BANNER & WITCOFF, LTD.
INTELLECTUAL PROPERTY LAW

Intellectual Property Alert:

Athena v. Mayo: Are pure diagnostic claims *per se* ineligible for patenting?

By Sarah A. Kagan

February 8, 2019 — The U.S. Court of Appeals for the Federal Circuit issued its decision in *Athena Diagnostics, Inc., v. Mayo Collaborative Services, LLC*, (2017-2508) on February 6, 2019. The court held diagnostic method claims subject-matter ineligible, unless they embody a separate technical improvement distinct from the association of an analyte to a disease. The opinion of the court, filed by Judge Alan Lourie, and the dissenting opinion, filed by Judge Pauline Newman, operate as point-counterpoint, crystallizing two conflicting methods of analyzing claims for subject-matter eligibility under Supreme Court precedent.

Both Judge Lourie and Judge Newman trained as chemists and worked in the chemical-pharmaceutical industry. The two agree that protection of diagnostic methods would be a societal good. See majority opinion at footnote 4 and dissenting opinion at paragraph spanning pages 13 and 14. These judges subscribe to the patent catechism that patents serve as an incentive to innovation. Nonetheless, they read the precedents differently, with Judge Lourie stating that his hands were tied by the precedents.

Background facts and positions of the litigants are described here in our report of the oral arguments.

The two opposing Federal Circuit opinions highlight the criticality of the mode of analysis to outcome. In step one of the *Alice/Mayo* test, Judge Lourie found that the claims are directed to a natural law, which is "the correlation between the presence of naturally occurring MuSK[1] autoantibodies in bodily fluid and MuSK-related neurological diseases like MG (Myasthenia Gravis)." Judge Newman, in contrast, found at step one of the test that the claims are directed to a multistep method of diagnosis, not a law of nature. She found that the inventors discovered MuSK autoantibodies and applied their discovery to create a new diagnostic method. She criticized the panel majority's analysis for failing to consider the claim as a whole, and discarding elements viewed as old or conventional from its analysis. Judge Newman completed her *Alice/Mayo* analysis at step one, because the claim was not directed to a law-of-nature exception to patentability.

Judge Lourie, however, continued to perform the second step of the *Alice/Mayo* test, asking whether any of the steps of the method not drawn to ineligible subject matter transform the claim into a patent-eligible application of the law of nature. Judge Lourie found no such transformation among the remaining steps, because they were standard techniques. He relied on statements in the

[1] Muscle specific tyrosine kinase

specification that individual techniques employed in the method were conventional. Judge Lourie stated that to be patent eligible at step two, a claim must supply "an inventive application beyond the discovery of the natural law itself."

One of the starkest statements in the majority opinion compares the Athena claims to the claims held to be patent eligible in *Vanda Pharm.Inc. v. West-Ward Pharm. Int'l Ltd.,* 887 F.3d 1117 (Fed. Cir. 2018). Judge Lourie characterized the Athena claim as a mere diagnostic method whereas the *Vanda* claim was a diagnostic method having a therapeutic step appended to it. Judge Lourie considered the appended therapeutic step to be an "application" of the natural law:

> Claiming a natural cause of an ailment and well-known means of observing it is not eligible for patent because such a claim in effect only encompasses the natural law itself. But claiming a new treatment for an ailment, albeit using a natural law, is not claiming the natural law.

Majority opinion at page 14.

Despite his agreement with Judge Newman on the desirability of protection for diagnostics, Judge Lourie explained that his reading of the binding Supreme Court precedent, particularly *Mayo*, mandates his analysis and outcome. He read *Mayo* as requiring that "correlations between the presence of biological material and a disease are laws of nature" and that "purely conventional or obvious pre-solution activity is normally not sufficient to transform an unpatentable law of nature into a patent eligible application of such a law." Judge Newman's mode of analysis differs in the construction of the claim. She steadfastly refused to dissect or simplify the claim so that nothing less than the whole claim is considered.

A legislative fix may be the only solution to the socially harmful results of the case law, on which both majority and dissent agree. The recent January 2019 Revised Patent Subject Matter Eligibility Guidance (Federal Register, 84: 4, 50-57) offers a liberalized *Alice/Mayo* analysis for the Patent and Trademark Office employees, but such guidance is likely to have little effect on district court and appellate court judges.

Click here to download the decision in *Athena v. Mayo*.