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Supreme Debate: Are Human Genes Patentable?

IP Buzz

On April 15, 2013, tackling an issue of significant importance to the biotechnology and health care industries, the U.S. Supreme Court heard oral arguments over whether human genes are patentable and more specifically, whether isolated DNA is patentable.

The debate in the case, *Association for Molecular Pathology v. Myriad Genetics, Inc.*, U.S., No. 12-398, centered around whether isolated DNA encoding BRCA1 polypeptides are unpatentable as products of nature. The patent at issue covers the isolated DNA molecules used for testing breast and ovarian cancer risk, which the Association for Molecular Pathology argued are not eligible for patents under 35 U.S.C. §101 because they are DNA found in nature. Myriad defended the patent as claiming isolated and extracted molecules created by the inventors as products of "manipulation."

The Justices actively engaged in questioning around the issue of patentability of isolated DNA, complementary DNA (cDNA), and processes for extracting and isolating natural products. In response to Justice Ginsberg questioning why isolated DNA should be considered differently from other isolated natural products, the Association argued that manipulation of a product of nature requires alteration to a product that is no longer what it was in nature. The Association emphasized that the isolated DNA are naturally-occurring sequences.

Justice Sotomayor and Chief Justice Roberts characterized the invention as merely "snipping" pieces from naturally occurring material (genetic sequence). Justice Sotomayor questioned how one can patent a sequential numbering series (of DNA sequences) occurring in nature. Myriad explained that the isolated DNA was not merely "snipping" a sequence out of a gene. Rather, it involves a transformation to a new molecule.

The Department of Justice presented a position that isolated DNA should not be eligible for patenting, but the cDNA would be patentable subject matter. Justice Alito noted that this new position from the government is contrary to the U.S. Patent and Trademark Office's long-standing practice of granting patents to isolated DNA.

While questioning appropriate limits for the expansive view of patentable subject matter, Justice Ginsburg and Chief Justice Roberts noted that patentability is further assessed by review for obviousness. Chief Justice Roberts wondered whether patentability of DNA should be addressed under the rubric for obviousness rather than patent-eligible subject matter.

A few justices noted the incentives of patents for innovation, and the negative impact if patentability is restricted at the broadest level under § 101. Justices Kagan, Scalia, Kennedy, Alito and Sotomayer each questioned the result of limiting patent protection for products isolated from nature, but they offered that "process" patents (process of extracting a product of nature) and "use" patents (new use for the isolated product) would be alternatives.

The Court of Appeals for the Federal Circuit twice ruled that the claims in Myriad's patent are eligible for patent protection. By a 2-1 decision, claims to isolated DNA were found to be patentable subject matter, and the panel unanimously held that claims to cDNA and a method of using genes to screen for potential cancer therapeutics are patentable. The Supreme Court appeared to agree that cDNA claims satisfy § 101 for patentability as sequences that do not occur in nature (conceded by the Solicitor General). Patent eligibility for the extraction and isolation process was undisputed. Overall review of this case and the debate at the hearing hints that the Court may have a different opinion of eligibility for the isolated DNA.

This case follows a few recent high-profile decisions in which the Court struck down patents as claiming ineligible laws of nature or abstract ideas. Decisions in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 132 S. Ct. 1289 (2012), and *Bilski v. Kappos*, 130 S. Ct. 3218 (2010), are

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indications of the Court's willingness to limit the broad view of patentable subject matter. Further clarification of ineligible "products of nature" is expected in this case.

With the validity of thousands of patents previously issued to genes and isolated DNA molecules potentially at risk, many others join the biotechnology industry to await the Court's decision. We expect an opinion in June.

In the meantime, additional information about this case can be found in previous IP Buzz articles of **December 2012** and **August 2011** (Federal Circuit decision). If you have any questions regarding this case, please contact the attorneys in **Venable's Patent Group**.