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Federal Circuit Again Affirms Patent-Ineligibility of Diagnostic Method Claims: Key Takeaways from the Athena v. Mayo *Decision*

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On February 6, 2019, the Federal Circuit affirmed that patent claims covering a diagnostic test for a form of *myasthenia gravis* were patent-ineligible under 35 U.S.C. § 101. *Athena Diagnostics, Inc. v. Mayo Collaborative Services, LLC*, No. 2017-2508 (Fed. Cir. Feb. 6, 2019). The majority opinion, authored by Judge Lourie and joined by Judge Stoll, aligns with recent Federal Circuit decisions finding similar diagnostic method claims ineligible under the Supreme Court's *Mayo* test.[1] Judge Newman dissented, but her view did not carry the day. The *Athena* decision continues the trend of the susceptibility of diagnostic method claims to being found ineligible under § 101, including at the stage of a Rule 12(b)(6) motion to dismiss.

I. Background of the Decision

Myasthenia gravis ("MG") is a neurological disorder where patients experience muscle weakness caused by the generation of antibodies against the patients' own acetylcholine receptors (known as "autoantibodies"). Majority Op. at 3-4. About 20% of patients, however, suffer from MG symptoms without producing these autoantibodies. *Id.* at 4. The inventors of the patent-at-issue, U.S. Patent No. 7,267,820 ("the '820 patent"), discovered that many of this subgroup of patients instead generate autoantibodies to a membrane protein called muscle-specific tyrosine kinase ("MuSK"). *Id.* Prior to this discovery, the MuSK protein had not been associated with any disease. *Id.*

Athena Diagnostics, Inc. ("Athena"), the exclusive licensee to the '820 patent, markets a diagnostic test for MG called FMUSK that evaluates MuSK autoantibodies. *Id.* at 3. Mayo Collaborative Services, LLC ("Mayo") developed two competing diagnostic tests, prompting Athena to sue for infringement of the '820 patent. *Id.* Athena asserted claims 6-9 of the '820 patent, and only these claims were at issue. *Id.* Claims 7-9 successively depended from each other, and ultimately depended from unasserted independent claim 1; these claims read as follows:

> 1. A method for diagnosing neurotransmission or developmental disorders related to [MuSK] in a mammal comprising the step of detecting in a bodily fluid of said mammal autoantibodies to an epitope of [MuSK].
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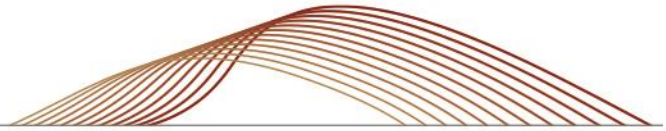
> 7. A method according to claim 1, comprising



> contacting MuSK or an epitope or antigenic determinant thereof having a suitable label thereon, with said bodily fluid,
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> immunoprecipitating any antibody/MuSK complex or antibody/MuSK epitope or antigenic determinant complex from said bodily fluid and
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> monitoring for said label on any of said antibody/MuSK complex or antibody/MuSK epitope or antigen determinant complex,
>
> wherein the presence of said label is indicative of said mammal is suffering from said neurotransmission or developmental disorder related to [MuSK].
>
> 8. A method according to claim 7 wherein said label is a radioactive label.
>
> 9. A method according to claim 8 wherein said label is 125I.

Asserted claim 6, which depended from a different series of claims, was different from the other asserted claims 7-9 in that it recited the use of a "reporter molecule" rather than a radioisotope in the detection of MuSK autoantibodies, in an exemplification of the enzyme-linked immunosorbent assay ("ELISA"). *Id.* at 6.

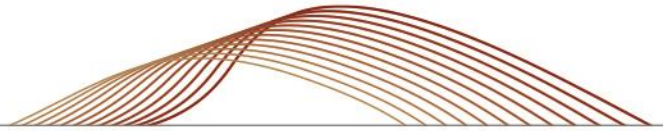
Mayo moved to dismiss Athena's complaint under Rule 12(b)(6), arguing that the asserted claims were invalid under 35 U.S.C. § 101. *Id.* at 3. In resisting the motion to dismiss, Athena focused its arguments on claims 7-9 of the '820 patent, although it had also asserted claim 6 and grouped all four claims together. *Id.* at 7. The United States District Court for the District of Massachusetts granted the motion to dismiss, finding under the Supreme Court's *Mayo* test that the claims (i) were directed to a law of nature, and (ii) lacked an inventive concept. *Id.* Athena appealed to the Federal Circuit.

