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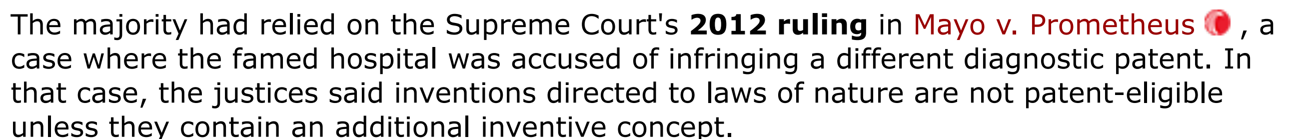
IP Law Group Urges High Court To Fix Patent Eligibility

By **Tiffany Hu**

Law360 (October 31, 2019, 7:37 PM EDT) -- The U.S. Supreme Court should clarify when medical diagnostic tests can be patent-eligible, a Chicago-based intellectual property organization said Thursday, joining a number of voices asking the justices to take on an appeal of a Federal Circuit ruling that invalidated a patent on a diagnostic test for an autoimmune disease for claiming a natural law.

In an amicus brief, the Intellectual Property Law Association of Chicago urged the high court to grant Athena Diagnostics' **petition for certiorari** in its dispute with the Mayo Clinic after a split Federal Circuit **ruled that** Athena's patented method of diagnosing myasthenia gravis, a chronic disorder that causes waning muscle strength, was invalid for being directed to the natural correlation between certain antibodies and the presence of the disease.



The majority had relied on the Supreme Court's **2012 ruling** in Mayo v. Prometheus, a case where the famed hospital 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.

But the IPLAC, which has over 1,000 members, 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.

"Accordingly, this court's language in Mayo on the unpatentability of 'laws of nature' needs further clarification," the organization wrote. "Neither 'laws of nature' nor 'natural phenomena' may be patentable, but the specific application of such 'laws' and phenomena through detailed process claims — as in the present case — most certainly should be."

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, like 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.

In addition to IPLAC, 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.

An attorney for Athena declined to comment Thursday. Counsel for Mayo and amici IPLAC did not immediately respond to requests for comment Thursday.

Amici IPLAC is represented by its own president Charles W. Shifley, David L. Applegate of Williams Montgomery & John Ltd., Laura Labeots of Lathrop Gage LLP, Bryan G. Helwig of McDonnell Boehnen Hulbert & Berghoff LLP and Robert H. Resis of Banner & Witcoff.

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 Daniel King.

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