

DISTRICT COURT CONCLUDES THAT ISOLATED DNA IS NOT PATENTABLE

Earlier this year, the American Civil Liberties Union (“ACLU”) and several other plaintiffs filed a lawsuit to invalidate patents covering the breast cancer susceptibility genes, BRCA1 and BRCA2. The patents are exclusively licensed by Myriad Genetics, who has made a clinical diagnostic test available. On March 29, 2010, the District Court for the Southern District of New York granted plaintiff’s motion for summary judgment concluding that isolated DNA compositions are not patent eligible subject matter under the patent statute, and invalidating the patents covering BRCA1 and BRCA2. *Association for Molecular Pathology v. United States Patent and Trademark Office* (09 Civ. 4515, S.D.N.Y. March 29, 2010).

In their motion for summary judgment, the plaintiffs alleged that the patents were invalid because human genes are products of nature, laws of nature and/or natural phenomena, and abstract ideas or basic human knowledge or thought. Although the patents claim “isolated DNA” (i.e., not DNA in anyone’s body) and diagnostic tests using the isolated DNA, the plaintiffs argued that the claimed DNA was the same as, and performed the same function as, its natural counterpart.

The District Court determined that the purification of a product of nature, without more, cannot transform the product into patentable subject matter. Rather, the purified product must possess “markedly different characteristics” in order to be considered patent eligible subject matter. The District Court determined that DNA is distinct in its essential characteristics from any other chemicals found in nature because it is the only compound in nature that represents physical embodiments of biological information. The District Court reasoned that DNA’s existence in “isolated” forms alters neither this fundamental quality of DNA as it exists in the body nor the information it encodes. The District Court concluded that the patents directed to “isolated DNA” containing sequences found in nature do not possess markedly different characteristics from their natural counterpart, and thus are not patent eligible subject matter.

This is a District Court case and the decision will likely be appealed; however, this decision may have a significant impact on the biotechnology industry. The decision concludes that the discovery of new genes, gene variants, and proteins are not patentable when isolated from human cells and used as the basis of a diagnostic or therapeutic without proof of some “markedly different characteristics” of those compounds compared to their natural form. The decision raises



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a question as to whether companies will invest the significant capital required to develop these technologies and bring them to the healthcare marketplace if they cannot secure protection for their investment.

The advantages of early disease detection are clear. Moreover, many of the next generation of therapeutics will come from the biotechnology industry. Absent the limited exclusivity provided by patents, it is not clear that companies will invest in technologies based upon novel genes and proteins. Myriad has at least until April 29, 2010 to appeal the District Court's decision, and this case will continue to be one that the entire industry will be watching closely.

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