

# District Court Holds Myriad's Gene Patents Invalid

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The United States patent system is an important catalyst for innovation. The patent system is based on the U.S. Constitution which specifically grants Congress the power to "promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries." *U.S. Constitution, Art. I, section 8, clause 8*. The classic *quid pro quo* justification of the patent system is that in exchange for the time-limited, exclusive rights of a patent, an innovator will invest time, intellect, and money to provide the public with important and novel technologies.

In no industry is this exchange more apparent than the life sciences. Each year, biotechnology and pharmaceutical companies funnel billions of dollars into research and development of new products, therapies and diagnostic aids. According to the Biotechnology Industry Organization ("BIO"), U.S. publicly traded biotech companies spent \$27.1 billion on research and development in 2006. *BIO, Guide to Biotechnology 2008*. Because the development of biotechnology and pharmaceuticals can be time intensive, unpredictable, and expensive, life sciences innovators need the mechanisms provided by the patent system to recoup their investments and ensure a steady revenue stream for further research and development.

A recent district court case now threatens to disrupt the balance of this exchange. In *Association for Molecular Pathology v. U.S. Patent and Trademark Office*, Judge Sweet of the Southern District of New York held that the patents-in-suit (the "Myriad patents") are unsustainable as a matter of law and constitute unpatentable subject matter for being directed to isolated DNA containing sequences found in nature. *Association for Molecular Pathology v. U.S. Patent and Trademark Office*, 209 Civ. 4515 (RWS), March 29, 2010.

## The Case

The case was brought by a multitude of plaintiffs, including the Association for Molecular Pathology, the American Civil Liberties Union, researchers whose work is affected by the Myriad patents, and patients unable to afford the high cost of the screening process covered by the Myriad patents (collec-

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tively the "Plaintiffs"). The Defendants were Myriad Genetics, the U.S. Patent and Trademark Office ("USPTO"), and the University of Utah Research Foundation (part owner of the patents-in-suit) (collectively "Myriad").

At issue were seven Myriad patents directed to isolated DNA encoding for BRCA1 and BRCA2 polypeptides, and methods for detecting mutations in these genes. Women with certain mutations in the BRCA1 and BRCA2 genes have a significantly increased risk of developing breast cancer. The technology covered by the Myriad patents has thus proved incredibly valuable in screening women for these mutations. The fact that this technology is patented, however, means that access to this important technology is not as freely available as some would like.

The Plaintiffs alleged that multiple claims in the Myriad patents were invalid because they cover products of nature, laws of nature and/or natural phenomena, and abstract ideas or basic human knowledge or thought. On summary judgment Judge Sweet agreed, characterizing the USPTO's practice of granting patents on DNA sequences claimed in the form of "isolated DNA" as a "lawyer's trick that circumvents the prohibitions on the direct patenting of the DNA in our bodies but which, in practice, reaches the same result." *Opinion page 3*. Judge Sweet further found the claimed methods to be "abstract mental processes" and held that they "constitute unpatentable subject matter under §101." *Opinion page 4*.

Judge Sweet articulated the standard for assessing validity of the composition claims under §101 as whether the claimed composition possesses "markedly different characteristics" or has "a new or distinctive form, quality, or property" from a product of nature. *Opinion page 110*. Judge Sweet particularly focused on the characterization of DNA as a "physical embodiment of information," concluding that none of the structural and functional differences cited by Myriad between native BRCA1/2 DNA and the isolated BRCA1/2 DNA claimed in the patents-in-suit render the claimed DNA "markedly different." *Opinion page 125*.

