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Will SCOTUS Solve the Section 101 Problem with *Athena*? These Patent Attorneys Hope So

By **IPWatchdog**
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Print Article

"The entire point of the Supreme Court's *KSR v. Teleflex* decision was to prevent the patenting of trivial inventions because patents are supposed to be granted to truly innovative inventions. Well, *Athena* is the Supreme Court's chance to apply that rather common-sense philosophical approach to the law of patent eligibility." – Gene Quinn

Athena Diagnostics filed its petition for certiorari with the U.S. Supreme Court yesterday in *Athena Diagnostics v. Mayo Collaborative Services*. There is a strong argument for the Court to grant the petition, and patent stakeholders on all sides are sure to weigh in via amicus briefs over the next month. The petition could represent the best chance for clarifying Section 101 law in the near-term, since patent reform efforts on the topic have been seemingly stalled.

Below are a few initial reactions from the patent community to Athena's arguments, which are outlined here.

A Better Option Than *Vanda*

Todd Dickinson  **,** Senior Partner, Polsinelli and Former USPTO Director

"Among other things, *Athena* represents a much better opportunity to address the notorious ambiguity and negative results wrought by *Mayo* (and possibly, *Alice*) than the other §101/diagnostics/personalized medicine case the Supreme Court is considering this term, *Vanda v. West-Ward Pharmaceuticals* (Fed.Cir., 4/13/2018), (now styled *Hikma Pharm. v. Vanda Pharm.* (S.Ct.,18-817)). It is worth noting that they have asked the Solicitor General for the government's views on *Vanda* in a CVSG [Call for the Views of the Solicitor General).

In *Vanda*¸ the CAFC panel held the claims "not ineligible" under the first step of the *Alice/Mayo* framework, i.e. drawing a distinction between the so-called "correlation/optimization" claims in *Mayo* vs. the "method of treatment" claims that the CAFC felt they were dealing with in *Vanda*. "[T]he claims are not directed to a patent ineligible concept at step one [of *Alice*, therefore] we need not address step two of the inquiry." This drew a dissent from Chief Judge Prost, however, basically stating that the majority was ignoring the Supreme Court in *Mayo* regarding the "natural law" exception, and that the claims were ineligible. Conversely, in *Athena* you have the entire CAFC involved, considering and denying *en banc* review, and splitting 7-5 on §101 eligibility under *Mayo*. The majority held the claims "ineligible", but with all judges voting, with 8 writing separately, to tell the Supreme Court that *Mayo* is unworkable, leads to inequitable results, and that they need to fix it.

These two cases present very different ways for the Supreme Court to approach this issue, which might even affect the outcome relative to *Mayo*. In *Vanda*, they are being asked to revisit a fairly recent precedent in which the CAFC drew a distinction with that precedent and upheld patentability in the face of *Mayo*. In *Athena* they would basically be affirming the CAFC's views interpreting the Supreme Court in *Mayo/Myriad*, finding in the Supreme Court's favor, but they would have the opportunity to adjust their precedent to fit medical diagnostics as eligible and address those eight other opinions, if they chose. *Athena* is also an *en banc* review case, whereas *Vanda* is a panel decision. Lastly, if they chose to consider the equities/fundamental unfairness of the outcome in *Athena*, they are much clearer and

cleaner in *Athena* than in *Vanda*. Accordingly, if the Supreme Court wants a good case to revisit *Mayo*-type diagnostics or even the *Alice/Mayo* framework as a whole, they should take *Athena*."

Other Jurisdictions Seem to Get It

Stephen Kunin, Partner, Maier & Maier PLLC

"The *Athena* petition for certiorari serves the critical need to urge the Supreme Court to clarify and reconsider its decision in *Mayo* at a time when the Federal Circuit and the USPTO are frustrated by the binding nature of the two-part test applied in *Mayo* for patent subject matter eligibility. Congress has begun the process of addressing the section 101 problems through the work of Senator Coons' Subcommittee on Intellectual Property, but progress is slow and it may take years before a new section 101 law emerges. Note that a number of foreign patent experts have pointed out how the Supreme Court's decision implicates a basis for establishing a violation of TRIPs Article 27(1) based on patent subject matter eligibility by field of technology discrimination. Other major jurisdictions in the world have granted patents to Athena finding their claimed invention passes patent subject matter eligibility.

Very notably, the Federal Court of Australia recently held Sequenom's patent for methods of prenatal testing to be valid and infringed, confirming that diagnostic methods which involve the practical application of a natural phenomenon remain patentable in Australia. *See Sequenom, Inc. v Ariosa Diagnostics, Inc*. [2019] FCA 1011. The court held that the conclusion of the U.S. Federal Circuit was problematic and was a result of its dissection of the claims into their constituent parts, which was contrary to *National Research Development Corporation v. Commissioner of Patents* (1959) 102 CLR 252 (NRDC) and *D'Arcy v. Myriad Genetics Inc* (2015) 258 CLR 334 (Myriad) [524]. In summary, at [526] that:

The Patent does not simply claim the discovery of cffDNA in maternal blood. Rather, it claims a new and inventive practical application of the discovery comprising a method requiring human action to detect, in an artificially created sample of maternal plasma or serum, a DNA sequence as being of fetal rather than maternal origin. And

prior to the invention, no-one had worked or was working a method comprising the detection of cffDNA in plasma or serum samples extracted from pregnant females."

The Right Counsel and the Right Case

Gene Quinn, Founder and CEO, IPWatchdog

"My first thought is that, considering the stakes involved for the industry and the health and welfare of all Americans, it would be shocking if the Supreme Court decides not to grant cert. in *Athena Diagnostics*. After all, the Supreme Court is responsible for having created this crisis in the first place. My second thought is that, despite what is at stake, the Supreme Court may well just punt this issue like they have punted every other patent eligibility petition over the last five years. Perhaps with Justice Gorsuch having hired law clerks with patent background things will be different this term.

Assuming the Supreme Court steps up and does the responsible thing, Athena Diagnostics has the right attorney as counsel of record for this extremely important fight for the future of diagnostics in America. Seth Waxman is the premiere Supreme Court advocate in the patent space, and absolutely the right person for this job, so kudos to Athena Diagnostics.

Waxman and his team are exactly right when they say the Federal Circuit issued an unprecedented cry for help in the decision to refuse *en banc* consideration. All 12 judges agreed that the invention should be patent eligible, but a majority of the judges for various different reasons concluded they could not hold the invention patent eligible. Making matters worse, no opinion gained more than a plurality. To call this a mess under-sells the gravity of the confusion and problems created by current Supreme Court precedent.

My final thought is simple: The Supreme Court should take this case, provide much needed clarity as Athena Diagnostics requests, and once and for all rule that medical diagnostics are patent eligible. It is utterly idiotic for revolutionary innovations to be

refused patents while incremental innovations are patented every week. Although about obviousness, the entire point of the Supreme Court's *KSR v. Teleflex* decision was to prevent the patenting of trivial inventions because patents are supposed to be granted to truly innovative inventions. Well, here is the Supreme Court's chance to apply that rather common-sense philosophical approach to the law of patent eligibility."

Short and Semi-Sweet: Do No Harm

Robert Stoll, Partner at Drinker Biddle, Former Commissioner for Patents at the USPTO

"I hope, somehow, we get more clarity. And that any decision will not further harm job creation and economic growth."