II. The Court's Holding on Patent Eligibility

In a split decision, the Federal Circuit affirmed the district court's dismissal. The judges applied the Supreme Court's two-step patent eligibility framework under *Mayo*, which asks: (1) whether the claims at issue are directed to a patent-ineligible concept, *i.e.*, a law of nature, abstract idea, or natural phenomenon; and if so, (2) whether additional elements transform the nature of the claims into a patent eligible concept, *i.e.*, something more than routine or convention steps.

At step one of the *Mayo* test, the majority found the asserted claims were directed to a natural law, namely, the "correlation between the presence of naturally-occurring MuSK autoantibodies in bodily fluid and MuSK-related neurological diseases like MG." Majority Op. at 9-10. Even focusing on claim 9, which it described as the "most specific claim at issue," the majority concluded that "the claimed advance was only in the discovery of a natural law, and that the additional recited steps only apply conventional techniques to detect that natural law," and likened the claims at issue to those found ineligible in the prior decisions of *Cleveland Clinic*[2] and *Ariosa*.[3] *Id.* at 12-13. The majority further noted that "the specification describes the claimed concrete steps for observing the natural law as conventional." *Id.* at 12.

The majority rejected Athena's argument that the asserted claims were directed to an innovative laboratory technique rather than a natural law, noting that "Athena does not point to any innovation other than its discovery of the natural law." *Id.* at 13. Moreover, the majority distinguished the Federal Circuit's decision in *CellzDirect*,[4] stating that there, the Court had found "the 'end result' of the claims at issue was 'not simply an observation or detection' of a natural law," whereas "the claims before us only involve detecting a natural law 'with no meaningful non-routine steps.'" *Id.* (internal

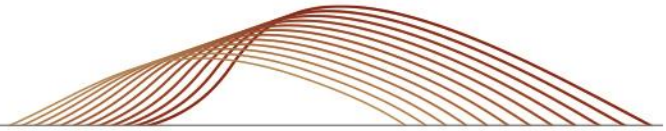


citations omitted). The majority also rejected Athena's lack-of-preemption argument, noting that while the public would still have had other ways of "interrogating the correlation between MuSK autoantibodies and MuSK-related disorders," the claims were nonetheless directed to a natural law. *Id.* ("Preemption is sufficient to render a claim ineligible under § 101, but it is not necessary."). Finally, the majority reaffirmed that method claims reciting the use of man-made substances can still be directed to a natural law, dismissing Athena's argument that the recitation of a man-made substance set its asserted claims apart from the diagnostic claims which had been found directed to natural law in prior decisions. *Id.* at 14.

At step two of the *Mayo* test, Athena argued that the claims provided for an innovative sequence of steps involving man-made molecules. *Id.* at 16. The majority noted, however, that the specification of the '820 patent described the "actual steps of detecting autoantibodies" as being "performed in accordance with immunological assay techniques known per se in the art." *Id.* The majority further observed that the recited steps of iodination and immunoprecipitation were "likewise described as standard techniques" in the specification. *Id.* And even accepting Athena's assertion that these techniques had never before been applied to detect MuSK autoantibodies prior to the inventors' discovery, the majority held that "performing standard techniques in a standard way to observe a newly discovered natural law" does not provide an inventive concept, because "the inventive concept necessary at step two [of the *Mayo* test] cannot be furnished by the unpatentable law of nature itself." *Id.* at 17-18 (internal quotations and citations omitted). Finally, the majority was again not swayed by Athena's invocation of the recitation of man-made molecules in the method claims at issue, which were unlike the composition claims found patent-eligible by the Supreme Court in *Myriad*.[5]

Athena also attempted two procedural arguments against Rule 12(b)(6) dismissal—both of which the majority rejected. First, Athena argued that the district court erred in not considering a submitted expert declaration, which had asserted that iodination and immunoprecipitation were not routine as applied to the claimed invention. *Id.* at 18-19. Applying First Circuit law, the majority held that the district court had discretion to refuse to convert the motion to dismiss into one for summary judgment. *Id.* at 19. Further, the majority found that the assertions in the expert declaration were "not consistent" with the complaint read in light of the patent—a complaint that had already been amended three times—and so the district court had no obligation to accept its assertions as true. *Id.* at 18, 20. Second, Athena argued that at least claim 6 should be remanded because it involved different technology than claims 7-9 and was never specifically analyzed by the district court. *Id.* at 20-21. The majority rejected this argument too, finding that "Athena waived its arguments specific to claim 6 by not making them before the district court," and went on to state that even on the merits, it would find claim 6 patent-ineligible, as the specification described ELISA as "known per se in the art." *Id.* at 20-22.

