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Supreme Court to Consider Whether (Isolated) Human Genes are Patentable

IP Buzz

On November 30, 2012, the U.S. Supreme Court agreed to decide a case presenting the seemingly simple, but legally complex, question, "Are human genes patentable?"After *Bilski v. Kappos*, 130 S. Ct. 3218 (2010) and *Mayo Collaborative Services v. Prometheus Laboratories Inc.*, 132 S. Ct. 1289 (2012), this grant of certiorari represents the third time in recent years that the Supreme Court will assess the scope of patentable subject matter under 35 U.S.C. § 101.

The patents at issue in the case, held by Myriad Genetics, Inc. (Myriad), pertain to technologies for assessing a woman's risk of breast and ovarian cancers and making clinical decisions on prophylactic courses of action, based on the discovery that mutations in the human BRCA1 and BRCA2 genes are associated with a greater risk of these cancers. The patents include claims directed to isolated DNA for BRCA1 and BRCA2.

In its petition seeking Supreme Court review, the American Civil Liberties Union (ACLU) argued that the patents are directed to naturally occurring, and therefore, unpatentable, segments of the human genome. The ACLU argued that the patents limit further research into the genes and the accessibility of at-risk individuals to testing. By contrast, Myriad argued in opposition that "[t]he challenged composition claims are instead narrowly drawn to specific, defined DNA molecules, isolated by human scientists in laboratories, that do not naturally occur," citing the decision of the Court of Appeals of the Federal Circuit below. In other words, because human ingenuity was required to isolate the molecules, they represent patentable subject matter. Myriad referenced long-standing precedent supporting the issuance of patents directed to isolated DNA.

This case has a long procedural history, and this is the second time that the U.S. Supreme Court is considering the Myriad patents. The challenge to the Myriad patents began in 2009, when the ACLU and the Public Patent Foundation, on behalf of numerous plaintiffs, filed a declaratory judgment alleging that certain claims were invalid for not being directed to patentable subject matter. In March 2010, the U.S. District Court for the Southern District of New York agreed with the plaintiffs and found the claims invalid. On appeal in July 2011, the Federal Circuit reversed the District Court's finding and deemed claims directed to isolated DNA molecules to be patentable subject matter. (See previous ***IP Buzz* article** on this decision). Then, following the ACLU's petition for *writ of certiorari*, on March 26, 2012, the Supreme Court vacated the Federal Circuit's decision and remanded the case for further consideration in view of its *Mayo v. Prometheus* decision. On remand, the Federal Circuit again reached the same conclusions. That led to this recently granted petition for *certiorari*.

In deciding this important case, which is likely to have a significant impact on the biotech industry, the Supreme Court will have to consider long-standing precedent dealing with the scope of patentable subject matter in the life sciences. The case is *Association for Molecular Pathology v. Myriad Genetics, Inc.*, Supreme Court Docket No. 12-398. Venable will be monitoring the case and will provide an alert once it is decided. In the meantime, if you have any questions regarding this case or article, please contact the authors or any other attorney in **Venable's Patent Group**.

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