This decision is contrary to the long-accepted USPTO practice of deeming gene patent claims to be §101-compliant so long as such claims are directed to an isolated and purified form. In 2001, the USPTO published a revised version of guidelines to be used by its examiners in reviewing patent applications for compliance with the utility

requirement of §101 and responded to public comments submitted in connection with the new guidelines. Several comments urged the USPTO not to issue patents for genes because genes "are discoveries rather than inventions" and because "genes are products of nature." *Federal Register, vol. 66, No. 4, 1092-1093*. The USPTO's response cited 35 U.S.C. §101, which allows a patent to be granted to "whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof," and stated its position that "thus, an inventor's discovery of a gene can be the basis for a patent on the genetic composition isolated from its natural state and processed through purifying steps that separate the gene from other molecules naturally associated with it." *Id. at 1093 (emphasis added)*. The USPTO went on to state its position that an isolated and purified DNA molecule of an excised gene that has the same sequence as a naturally occurring gene is eligible for a patent because it does not occur in that isolated and purified form in nature. The USPTO further stated that an isolated and purified synthetic DNA molecule that has the same sequence as a naturally occurring gene is eligible for a patent because its purified state is different than the naturally occurring compound. When requested by a commenter to seek guidance from Congress as to whether naturally occurring genetic sequences are patentable subject matter, the USPTO declined, indicating that the legislative history of §101 clearly demonstrates Congress's intent that "anything under the sun that is made by man" is eligible for patenting. *Id. at 1093, citing S. Rep. No. 1979, 82d Cong., 2d Sess., 5 (1952); H.R. Rep. No. 1923, 82d Cong., 2d Sess., 6 (1952)*.

## Industry Impact

With appeal to the Federal Circuit and Supreme Court virtually inevitable, it is too early to gauge the long-term impact this decision will have, as a final resolution is likely years away. In the short term, there may be some investors who shy away from major investment in particular biotechnology companies until there is greater certainty moving forward. This will not be the first time the biotechnology industry has dealt with a perceived blow to its ability to obtain solid patent protection. In mid-March 2000, a misinterpreted White House announcement regarding gene patents led to a drastic drop (up to 30 percent) in stock prices of major biotechnology companies. President Clinton and British Prime Minister Tony Blair had planned to announce their shared position that Human Genome Project data should reside in the public domain. In communications by the press, however, this announcement was incorrectly conveyed as an agreement to jointly advocate a ban on gene patents. The misunderstanding was ultimately cleared up, but the temporary stock plunge that followed the

announcement illustrates the importance placed upon patents within the biotechnology industry. Without the availability of a patent, biotechnology companies will lose a major tool for recovering their investments. BIO has already attempted to allay concerns that may arise from this decision by issuing a press release that emphasizes that this decision is "only a preliminary step in the legal process that does not affect how the U.S. Patent and Trademark Office (PTO) evaluates patent applications relating to DNA-based inventions." *BIO Statement on Initial Decision in Myriad Genetics Lawsuit, press release dated March 30, 2010*.

## Congressional Action

The courts are not the only arm of government involved in the gene patent debate. In 2002, the Secretary's Advisory Committee on Genetic Testing ("SACGT") was chartered to, among other things, examine current patent policy and licensing practices for their impact on access to genetic technologies. In its February 25, 2010 report, the SACGT recommendations included two statutory changes: (1) the creation of an exemption from liability for infringement of patent claims on genes for anyone making, using, ordering, offering for sale, or selling a test developed under the patent for patient care purposes; and (2) the creation of an exemption from patent infringement liability for those who use patent-protected genes in the pursuit of research.

While these statutory changes would certainly improve patient access to important medical tests already developed, these changes would also deflate the power of any patents granted for future technologies, thus resulting in a lack of incentive to create new groundbreaking tests.

A compromise between the recommendations of SACGT and the issue of patent access could be legislation establishing a compulsory licensing scheme, whereby patented technologies are available for limited uses (such as patient care) in exchange for reasonable licensing fees. That way, patient access is increased but innovators maintain their ability to recoup their investment. Any consideration by Congress would need to study the impact of such legislation on investment in research and development and the proliferation of technology.

## Going Forward

If not for the incentives provided by the patent system, a commercially available screening test utilizing BRCA1 and BRCA2 DNA molecules may not have ever been developed in the first place. Thus, the system whose incentives provided for the development of such an important diagnostic tool is now being attacked for providing the very results that it was intended to incentivize. Those who minimize (or villainize) the contributions of the patent system to promoting the progress of science should consider the message taught by the old axiom "Never bite the hand that feeds you."