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Athena Implores Supreme Court to Heed Federal Circuit's 'Unprecedented Cry for Help'

By **IPWatchdog**
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Print Article

"In the month after *Mayo* was decided, the PTO rejected 32% of the patent applications for medical diagnostics, up from 7% before…. Everyone loses as a result." – Athena petition for certiorari

As expected, Athena Diagnostics last night filed its petition for certiorari to the U.S. Supreme Court, asking it to fix the United States' patent eligibility law problem. Adam Gahtan and Eric Majchrzak of

Fenwick & West and Seth Waxman, Thomas Saunders, Joshua Koppel and Claire Chung of WilmerHale filed the petition for Athena.

The specific question Athena is presenting is:

Whether a new and specific method of diagnosing a medical condition is patent-eligible subject matter, where the method detects a molecule never previously linked to the condition using novel man-made molecules and a series of specific chemical steps never previously performed.

Athena urged the Court to take the case considering the Federal Circuit's eight separate opinions in which the court divided 7-5 on denying en banc review—evidence of "much-needed guidance on the proper application of the judicially-created exceptions to Section 101 of the Patent Act."

The Federal Circuit in July issued an 86-page order comprising eight separate opinions. Throughout the opinions, it seemed clear that the Federal Circuit was eager to have the Supreme Court take the case up on appeal in order to clarify *Mayo*'s judicial exception to laws of nature and its impact on patent claims covering medical diagnostics.

In the petition, Athena warned the Supreme Court that failure to clarify the law in favor of finding claims like the ones at issue in the case patent eligible will be a death-knell for medical diagnostics. The petition said:

If these claims do not even meet the threshold requirement of being the kind of subject matter eligible for patent protection, that is the end of patent eligibility for the overwhelming majority of medical diagnostic methods—leading to profound consequences for future investment in scientific research and public health.

The petition identifies for the Court five points of confusion that have emerged over the Court's precedent in this area. They are:

- Courts have struggled with the tension between the Federal Circuit's striking down a diagnostic method claim that uses novel man-made molecules and this Court's holding that a "molecule that is not naturally occurring" is "not a 'product of nature' and is patent eligible under § 101."
- Courts have struggled to apply the principles articulated in the context of the unusual facts of Mayo to more typical patent claims.
- Courts have struggled with the level of abstraction at which to determine whether the steps of a claim "transform an unpatentable law of nature into a patent eligible application of such a law."

- The Federal Circuit's approach gives little consideration to the "preemptive" scope of a claim, contrary to this Court's guidance.
- Courts have struggled with what it means to review a claim "as a whole."

Athena also cited broad agreement among prominent members of the patent bar on the need for clarity. Retired Federal Circuit Chief Judge Paul Michel, current and former directors of the USPTO, practitioners, the American Bar Association, and patent scholars, have all decried the state of the law, said the petition.

Perhaps most importantly, the chaos threatens to disrupt crucial medical innovation, wrote Athena. The petition explained:

"Since Mayo, the Federal Circuit "ha[s] held every single diagnostic claim in every case before [it] ineligible" for patent protection…. This rule will have devastating consequences. In the month after Mayo was decided, the PTO rejected 32% of the patent applications for medical diagnostics, up from 7% before. Chien & Wu, Decoding Patentable Subject Matter, 2018 Patently-O Pat. L.J. 1, 15 (Oct. 21, 2018), https://bit.ly/2oBO1i5. By the time Alice was decided, that rejection rate had climbed to more than 50%, and at one point hit a high of 64%. Id. With the decision below, that rate will climb significantly higher—if inventors even bother to apply for patents for diagnostic methods at all.

Everyone loses as a result. "Diagnostics are an essential category of medical technologies, critical to treating illnesses and saving lives."

Athena also argues that the specific claims at issue in the case are particularly well-suited to clarify the law, since they are a far cry from the "'methods of entering into contracts, or horse whispering, or speed dating or other methods' that have animated this Court's concerns regarding Section 101," said Athena. In particular, the claims:

- use novel man-made molecules; and
- recite specific chemical steps to achieve a new and useful result.

Athena further noted that the Federal Circuit's rules used to invalidate medical diagnostic claims find no support in the statute. Since the Supreme Court created the problem, it is up to them to fix it, the petition concluded:

"This Court, as the creator of those non-textual exceptions, bears a special responsibility to ensure that they are properly interpreted and applied. The Court has admonished courts to "tread carefully" lest the exceptions "swallow all of patent law." Alice, 573 U.S. at 217. But the Federal Circuit has not heeded that admonition, allowing those exceptions to expand ever outward and swallow the field of medical

diagnostics. The legal issues are too fundamental, and the stakes too high, to allow that misapplication of the law to stand."

Considering the stakes, it would be shocking if the High Court decides not to grant cert.

Stay tuned for reaction from the bar.