dismiss, attacking the procedural merits of plaintiffs' case. The defendants argued the plaintiffs lacked standing and subject matter jurisdiction. Judge Sweet denied the motion to dismiss, finding the plaintiffs — third parties who may be threatened by the BRCA patents — have standing to sue.



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The lawsuit moved forward quickly, with the plaintiffs moving for summary judgment that isolated genetic material is not patentable subject matter under Section 101, and that the patent claims are unconstitutional under the First Amendment. They also argued the BRCA patents are invalid under Article 1, Section 8, Clause 8 of the Constitution, which grants Congress the right to promote the progress of science by granting patents.

The defendants opposed and countered with their own motions for summary judgment seeking a declaration that the patent claims were valid. The Patent and Trademark Office also moved for dismissal of the plaintiffs' constitutional claims.

In a much anticipated decision handed down in March, Judge Sweet partly granted the plaintiffs' motion for summary judgment, finding Myriad's contested patent claims invalid under Section 101. Specifically, Judge Sweet concluded DNA's existence in an isolated form does not alter the fundamental nature of the DNA or the information it encodes. As such, the patents containing sequences found in nature are unpatentable subject matter under Section 101.

The decision was not a complete loss for all of the defendants, as Judge Sweet also dismissed the constitutional claims against the Patent and Trademark Office.

Myriad promptly filed a Notice of Appeal to the U.S. Court of Appeals for the Federal Circuit, and is scheduled to file an

appeal brief this Friday.

Myriad's non-U.S. patents directed to the BRCA-1 and BRCA-2 genes are the center of similar legal disputes throughout the world. In June, a group of Australian plaintiffs' commenced a lawsuit against Myriad also challenging the validity of Myriad's Australian BRCA patents. In a surprising turn of events in response to the lawsuit, Myriad offered to surrender one of its key Australian BRCA patents to the people of Australia. Although Myriad's motives for "gifting" the patent to the Australian people remain a mystery, there is speculation that Myriad was attempting to prevent any persuasive effect an adverse ruling in Australia may have on the U.S. litigation.

Resolution of Myriad's case pending before the Federal Circuit likely will be followed by an appeal to the Supreme Court, meaning the litigation is far from being finally resolved. There is no question, however, that the BRCA-1 and BRCA-2 patent dispute is shaping up to be a landmark case pertaining to the patenting of genetic material.

Its final resolution, whatever it may be, will have a significant and global impact on biomedical companies, scientific researchers and patients alike.

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