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Supreme Court Has 'No Work' To Do On Mayo, Clinic Says

By **Dani Kass**

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Law360 (November 25, 2019, 3:34 PM EST) -- The Mayo Clinic has asked the U.S. Supreme Court not to give special patenting treatment to diagnostic tests, saying the justices have already made clear that natural laws without inventive concepts aren't eligible for patents, even if the discovery was "innovative" or "groundbreaking."

The Minnesota-based medical center pushed back Friday on a **petition for a writ of certiorari** filed in October by Quest Diagnostics unit Athena Diagnostics Inc., which is asking for clear guidance on when medical diagnostic tests can be patent eligible under Section 101 of the Patent Act. Mayo said that guidance has already been provided in an earlier high court decision involving the clinic, which set a test asking first whether the claimed invention is directed to a natural law and then whether there's an added inventive concept.

"There is thus no work for this court to do here," Mayo's opposition states. "This court has already interpreted Section 101 of the Patent Act and laid down a clear boundary around what is and is not patent eligible. Athena's patent claims fall squarely on the ineligible side of that boundary."

If Athena wants to change that framework, it needs to go through Congress, not the courts, the clinic said.

The litigation is over a test for diagnosing myasthenia gravis, a chronic disorder that causes muscles to weaken. Athena's patent, which it has accused Mayo of infringing, 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 had **invalidated** the patent under the Supreme Court's 2012 ruling in Mayo v. Prometheus, and the Federal Circuit **affirmed** that decision 2-1 in February. The full court was **split 7-5** against rehearing the case, with all 12 judges agreeing the invention should have been patent eligible, but many saying precedent mandated a ruling otherwise.

Several amicus briefs have been filed asking the justices to take up the case, including by the

New York Intellectual Property Law Association, the Intellectual Property Law Association of Chicago, the Biotechnology Innovation Organization, the Pharmaceutical Research and Manufacturers of America and **former Federal Circuit Chief Judge Paul Michel**.

But in Friday's opposition, Mayo said medical diagnostics don't deserve special treatment, and that if they only cover a natural law without an inventive concept, they don't deserve a patent.

"The [Supreme Court] set forth [the Mayo] framework against the backdrop of over 150 years of precedent, and with due knowledge of the policy considerations in play," the clinic said. "The Federal Circuit has applied Mayo consistently, so no intervention by this court is warranted"

Mayo pointed to another Supreme Court case, Association for Molecular Pathology v. Myriad Genetics Inc., which says "groundbreaking, innovative, or even brilliant discovery does not by itself satisfy the Section 101 inquiry."

The clinic also argued that there hasn't been harm to research and development stemming from the Mayo decision, as Athena warns, noting that Quest's share prices have almost doubled since the landmark decision came out. To top it off, the future of the industry is in personalized medicine and diagnostics, which will likely have inventive concepts able to beat the Mayo test, the clinic said.

"For such significantly improved diagnostic techniques, patent eligibility remains available," Mayo said. "But merely plugging a new correlation between a naturally occurring bio-product and a disease into a known technique is not the type of activity the Patent Act protects."

A Mayo spokesperson declined to comment Monday. Corporate representatives for Quest didn't immediately respond to a request for comment Monday.

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

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, Elizabeth M. Flanagan and Deanna J. Reichel of Fish & Richardson PC.

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

--Additional reporting by Ryan Davis. Editing by Jill Coffey.