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Ex-Fed. Circ. Judge Decries 'Fundamental Rift' Over Eligibility

By **Tiffany Hu**

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Law360 (November 4, 2019, 9:35 PM EDT) -- The former chief judge of the Federal Circuit on Friday urged the U.S. Supreme Court to clarify when medical diagnostic tests can be patent-eligible, saying that the Federal Circuit's decisions on what is patentable are "devoid of any semblance of consistency."

In an amicus brief, former Federal Circuit Chief Judge Paul Michel asked the justices to take on Athena Pharmaceuticals' **appeal** of a **split Federal Circuit ruling** that its patented method for diagnosing myasthenia gravis, a chronic disorder that causes waning muscle strength, was invalid for claiming a natural law.

The majority had relied on the high court's **2012 ruling** in Mayo v. Prometheus, a case where the famed Mayo Clinic was accused of infringing a different diagnostic patent. In that case, the justices said inventions directed to laws of nature are not patent-eligible unless they contain an additional inventive concept.

In all his years on the bench, Michel said, there has been no issue like patent-eligibility that has caused as much "disharmony, disagreement, and inconsistency." Neither has there been a similar outcome where a Federal Circuit majority found a groundbreaking medical invention to be eligible for patent protection but chose not to consider the merits of the invention anyway, he said.

Referencing Malcolm Gladwell, Michel said that patent law had reached a "tipping point" and that certiorari was needed to clear up the "fundamental rift" within the circuit court — much like the "the fantastical land of Lewis Carroll's 'Through the Looking-Glass,'" he said.

"Whatever the most apt literary reference or analogy, one thing is absolutely certain: The Federal Circuit's menagerie of patent-eligibility decisions over the past decade are devoid of any semblance of consistency," Michel wrote. "They have created an unbounded and detrimental uncertainty in biotechnology innovation, and the law needs clarification and correction."

Matthew Dowd of Dowd Scheffel PLLC, an attorney for Michel, told Law360 in a Friday email that he hoped that the justices "accepts the invitation to make the necessary corrections."

"Judge Michel's brief poignantly identifies the importance of this case and why current patent eligibility law is detrimental to life-saving diagnostics inventions," Dowd said.

The dispute began when Athena sued the Mayo Clinic in 2015 over a test for diagnosing myasthenia gravis. According to court records, Athena's patent covers the correlation between certain antibodies and the presence of the disease. The invention allowed the disease to be diagnosed in the 20% of patients who don't have antibodies that are typically associated with the disease.

A Massachusetts federal judge **granted** Mayo's motion to dismiss the suit in 2017, finding that Athena's patent was invalid under the Supreme Court's 2012 Mayo ruling.

The Federal Circuit panel affirmed in February, ruling that Athena's patent claims only cover the natural correlation between the presence of the antibodies and the disease and merely "apply conventional techniques" to detect them, such as using radioactive iodine.

Athena said in its Supreme Court petition that its invention should be patent-eligible because it involves man-made molecules created from the antibodies and iodine to detect something never before associated with a disease. The Federal Circuit has "badly misinterpreted" the 2012 Mayo decision to bar patent protection for inventions that deserve patents, it said.

Moreover, Athena said the Federal Circuit's split en banc ruling shows that even the nation's specialist patent court cannot agree on what makes diagnostic methods patent-eligible. While a slim majority said their hands were tied by the Supreme Court, the other judges said the patent was found invalid only because the Federal Circuit is misinterpreting high court precedent.

"The collective and consistent cry for help from the Federal Circuit, culminating in this case, is extraordinary and emphasizes just how critical this court's guidance is," the company said.

Friday's brief comes on the heels of the Intellectual Property Law Association of Chicago's amicus brief **filed a day earlier**, which argued that nothing in Athena's patent attempts to monopolize a natural phenomenon. Instead, the patent "purports to claim only a novel application of a novel process for diagnosing certain medical disorders," the IP group said.

University of California law professors Jeffrey A. Lefstin and Peter S. Menell and the New York Intellectual Property Law Association have also filed separate amicus briefs in support of Athena, according to court documents.

The patent-in-suit is U.S. Patent No. 7,267,820.

Counsel for Michel did not immediately respond to a request for comment Friday.

Michel is represented Matthew J. Dowd and Robert J. Scheffel of Dowd Scheffel PLLC.

Athena is represented by Seth Waxman, Thomas Saunders, Joshua Koppel and Claire Chung of

WilmerHale and Adam Gahtan and Eric Majchrzak of Fenwick & West LLP.

Mayo is represented by Jonathan E. Singer of Fish & Richardson PC.

The case is Athena Diagnostics Inc. et al. v. Mayo Collaborative Services LLC, case number 19-430, in the U.S. Supreme Court.

--Editing by Jay Jackson Jr.