

U.S. District Court Invalidates Patents Claiming BRCA Genes

March 31, 2010

On March 29, a U.S. District Court sided with the American Civil Liberties Union (ACLU) and other plaintiffs in an ongoing lawsuit, declaring Myriad Genetics' patents directed toward nucleotides encoding BRCA genes as invalid. The BRCA genes (known as BRCA1 and BRCA2) are used as markers to determine susceptibility to breast and ovarian cancer in individuals who have a family history of these cancers. Myriad is the exclusive licensee of the patents and, as such, is the sole clinical provider of full sequencing of the BRCA1 and BRCA2 genes in the United States.

The lawsuit, *Association for Molecular Pathology v. United States Patent and Trademark Office*,¹ was filed in the U.S. District Court for the Southern District of New York against the U.S. Patent and Trademark Office (USPTO), as well as Myriad Genetics and the University of Utah Research Foundation, which hold the patents claiming nucleotide sequences encoding BRCA genes. The plaintiffs in the lawsuit include several patients, genetic specialists and medical associations.

The challenged patents cover diagnostic tests for mutations along the genes, which are responsible for most cases of hereditary breast and ovarian cancers. The suit claims that patents issued on two human genes associated with breast and ovarian cancer are unconstitutional and invalid because "human genes are products of nature, laws of nature and/or natural phenomena, and abstract ideas or basic human knowledge or thought."

Despite dealing solely with Myriad's patents, the suit essentially challenged the constitutionality of patenting all genetic sequences on First Amendment grounds. In his ruling, Judge Robert Sweet noted that the case hinged on the fact that the patents encompass "isolated DNA," which is "premised on the view that DNA should be treated no differently from any other chemical compound and that its purification from the body, using well-known techniques, renders it patentable by transforming it into something distinctly different in character." This is similar to other naturally occurring but isolated products, such as taxol, a compound isolated from yew trees and used to treat cancers.

1. *Association for Molecular Pathology v. United States Patent and Trademark Office*, 1:09-cv-04515-RWS (S.D.N.Y. Mar. 29, 2010).

However, the court noted that because “DNA represents the physical embodiment of biological information, distinct in its essential characteristics from any other chemical found in nature . . . [its] existence in an ‘isolated’ form alters neither this fundamental quality of DNA as it exists in the body nor the information it encodes.” Therefore, the court concluded, “the patents at issue directed to ‘isolated DNA’ containing sequences found in nature are deemed unpatentable subject matter.” Judge Sweet said his findings were consistent with Supreme Court rulings that have established that purifying a product of nature does not mean it can be patented. It should also be noted that the boundaries of “patentable subject matter” under 35 U.S.C. §101 are currently being considered by the Supreme Court in *Bilski v. Doll*, with an imminent decision pending. The holding in *Bilski* may shed further light on the effect of the *Molecular Pathology* decision.

The *Molecular Pathology* decision, which is expected to be appealed by Myriad, has broad potential implications for the biotechnology industry and, in particular, the molecular diagnostics industry, if upheld by the Federal Circuit. However, we recommend companies carefully consider all of the facts before relying on this case to change patent strategy or freedom-to-operate analyses relating to gene patents.

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