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# Mayo Responds to Athena's High Court Petition: Nothing to Do Here, SCOTUS

By **IPWatchdog**
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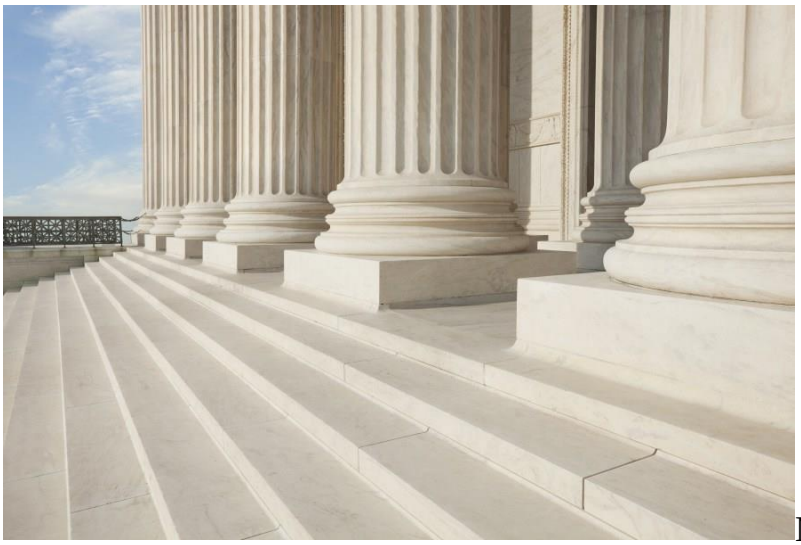
## "Any further action regarding the patentability of medical diagnostic claims such as Athena's that employ conventional, known techniques should and does rest with Congress." – Mayo brief in opposition



Mayo Collaborative Services has filed its brief in opposition to Athena Diagnostics' October petition to the Supreme Court asking the justices to weigh in on whether its patent claims for a

method of making a medical diagnosis are patent eligible under Section 101. Eleven amici have weighed in on the case, and the patent community is waiting to see if the High Court will grant the petition and help to solve the Section 101 problem, which has been particularly problematic for the field of medical diagnostics.

## We've Been Here Before

Mayo states its argument quite simply in the opening sentence of its brief, relying on the Court's 2012 precedent in *Mayo v. Prometheus*: "Patent claims directed to a natural law that employ only conventional and routine activities to detect that law are not patent eligible. *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66, 73 (2012). That rule disposes of this case, as the district court, appellate panel, and *en banc* Federal Circuit each concluded."

The brief goes on to explain that Athena's patent covers nothing more than a natural law—the discovery that some patients generate autoantibodies that bind to MuSK proteins in the body—without any "innovative application of that natural law." Athena's patent claims preempt all ways of diagnosing MuSK-related diseases and its discovery of the link between MuSK protein and Myasthenia gravis, a neuromuscular disorder, was nothing more than the identification of a previously existing natural law, says the brief.

## Take it to Congress

It adds that the amici's and several Federal Circuit judges' claims that innovation in the field of medical diagnostics—and consequently public health—is already and will continue to suffer are unsupported, and, in any case, that is a problem for Congress, not the courts, to solve:

There is thus no work for this Court to do here. This Court has already interpreted § 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. Any further action regarding the patentability of medical diagnostic claims such as Athena's that employ conventional, known techniques should and does rest with Congress.

The Federal Circuit's July opinion denying *en banc* rehearing was 86 pages and included eight separate opinions—four concurring with the *en banc* denial and another four dissenting from the decision. The separate opinions reflected a Federal Circuit that isn't divided so much on the issue of the importance of Athena's now invalidated patent claims but, rather, the application of the U.S. Supreme Court's

Section 101 jurisprudence under *Mayo Collaborative Services v. Prometheus Laboratories* (2012). Throughout the opinions, it seemed clear that the Federal Circuit was eager to have the Supreme Court take up the case.

But Mayo argues that the lower courts are not confused at all about how to apply the High Court's precedent in *Mayo v. Prometheus*, having all come to the same conclusion. The Federal Circuit also denied Athena's petition for rehearing *en banc*, which reflects the court's recognition that the case involves "a straightforward application of *Mayo*," says the brief.

After pointing to Judge Lourie's opinion to support its argument that the case law on Section 101 has been consistent overall since the 2012 *Mayo* decision, and that the outcome in this particular case is especially clear, the brief dismisses the reservations expressed in many of both the concurring and dissenting opinions from the Federal Circuit's denial of rehearing:

To be sure, the opinions in favor of denying rehearing express reservations about this Court's Mayo decision, and their authors suggest they may have

ruled differently if they could have written on a "clean slate." But they recognize that precedent plainly controls, and that any attempt to change the result in this case would be asking this Court to "reconsider" the breadth of the decision that it made—with full understanding of the issues and ample amicus participation—just seven years ago.

Indeed, even many of the dissenting judges recognize that Mayo has been applied consistently. They are just dissatisfied that this consistent application has found certain "diagnostic" claims to come before the court ineligible. They set forth various purported policy justifications for changing the law to allow for the eligibility of these types of claims. But notably, nothing in the record of this case substantiates the expressed concerns, particularly in relation to stifling innovation.

The brief adds that the Supreme Court would have to substantially revise its own precedent on Section 101 in order to find Athena's claims eligible, and that Athena's arguments are no different from the arguments made in the petitions for certiorari in the *Ariosa*, *Genetic Technologies*, and *Cleveland Clinic* cases, which were all denied cert.

## Show Me the Evidence

To support its argument that Athena's and the amici's concerns about stifling innovation in the field are unwarranted, Mayo cites evidence that "investment in diagnostics has increased tenfold since 2009, according to an article by Alex De

Winter, "Why It's a Good Year for Diagnostic Startups" (MedCity News [Aug. 24, 2017]); a 2018 presentation by Professors Arti Rai and Colleen Chien that "material biomarker transactions and FDA approvals of diagnostics" have increased since the *Mayo* decision; and a 2017 report showing that "an average of ten new genetic testing products were added to the market each day from 2015-17."

Furthermore, adds Mayo's brief, Athena is hardly suffering—the stock price of Athena's parent company, Quest Diagnostics, "has grown from around $57 per share at the beginning of 2013 to over $100 per share currently, with the price hitting an all-time high in mid-2018."

In a nutshell, the policy concerns outlined by the Federal Circuit and amici matter must be taken up with Congress, says the brief. But as far as the instant petition, "there is no work for this Court to do," says Mayo.

Jonathan Singer, Elizabeth Flanagan and Deanna Reichel of Fish & Richardson are representing Mayo.