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U.S. Supreme Court Again Grants *Certiorari* in *Myriad* to Address the Patent-Eligibility of Human Genes

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On November 30, 2012, the U.S. Supreme Court granted *certiorari* for the second time in A*ssociation for Molecular Pathology v. U.S. Patent & Trademark Office*, No. 12-368, 2012 U.S. LEXIS 9219 (U.S. Nov. 30, 2012) to address the question: "Are human genes patentable?" The Supreme Court is expected to hear argument and decide the case during the present term.

Procedural Background

This case relates to patents owned by Myriad Genetics, which relate to isolating BRCA1 and BRCA2 genes from a human body and using the isolated genes to diagnose breast cancer.

This case began in 2009, when a number of medical associations, doctors and patients challenged the patent eligibility of claims in seven patents held in part by Myriad Genetics, Inc. and the University of Utah Research Foundation ("Myriad"). At the trial court level, all of the claims were held to be patent- ineligible on summary judgment. *Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office*, 702 F. Supp. 2d 181, 220-37 (S.D.N.Y. 2010) ("*Myriad I*").

On appeal, in a split decision, the Federal Circuit reversed in part, finding all of the isolated DNA composition claims, as well as one method claim directed to screening potential cancer therapies based upon changes in the growth rates of transformed cells, to be patent-eligible. *Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office*, 653 F.3d 1329, 1358 (Fed. Cir. 2011) ("*Myriad II*"). The Federal Circuit also found one set of method claims directed to identifying cancer-predisposing mutations by analyzing or comparing a patient's DNA sequence to a normal sequence to be patent- ineligible. *Myriad II*, at 1355-57.

On petition for *certiorari* for the first time, the U.S. Supreme Court summarily granted *certiorari* , vacated *Myriad II* and remanded the case to the Federal Circuit to be reconsidered in light of its recent decision in *Mayo Collaborative Services v. Prometheus Labs., Inc.*, 132 S. Ct. 1289 (2012). See Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 132 S. Ct. 1794 (2012) ("*Myriad III*"). In *Mayo*, the Supreme Court invalidated certain blood testing method claims directed towards diagnosing and treating a disease, finding that the subject method claims impermissibly claimed unpatentable laws of nature.

On remand in *Myriad III*, the same panel of the Federal Circuit reheard arguments to consider the question: "What is the applicability of the Supreme Court's decision in *Mayo* to Myriad's isolated DNA claims and to method claim 20 of the '282 patent?" *Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office*, 467 F. App'x 890 (Fed. Cir. 2012).

This past summer, in its decision on remand, the Federal Circuit panel issued another split decision. The Federal Circuit decision on remand generally mirrored its original decision and stated that the Supreme Court's decision in *Mayo* had little impact on the issue of whether Myriad's claims were patent eligible. See *Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office*, 689 F.3d 1303 (Fed. Cir. 2012) ("*Myriad IV*").

For a detailed discussion of the procedural history to date and the court's holding in *Myriad IV* , please *see* Charles R. Macedo, Michael J. Kasdan and David P. Goldberg, *Decision by U.S. Court of Appeals for the Federal Circuit in Myriad Remand Mirrors Reasoning in NYIPLA Amicus Brief*, N.Y. Intell. Prop. L. Ass'n Bull. (Aug./Sept. 2012), *available at* www.arelaw.com ; *see also* M. Kasdan, *Webinar: Patent Eligibility for Pharma, Biotech and Beyond: A Review and Discussion of the Mayo and Myriad Cases*, from the Celesq®- West LegalEdcenter IP Master Series (Oct. 3, 2012)

The Latest Petition

In the latest petition in the *Myriad* case, the American Civil Liberties Union requested that the Supreme Court hear the following three questions:

1. Are human genes patentable?
2. Did the court of appeals err in upholding a method claim by Myriad that is irreconcilable with the Court's ruling in *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289 (2012)?
3. Did the court of appeals err in adopting a new and inflexible rule, contrary to normal standing rules and this Court's decision in *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118 (2007), that petitioners who have been indisputably deterred by Myriad's "active enforcement" of its patent rights nonetheless lack standing to challenge those patents absent evidence that they have been personally threatened with an infringement action?

Petition for a Writ of Certiorari at 1, *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, No. 12-368 (Sept. 24, 2012).

On November 30, 2012, the Supreme Court issued an order simply stating: "The petition for a writ of certiorari is granted limited to Question 1 presented by the petition." *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, No. 12-398, 2012 LEXIS 9219, at *1 (U.S. Nov. 30, 2012) ("*Myriad V*").

Practical Significance

Myriad V will present the Supreme Court with yet another opportunity to address the law of patent- eligibility for the third consecutive year. The Court's prior decisions in *Bilski* and *Mayo*, combined with seemingly conflicting opinions from the Federal Circuit and District Courts concerning patent -eligible subject matter, have caused much unrest in the patent law. The significance of the Supreme Court's declining to accept the second question in the ACLU petition is unclear, but suggests that the Supreme Court may agree that Mayo should not affect the result in *Myriad*.

Please continue to monitor our website as we continue to track the status of this decision and other decisions relating to patent-eligible subject matter.

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Mr. Macedo, along with Anthony F. Lo Cicero, Partner at Amster, Rothstein & Ebenstein LLP, and Ronald M. Daignault and Matthew B. McFarland of Robins, Kaplan, Miller & Ciresi LLP, prepared the NYIPLA Amicus Brief in *Myriad IV*. The firm also acknowledges Sandra Hudak, a summer associate at Amster, Rothstein & Ebenstein LLP, for her work on that Amicus Brief.