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## U.S. District Court Decides That Isolated Genes Cannot Be Patented

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The District Court for the Southern District of New York has released an important decision holding that isolated genes cannot be patented under U.S. law. In a summary judgment ruling in *Association for Molecular Pathology v. U.S. Patent and Trademark Office*, the Court held that composition claims directed to DNA sequences are invalid because they violate the U.S. prohibition against patenting products of nature. The Court also found related process claims to be invalid because they were directed to mental processes that failed to include the machine or transformation steps required by the recent decision in *In re Bilski*.

Myriad Genetics, one of the defendants, has indicated that it will appeal the decision. Nonetheless, if it is affirmed, the decision could have far-reaching implications for U.S. patents claiming DNA-based inventions and for the biotechnology industry generally.

### Facts

In the mid-1990s, Myriad and a group of academic researchers announced that they had sequenced Breast Cancer Susceptibility Genes 1 and 2 (BRCA1 and BRCA2), two human genes linked to breast cancer. Myriad and others applied for and obtained several U.S. patents relating to the isolated and sequenced BRCA1 and BRCA2 genes. As the owner or exclusive licensee of these patents, Myriad developed and started marketing genetic tests designed to identify mutations in these genes.

The Association for Molecular Pathology (AMP) and other not-for-profit organizations and individuals brought an action to declare that a number of claims in Myriad's patents were invalid. AMP alleged that composition claims to the isolated, sequenced BRCA1 and BRCA2 genes were invalid because they claimed unpatentable subject-matter. AMP also alleged that related claims over the process of "analyzing" and "comparing" a gene sequence with the isolated BRCA1 and BRCA2 genes were invalid because they were directed to mere mental processes.

The plaintiffs brought a motion for summary judgment that Myriad's patents were invalid. On March 29, 2010, the District Court granted the motion.

### The District Court's Decision

The sole issue before the District Court was whether the claims at issue were for patentable subject-matter. Judge Robert Sweet held that under U.S. law, purification of a natural compound, "without more," cannot transform a product of nature into patentable subject-matter. As a result, he found that compositions containing isolated human DNA are not proper subject-matter for a patent because isolated DNA sequences are not markedly different from naturally occurring DNA. Myriad had

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argued that isolated DNA molecules differ from native DNA and should therefore be treated no differently from any other chemical compounds for patent eligibility. However, the Court held that DNA is unique among chemical compounds because it is a physical carrier of information. Moreover, the utility of isolated DNA is primarily a function of the nucleotide sequence being identical between native and isolated DNA. In the Court's view, this meant that isolated DNA is not markedly different from a product of nature (native DNA), despite the fact that there are structural and functional differences between isolated and native DNA.

The Court also held that the process claims at issue were invalid because they claimed mere mental processes. The Court's decision seemed to turn on the wording of the specific claims, which were directed to processes for "analyzing" or "comparing" a gene sequence with the BRCA sequences and noting whether the specified naturally occurring mutations existed. Judge Sweet held that this language fell short of satisfying the "machine or transformation" tests set out in the recent decision of the Court of Appeals for the Federal Circuit (CAFC) in *In re Bilski*, now under appeal to the U.S. Supreme Court.

The plaintiffs urged the District Court to make factual findings about the impact of the patents at issue on the testing for gene mutations, and on genetic research and the health of society generally. The plaintiffs also sought declarations about the constitutionality of the U.S. Patent and Trademark Office's (USPTO) practices regarding patent applications relating to DNA-based inventions. The Court declined to consider these issues.

Myriad has stated that it will appeal Judge Sweet's decision. This decision will therefore not be the last word and the CAFC will have the opportunity to comment on Judge Sweet's legal conclusions.

## Implications

What commercial impact this decision will have on the biotechnology industry remains to be seen. Until the CAFC, and possibly the U.S. Supreme Court, reviews the District Court's decision, U.S. law governing the patenting of DNA-based inventions will remain in a state of flux. While BIO, the U.S. Biotechnology Industry Organization, reports that the USPTO is not expected to change its current practices until all appeals from the District Court's decision have been exhausted, biotechnology patent applicants may wish to consult with their patent advisers regarding their patent- and claim-drafting strategies. **T**