New USPTO Guidance May Help Diagnostics Patents

By **Ping Wang, John Murray, Michael Ye and Angel Wang** (April 22, 2019)

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In February, in Athena Diagnostics v. Mayo Collaborative Services,[1] the U.S. Court of Appeals for the Federal Circuit upheld the current understanding that if patent claims only recite conventional technical steps in applying a natural law, then those claims are patent-ineligible.

This interpretation of patent law has been a barrier to the patenting of diagnostics and personalized medicine claims. Patent applicants constantly lose on patent subject matter eligibility rejections because virtually every time a biomarker is used for detection it is considered directed to a law of nature or natural phenomenon.

In Athena, the Federal Circuit considered an appeal by Athena Diagnostics concerning a patent infringement suit originally brought by Athena against Mayo Collaborative Services in the U.S. District Court for the District of Massachusetts. Athena sued Mayo for infringement of certain claims of U.S. Patent No. 7,267,820, which covered methods for diagnosing neurological disorders by detecting antibodies to a protein called muscle-specific tyrosine kinase, or MuSK. The district court dismissed the claims-in-suit as invalid because of patent-ineligible subject matter under 35 U.S.C. § 101.[2] The Federal Circuit affirmed.

The Federal Circuit applied the two-part test for patent-eligible subject matter established by the U.S. Supreme Court in Mayo Collaborative Services v. Prometheus Laboratories Inc.[3] First, the court determines whether patent claims are directed to a natural law. If they are, then the court proceeds to the second part of the test, which asks whether the limitations of the claim apart from the natural law, if considered individually and as an ordered combination, sufficiently transform the claims into being more than simply claims upon the natural law itself.

In practice, for claims to diagnostics methods that rely on conventional technical steps, courts have held that the nature of such diagnostics claims is not sufficiently transformative to render the claims patent-eligible subject matter. In theory the recitation of non-routine and unconventional steps in the claims could overcome this issue; however, diagnostic methods typically rely on conventional technical steps to detect biomarkers, often rendering it essentially impossible to get past a finding of patent ineligibility.

In Athena, the Federal Circuit first determined that the claims were directed to a natural law. The claims recite a diagnostic method relying on the observable association between naturally elevated levels of MuSK autoantibodies in the bodily fluid of certain patients with MuSK-related neurological diseases, such as myasthenia gravis. The Federal Circuit stated that the claims in Athena involved both the discovery of a natural law and certain concrete technical steps to observe its operation.

For the second part of the test, the Federal Circuit found that the steps of the claims dedicated to observation of the natural law only applied conventional techniques in a

conventional way. Thus, in Athena, the Federal Circuit affirmed the conclusion of the district court that the claims at issue were impermissibly directed to a natural law and lacked patent-eligible subject matter. This is representative of the current outcomes encountered by diagnostics claims that are challenged in court or rejected during prosecution at the U.S. Patent and Trademark Office.

The Federal Circuit in Athena voiced serious policy concerns with this outcome by noting that "one can agree [that] from the standpoint of policy, and history, ... the public interest is poorly served by adding disincentive to the development of new diagnostic methods. ... We would add further that, in our view, providing patent protection to novel and non-obvious diagnostic methods would promote the progress of science and useful arts."[4] Nevertheless, the Federal Circuit lamented, "precedent leaves no room for a different outcome here."[5]

However, the 2019 revised guidance on patent subject matter eligibility issued by the U.S. Patent and Trademark Office in January 2019 may provide an opportunity for a comeback of diagnostics and personalized medicine patents by incorporating treatment steps into claims that are otherwise directed to diagnostic determinations.

In particular, as an example of claims that are not directed to a natural law, the 2019 guidance provides the claims to the use of a natural law "to effect a particular treatment or prophylaxis for a disease or medical condition." This particular example is based on the Federal Circuit decision in Vanda Pharmaceuticals Inc. v. West-Ward Pharmaceutical International Ltd.[6]

In Vanda, the method claims' primary steps include "determining" a specific genotype of a patient with a genotyping assay, and then "administering" a certain quantity of drug based on that determination of a genotype in order to "treat a particular disease."[7] The Federal Circuit distinguished this from Mayo because the claims recited a method of using a drug to treat a disease, rather than being solely based on a determination resting on a law of nature/natural phenomenon.[8]

In applying its analysis, the Federal Circuit considered the claims as a whole, rather than focusing on the diagnostic step to the exclusion of the treatment steps. This enabled the Federal Circuit to distinguish the claims in Vanda from those considered by the Supreme Court in Mayo because of the inclusion of treatment steps in the Vanda claims. Significantly, the Federal Circuit in Vanda did not consider whether or not the treatment steps were routine or conventional when determining patent subject matter eligibility.

The 2019 guidance states that consideration of the integration of a natural law into a practical application specifically excludes consideration of whether the additional elements represent well-understood, routine, conventional activity. Furthermore, under the 2019 guidance, even a routine and conventional application is capable of overcoming the finding that claims are directed to a natural law, so long as there is an integration of the natural law into a practical application.

Thus, the 2019 guidance appears to open the door on a new way of pursuing diagnostics and personalized medicine claims that may survive judicial scrutiny. However, since the Federal Circuit has not had an opportunity to compare and contrast the analysis of Vanda with that of Athena, there remains a cloud of uncertainty over the patent eligibility of diagnostics claims.

Correction: A previous version of this article misstated the titles of authors Michael Ye and John Murray. The error has been corrected.

Ping Wang, M.D., and Michael Ye, Ph.D., are partners, John Murray, Ph.D., is counsel, and Angel Wang, Ph.D., is an associate at Morris Manning & Martin LLP.

[1] Athena Diagnostics v. Mayo Collaborative Services, Appeal No. 2017-2508 (Fed. Cir., February 6, 2019) (Athena I).

[2] Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC, 275 F. Supp. 3d 306 (D. Mass. 2017) (Athena II).

[3] Mayo Collaborative Services v. Prometheus Laboratories, Inc., 566 U.S. 66, 72-79 (2012).

[4] Athena I, at footnote 4.

[5] Id.

[6] Vanda Pharms. Inc. v. West-Ward Pharms. Int'l Ltd., 887 F.3d 1117 (Fed. Cir. 2018).

[7] Id. at 1134.

[8] Id. at 1135.