

To: Our Clients and Friends

March 30, 2010

District Court Finds Isolated DNA To Be Unpatentable Subject Matter

Yesterday, the United States District Court for the Southern District of New York issued an opinion, on partial summary judgment, which invalidated, as non-statutory subject matter, 15 claims covering isolated DNA and diagnostic and screening methods underlying a test used for detecting breast cancer. [*Association for Molecular Pathology, et al. v. United States Patent and Trademark Office*, 09 Civ 4515 \(March 29, 2010\)](#). The decision, if upheld, could disturb over 30 years of jurisprudence and cast doubt upon the validity of many so-called “gene patents” directed to other isolated DNA sequences and similarly claimed subject matter.

The patents-in-suit are exclusively licensed to Myriad Genetics, Inc. by the owner, University of Utah Research Foundation, and cover a widely used test for detecting breast cancer marketed by Myriad. The test is based on the discovery that mutations in two genes, the BRCA1 and BRCA2 genes, are associated with an increased risk for breast cancers.

The American Civil Liberties Union and the Public Patent Foundation at the Benjamin N. Cardozo School of Law in New York joined with individual patients, researchers, physicians, and medical organizations to challenge the patents. They argued that genes are products of nature and do not fall within the scope of patentable subject matter.

Myriad asked the court to dismiss the case, claiming that the step of isolating the DNA from the body transforms it and makes it patentable. Myriad argued that a long line of court decisions support the patentability of isolated DNA and its use in diagnostic methods.

U.S. District Judge Robert Sweet, however, concluded that the claims “are directed to a law of nature and were therefore improperly granted.” *Association for Molecular Pathology* at *149. More specifically, the judge found “[b]ecause the claimed isolated DNA is not *markedly different* from native DNA as it exists in nature, it constitutes unpatentable subject matter under 35 U.S.C. §101.” *Id.* at *135 (emphasis added). With respect to the method claims, the judge, relying on the so-called machine or transformation test of *In re Biliski* (now awaiting decision at the Supreme Court) further found they along with “the plain and ordinary meanings of the terms ‘analyzing’ or ‘comparing’

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establish that the method claims-in-suit are directed only to the abstract mental processes of ‘comparing’ or ‘analyzing’ gene sequences” and purely mental processes have long been deemed to be outside the scope of patentable subject matter. *Id.* at *141.

Myriad has said it will appeal the decision to the Court of Appeals for the Federal Circuit, and the appeal will undoubtedly be followed closely because of its potentially far-reaching implications. If upheld, this decision could impact many other gene patents. But the impact may not stop there. For example, the decision, if left unchanged, may extend to patents claiming other isolated naturally occurring compositions used as pharmaceuticals, in diagnostics, or even as reagents in chemical processes.

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