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U.S. District Court Invalidates Breast Cancer Gene Patents

In March 2010, a federal district court in New York invalidated patents on genes associated with hereditary breast and ovarian cancer owned by Myriad Genetics and the University of Utah Research Foundation. The ruling marks the first time a U.S. court has found patents on genes unlawful and calls into question the validity of patents now held on approximately 2,000 human genes. The case is currently on appeal to the Federal Circuit, but a decision is not expected until next year. The district opinion can be found [here](#).

The lawsuit was brought by a group of patients and scientists represented by the American Civil Liberties Union and the Public Patent Foundation (PUBPAT), a not-for-profit organization affiliated with the Benjamin N. Cardozo School of Law.

The specific patents challenged involved on the *BRCA1* and *BRCA2* genes. Mutations in the *BRCA1* and *BRCA2* genes are responsible for most cases of hereditary breast and ovarian cancers. As such, women with a history of breast and ovarian cancer in their families may undergo genetic testing to determine if they are at increased risk for these cancers. This genetic information is important to treatment and prevention of the cancers as well.

The ACLU's and PUBPAT's lawsuit asserted that the patents are illegal and restrict both scientific research and patients' access to medical care. The plaintiffs also argued that patents on human genes violate the First Amendment as prohibiting the free flow of genetic information and patent law because genes are "products of nature." The ACLU filed a broad constitutional challenge to the patentability of gene sequences, but did not obtain the constitutional review it sought. Rather, the district court decided that the *BRCA1* and *BRCA2* genes patents were invalid under 35 U.S.C. §101 because they did not contain patentable subject matter. Under the doctrine of constitutional avoidance, the court dismissed without prejudice the ACLU claims of constitutional violations.

The patent claims at issue were of three types: (a) isolated DNA encoding *BRCA1* or *BRCA2* polypeptide; (b) method of detecting mutations in *BRCA1* or *BRCA2* genes and (c) drug testing involving the genes. In finding that none involved patentable subject matter, the court cited to a number of old judicial decisions, which held that the isolation of a naturally occurring product does not render it patentable. The court reasoned that non-naturally occurring DNA (such as cDNA) is not eligible for patent protection because cDNA corresponds directly to naturally occurring mRNA and conveys the same information as genomic DNA. The court relied heavily on the fact that the gene sequences are dual functioning: they are both physical objects and they encode information. Thus the court reasoned that even if the claimed nucleic acid is physically different, if it encodes the same information, then it has not been transformed to be "markedly different."

The district court also found claims reciting methods of detecting a *BRCA* sequence for mutations were not eligible for patent protection. The court held that such claims encompassed merely abstract, mental steps. The methods did not meet the machine-or-transformation test of *In re Bilski*, 545 F.3d 943 (*Fed*



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Cir. 2008) (en banc), cert. granted, 556 U.S. 1 (June 1, 2009). Under this test (which is currently being reviewed by the Supreme Court), to be patentable, the claimed process either had to be tied to a particular machine or apparatus or transform a particular article into a different state or thing. The district court ruled that simply “analyzing” or “comparing” DNA sequences did not rise to the level of a patentable transformation. Further, the isolation and sequencing steps were not transformations that would impart patentability because they would be mere “data-gathering” steps.

Finally, the court held that the methods of cell-based drug screening were patent ineligible. The claims were directed to recombinant cells engineered to express the BRCA1 genes. Even though the court conceded that transformations may be involved in the methods, the court ultimately stated that claimed process “is, in fact, the scientific method itself.” The court saw the method as trying to capture “a basic scientific principle.”

The patentee in this case (Myriad Genetics) has already appealed the case, and thus the district court's decision is only the beginning of this story. Many businesses have developed businesses around patent-protected genetic tests supported by exclusive rights in underlying gene patents. Regardless of the outcome, the case promises to reinvigorate a broader policy debate surrounding gene and biotechnology patents, as well as the media and public attention paid to the issue.

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