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U.S. Supreme Court To Decide If Human Genes Can Be Patented

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On November 30, 2012, the U.S. Supreme Court granted *certiorari* in the "ACLU/Myriad" gene patenting case (*Association for Molecular Pathology v. Genetics, Inc.*), taking on the debate over the patent-eligibility of human genes. The Court will review the August 16, 2012 Federal Circuit decision that held for the second time that Myriad's claims directed to isolated DNA sequences satisfy 35 USC § 101.

The Court's order granting certiorari is limited to the following question:

> Are human genes patentable?

However, in order to assess Myriad's patents, it will have to decide whether Myriad's claims, which are directed to "isolated DNA" that encompass genomic DNA constructs, satisfy 35 USC § 101. Thus, the Court will have to delve into the issue of whether "isolated" DNA is sufficiently distinguished from naturally occurring DNA to be patented.

The Case History

This case stems from Myriad's appeal of the March 29, 2010 summary judgment decision of the U.S. District Court for the Southern District of New York (Sweet, J.) that invalidated the challenged claims in seven Myriad patents as patent-ineligible under 35 USC § 101. The Federal Circuit issued its **first decision** in this case on July 29, 2011.

After the Supreme Court issued its decision in ***Mayo v. Prometheus***, it granted *certiorari*, vacated the July 29, 2011 decision, and remanded the case to the Federal Circuit for reconsideration in view of *Mayo*. The Federal Circuit issued its **second decision** on August 16, 2012, and held that at least one plaintiff had standing, the diagnostic method claims based on "comparing" or "analyzing" DNA sequences are not patent-eligible, the drug screening method claim is patent-eligible, and all of the "isolated DNA" claims are patent-eligible, including those encompassing genomic DNA.

The Federal Circuit Decision Under Review

In his August 16, 2012, opinion for the court, Judge Lourie summarized the majority decision of the Federal Circuit as follows:

> The isolated DNA molecules before us are not found in nature. They are obtained in the laboratory and are man-made, the product of human ingenuity. While they are prepared from products of nature, so is every other composition of matter. All new chemical or biological molecules, whether made by synthesis or decomposition, are made from natural materials.

Judge Bryson drew on the Supreme Court's decision in *Mayo* to explain his dissenting opinion:

> Just as a patent involving a law of nature must have an "inventive concept" that does "significantly more than simply describe . . . natural relations," Mayo, 132 S. Ct. at 1294, 1297, a patent involving a product of nature should have an inventive concept that involves more than merely incidental changes to the naturally occurring product. In cases such as this one, in which the applicant claims a composition of matter that is nearly identical to a product of nature, it is appropriate to ask whether the applicant has done "enough" to distinguish his alleged invention from the similar product of nature. Has the applicant made an "inventive" contribution to the product of nature? Does the claimed composition involve more than "well-understood, routine, conventional" elements? Here, the answer to those questions is no.

A Decision By Summer?

The Supreme Court's decision to grant *certiorari* in *Myriad* creates a cloud of uncertainty over isolated DNA claims that read on human genes, at least until the Court renders its decision. It is possible that the case will be argued and decided before the end of the current term, in June 2013. Until then, it is likely that that the U.S. Patent Office will continue to grant patents on "isolated" DNA and other "isolated" products of nature.

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