

# Decision by U.S. Court of Appeals for the Federal Circuit in Myriad Remand Mirrors Reasoning in NYIPLA Amicus Brief

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On August 16, 2012, the U.S. Court of Appeals for the Federal Circuit (“Federal Circuit”) released its highly anticipated decision in *Ass’n for Molecular Pathology v. U.S. Patent & Trademark Office*, No. 2010-1406 (Fed. Cir. Aug. 16, 2012) (“*Myriad IV*”), concerning the patent eligibility of isolated DNA under 35 U.S.C. § 101, on remand from the U.S. Supreme Court. See *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 132 S. Ct. 1794 (2012) (“*Myriad III*”).

In *Myriad IV*, the Federal Circuit largely followed the rationale of its prior decision in the case. Cf. *Ass’n for Molecular Pathology v. U.S. Patent & Trademark Office*, 653 F.3d 1329 (Fed. Cir. 2011) (“*Myriad II*”). The *Myriad IV* majority decision reflects a reasoning similar to the positions set forth in the NYIPLA Amicus Brief filed in this case. Compare Brief for Amicus Curiae N.Y. Intellectual Property Law Ass’n in Support of Neither Party, *Ass’n for Molecular Pathology v. U.S. Patent & Trademark Office*, No. 2010-1406 (Fed. Cir. June 15, 2012), available at <http://www.nyipla.org/images/nyipla/Documents/Amicus%20Briefs/Myriad%202010%201406.pdf> (“NYIPLA Amicus Brief”), with *Myriad IV*, No. 2010-1406 (Fed. Cir. Aug. 16, 2012). Anthony F. Lo Cicero and Charles R. Macedo of Amster, Rothstein & Ebenstein LLP and Ronald M. Daignault and Matthew B. McFarland of Robins, Kaplan, Miller & Ciresi LLP prepared the NYIPLA Amicus Brief.

## Background

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”). On summary judgment at the trial court level, all of the claims were held to be patent ineligible. *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*”).

In a July 29, 2011 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. *Myriad II*, 653 F.3d at 1329, 1358. *Myriad II* 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. *Id.* at 1355-57.

Thereafter, the U.S. Supreme Court 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 *Myriad III*. In *Mayo*, the Supreme Court invalidated certain blood testing method claims directed towards diagnosing and treating a disease for claiming unpatentable laws of nature.

## The NYIPLA Amicus Brief

The NYIPLA filed an amicus brief not supporting either party to offer its views that the Supreme Court’s *Mayo* decision did not change existing patent-eligibility jurisprudence under 35 U.S.C. § 101, and that the composition claims at issue (for isolated DNA), as well as the method claim based on screening potential cancer therapies based upon changes in the growth rates of transformed cells, were patent eligible.

In pertinent part, the NYIPLA Amicus Brief argued:

*Mayo* maintained that patent-eligibility should be defined under Section 101’s four categories of statutory subject matter [*i.e.*, process, machine, manufacture, or composition of matter], and importantly, did not

overturn the holding in *Diamond v. Chakrabarty* that patent eligibility be broadly construed to “include anything under the sun that is made by man,” 447 U.S. 303, 309 (1980). *Mayo*, 132 S. Ct. at 1293. *Mayo* also continued to limit the judicial exceptions of patent-eligible subject matter subject to the same three “fundamental principles” set forth in its prior precedent: (1) laws of nature; (2) natural phenomena; and (3) abstract ideas. *Id.*

NYIPLA Amicus Br. at 4.<sup>2</sup>

The NYIPLA Amicus Brief asserted that applying these principles to the claims at issue should lead the court to find that:

- Myriad’s composition claims and one of its method claims fell within a statutory category of patent-eligible subject matter,
- these claims did not preempt any fundamental principles, and
- therefore, these claims were patent eligible under 35 U.S.C. § 101.