Judge Newman dissented. In her view, the majority had incorrectly applied step one of the *Mayo* test because it failed to consider the claims "as a whole" but instead had "eliminate[ed] the 'conventional' procedures" in finding the claims directed to a natural law. Dissent at 5. She would have found the claims patent-eligible under step one because the claimed "method of diagnosing Myasthenia Gravis is not a law of nature, but a man-made chemical-biomedical procedure." *Id.* at 11. Even if the claimed techniques were conventional, her view was that the "appropriate analysis of the role of conventional process steps in claims to a new method is under Sections 102 and 103, not Section 101." *Id.* Moreover, taking note of the concerns raised by various *amici curiae*, Judge Newman agreed that "the public interest is poorly served by adding disincentive to the development of new diagnostic methods." *Id.* at 12. In a responsive footnote to this last point, the majority did not disagree with Judge Newman



from the standpoint of policy and history, but stated that "[o]ur precedent leaves no room for a different outcome here." Majority Op. at 15 n.4.

III. Key Takeaways on Patent Eligibility

The *Athena* decision follows along a line of recent Federal Circuit decisions—from *Ariosa* to *Merial*[6] to *Cleveland Clinic*—finding diagnostic method claims ineligible for patenting under 35 U.S.C. § 101. The split decision in *Athena* reflects two competing viewpoints on the Federal Circuit regarding the application of the *Mayo* test with respect to diagnostic claims: Judge Lourie on the one hand, who in penning an opinion denying petition for rehearing *en banc* in the *Ariosa* case, wrote that there was "no principled basis to distinguish this case from *Mayo*, by which we are bound," *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 809 F.3d 1282, 1284 (Fed. Cir. 2015); and Judge Newman on the other, who would have granted rehearing *en banc* in *Ariosa*, and wrote in dissent there that "the new diagnostic method [in *Ariosa*] is novel and unforeseen, and is of profound public benefit," *id.* at 1294. These sentiments are echoed in the *Athena* decision. To date, however, the weight of Federal Circuit case law has aligned firmly with Judge Lourie's view when it comes to diagnostic method claims. And the Supreme Court has not expressed an appetite to speak to the issue, having denied petition for writ of *certiorari* in the *Merial* case. *Genetic Techs. Ltd. v. Merial L.L.C.*, 137 S. Ct. 242 (2016).

The *Athena* decision also exemplifies the potentially critical importance that the patent specification may have on the issue of patent-eligibility. Both at step one and step two of the *Mayo* test, the majority relied on the specification's description of the claimed immunological assay techniques as "known per se in the art" and "standard" to support its findings. The majority also affirmed the district court's refusal to consider an expert declaration submitted by the Athena appellants, in part because such declaration was at odds with the specification. Patent practitioners should bear in mind the potential impact of the patent specification on possible patent eligibility issues, in addition to considerations related to validity such as under 35 U.S.C. §§ 103 and 112.

Finally, patent practitioners should take note of the procedural posture by which the *Athena* decision arose. For the third time now (following *Merial* and *Cleveland Clinic*), the Federal Circuit has affirmed a Rule 12(b)(6) dismissal of diagnostic method claims on the basis of patent-ineligibility. The lesson is clear: whether on the side of plaintiffs or defendants, due consideration to § 101 must be given as early as possible where patent eligibility may be an issue—particularly for these types of diagnostic claims.

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If you have any questions concerning these developing issues, please do not hesitate to contact the following Paul Hastings New York lawyer:

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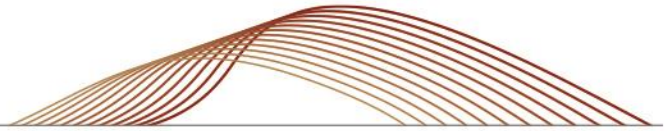
[1] *See Mayo Collaborative Serv. v. Prometheus Labs., Inc.*, 566 U.S. 66 (2012).

[2] *Cleveland Clinic Found. v. True Health Diagnostics LLC*, 859 F.3d 1352 (Fed. Cir. 2017).



[3] *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371 (Fed. Cir. 2015).

[4] *Rapid Litig. Mgmt. Ltd. v. CellzDirect, Inc.*, 827 F.3d 1042 (Fed. Cir. 2016).

[5] *Association for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576 (2013).

[6] *Genetic Techs. Ltd v. Merial L.L.C.*, 818 F.3d 1369 (Fed. Cir. 2016).