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Federal Circuit Upholds Invalidity of Athena's Claims Directed to Methods for Diagnosing Neurological Disorders

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In *Athena Diagnostics, Inc. v. Mayo Collaborative Services*[1], a divided panel of the Federal Circuit has provided another guidepost in the search for patent-eligible subject matter in the diagnostic industry. The Court upheld a judgment of invalidity under 35 U.S.C. § 101 against Athena's patent claims directed to diagnosing neurological disorders by detecting a patient's autoantibodies. Applying the Supreme Court's two-step analysis, the majority reasoned that Athena's claims were directed to a law of nature under step one and the additional steps recited in the claims "only apply conventional techniques to detect that natural law," failing step two. According to the majority, Athena did not point to any innovation other than its discovery of the natural law: that the presence of autoantibodies to a protein called muscle-specific tyrosine kinase ("MuSK") in a patient sample correlates to a MuSK-related neurological disorder. And because the patent specification admitted that the steps used to detect the natural law, which used a radiolabeled MuSK target, were conventional and routine, the majority held that the district court did not err in granting Mayo's motion to dismiss. Judge Newman dissented largely on policy grounds, noting that the "court's decisions on the patent-ineligibility of diagnostic methods are not consistent, and my colleagues today enlarge the inconsistencies and exacerbate the judgemade disincentives to development of new diagnostic methods, with no public benefit."

The *Athena* decision is a notable addition to the growing body of case law governing the patent eligibility of diagnostic methods. The Supreme Court's decision in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*[2] has been the primary benchmark for assessing the eligibility of diagnostic methods. Since *Mayo*, however, the Federal Circuit has sought to clarify, in cases including *Ariosa Diagnostics, Inc. v. Sequenom, Inc.,*[3] *Cleveland Clinic Found. v. True Health Diagnostics LLC*[4], and now *Athena*, that claims reciting naturally occurring correlations "with no meaningful non-routine steps in between" will generally not be considered patent eligible. By contrast, claims that recite "new and improved" laboratory techniques, as in *Rapid Litig. Mgmt. Ltd. v. CellzDirect, Inc.*[5], or a "novel method of treating a disease," as in *Vanda Pharm. Inc. v. West-Ward Pharm. International Ltd.*[6], will likely be considered patent-eligible. Whether claims fall on one side of this line or the other appears to depend heavily on whether the steps required to perform the method are either conventional and routine or new and improved.

The *Athena* decision is also notable because it reaffirms how the Federal Circuit analyzes diagnostic method claims. In particular, the Court continues to give significant weight to admissions in the patent specification about what was conventional, routine, and well-known[7]. In *Athena*, the Court found that "the claimed advance was only in the discovery of a natural law," and that "use of a man-made molecule [i.e., a radiolabeled antibody-antigen complex] in a method claim employing standard techniques [e.g., iodination and immunoprecipitation] to detect or observe a natural law may still leave the claim directed to a natural law." Thus, as in other facets of patent law, an admission in the

specification is likely to trump other evidence about the state of the art. *Athena* thus confirms that specifications, especially those involving this subject matter, should avoid making admissions that would jeopardize eligibility down the road.

As a procedural matter, the Federal Circuit disagreed with Athena that the district court erred by declining to consider its expert declaration about what was conventional at the time. Athena submitted the declaration in opposition to Mayo's motion to dismiss. As clarified by the Federal Circuit in *Aatrix Software, Inc. v. Green Shades Software, Inc.*[8], however, on a motion to dismiss (as distinct from a motion for summary judgment), factual allegations that a court must presume to be true in favor of the non-moving party must be pleaded in the complaint. While documents like the patent "merg[e] into the pleadings," expert declarations and the like do not. Therefore, as a practical matter, patentees seeking to leverage a factual dispute to defeat a motion to dismiss must be diligent about pleading the necessary facts in their complaint or else succeed in converting the motion into one for summary judgment. Only in the latter will courts consider matters outside of the pleadings under the elevated standards applicable to summary judgment.

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[1]No. 17-2508, 2019 WL 453489 (Fed. Cir. Feb. 6, 2019).
[2]566 U.S. 66 (2012).
[3]788 F.3d 1371 (Fed. Cir. 2015).
[4]859 F.3d 1352 (Fed. Cir. 2017).
[5]827 F.3d 1042 (Fed. Cir. 2016).
[6]887 F.3d 1117 (Fed. Cir. 2018).
[7]*Athena*, 2019 WL 453489, at *2; *Cleveland Clinic*, 859 F.3d at 1362; *Ariosa*, 799 F.3d at 1377.
[8]882 F.3d 1121, 1125 (Fed. Cir. 2018).

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