## The Federal Circuit Decision

The majority decision in *Myriad IV* follows this reasoning. See *Myriad IV*, slip op. at 36-52, 59-61. Writing for the court, Judge Lourie explained that the isolated DNA in Myriad’s composition claims was distinct from naturally occurring DNA:

BRCA1 and BRCA2 in their isolated states are different molecules from DNA that exists in the body; isolated DNA results from human intervention to cleave or synthesize a discrete portion of a native chromosomal DNA, imparting on that isolated DNA a distinctive chemical identity as compared to native DNA.

*Id.* at 45. The court went on to conclude that “the challenged [composition] claims are drawn to patent-eligible subject matter because the claims cover molecules that are markedly different – have a distinctive chemical structure and identity – from those found in nature.” *Id.* at 44.

Of note, the court pointedly rejected plaintiffs’ contention that the native and isolated DNA molecules were the same because they contained the same nucleotide sequence, holding:

[T]he patent eligibility of an isolated DNA is not negated because it has similar informational properties to a different, more complex natural material. The claimed isolated DNA molecules are distinct from their natural existence as portions of larger entities, and their informational content is irrelevant to that fact.

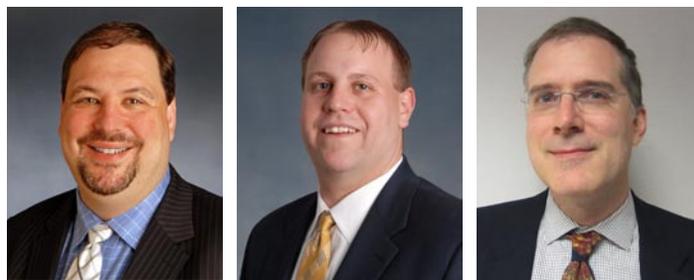
*Id.* at 48. Thus, because the isolated DNA molecules claimed did not fall within the product of nature exception, the claims were found to be patent eligible.

With respect to the method claim directed to screening potential cancer therapies based upon changes in the growth rates of transformed cells, the majority concluded that this claim was patent eligible because it recites a screening method based on the use of transformed, non-naturally occurring cells, and thus “includes more than the abstract mental step of looking at two numbers and ‘comparing’ two host cells’ growth rates.” *Id.* at 60. The majority also noted that the fact “that the claim also includes the steps of determining the cells’ growth rates and comparing growth rates does not change the fact that the claim is based on a man-made, non-naturally occurring transformed cell – patent-eligible subject matter.” *Id.*

The *Myriad IV* decision indicates that the Federal Circuit is committed to maintaining the fundamentals of the patent-eligibility jurisprudence under 35 U.S.C. § 101. The decision also reminds practitioners that § 101’s proper and limited role is to function as a “coarse filter” only. See, e.g., *MySpace, Inc. v. GraphOn Corp.*, 672 F.3d 1250, 1261 (Fed. Cir. 2012).

Importantly, the majority’s discussion of Myriad’s composition claims opens by stating this is not a case about genetic policy making,<sup>3</sup> nor is it about whether the claims at issue would pass muster under 35 U.S.C. §§ 102, 103 or 112. Rather, the majority’s opinion is solely limited to addressing the question of patent eligibility. Nevertheless, because of the charged political context of the case, there is a possibility that this decision will lead either to an *en banc* rehearing or another grant of *certiorari* by the U.S. Supreme Court.

### (Endnotes)



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<sup>2</sup> The NYIPLA also submitted an amicus brief in *Mayo* that advocated similar positions to those set forth in the NYIPLA Amicus Brief in *Myriad IV*. See <http://www.nyipla.org/images/nyipla/Documents/Amicus%20Briefs/MayoPrometheusNo2010-1150%20090811.pdf>.

<sup>3</sup> “Whether its unusual status as a chemical entity that conveys genetic information warrants singular treatment under the patent laws,” the majority opined, “is a policy question that we are not entitled to address.” *Myriad IV*, slip op. at 49. ■