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Athena and Mayo Spar Over Which Branch of Government Should Resolve Section 101 Quandary

By Sarah A. Kagan, Ph.D.

Briefing on a petition for writ of certiorari to the U.S. Supreme Court ended last week for *Athena Diagnostics, Inc. v. Mayo Collaborative Services LLC* (No. 19-430).

Petitioner Athena seeks review of the patent eligibility of its diagnostic method claims. Athena characterizes its method as involving a hitherto unknown link between an analyte and a disease, a novel, man-made reagent, and novel steps.[1] In addition to the involved parties, 11 entities filed amicus briefs, including commercial entities, trade associations, law professors, associations of lawyers, and a retired chief judge of the U.S. Court of Appeals for the Federal Circuit. The justices are set to confer on the petition within the month.

Athena's petition got a boost from the U.S. Department of Justice (DOJ), but not in the normal way. The Supreme Court did not ask the DOJ for its opinion by inviting an amicus brief about Athena's petition. Rather, the DOJ used its amicus brief in a different case (*Hikma Pharmaceuticals USA Inc. v. Vanda Pharmaceuticals Inc.*, (No. 18-817) to recommend that the Supreme Court grant Athena's petition. The DOJ filed its *Hikma* amicus brief Dec. 6, after Mayo had filed its respondent's brief but before Athena filed its reply brief. The DOJ urged the Court to grant Athena's petition as a better vehicle for clarification of the law of subject matter eligibility than Hikma's.

Athena's petition repeats Circuit Judge Kimberly Moore's striking statement that the Federal Circuit has invalidated every diagnostic claim that it has considered since the Supreme Court's 2012 *Mayo* decision. It also points to other statements from the many separate opinions of judges of the Federal Circuit when the court denied en banc review in July. In

[1] Click here, here, and here for Banner Witcoff's prior alerts regarding the dispute.

their separate opinions, the appellate judges implore the Supreme Court to reconsider the law regarding diagnostic methods. Whether the judges lay the blame at the feet of the Supreme Court or the Federal Circuit itself, Athena asserts that they all desire a more lenient framework that would not categorically ban diagnostic method claims. Athena strategically tells the Supreme Court that the panel opinion of the Federal Circuit misinterpreted the Supreme Court's exception to patent eligibility.

Notwithstanding the many Federal Circuit judges pleading for clarification from the Supreme Court, Mayo had the easier argument to make, urging the court to leave its precedent undisturbed and deny certiorari. Mayo argues in its opposition brief that the circuit judges were not confused by the current state of the law, but they merely disagreed with the outcome. Mayo characterizes Athena's disagreement with the current law as a policy difference, which should be the domain of Congress rather than the Court.

Mayo further characterizes Athena's diagnostic method as nothing more than an ineligible law of nature with known techniques appended; the appended techniques are insufficiently inventive to shift the method to patent eligibility.

In response to Mayo's characterization of the Federal Circuit judges' gaggle of opinions (denying rehearing) as merely reflecting policy differences, Athena asserts that the judges expressed confusion over how to interpret and apply Supreme Court precedents. Athena notes that the DOJ agreed in its amicus brief in *Hikma*.

Athena also counters Mayo's argument that Congress, not the Court, should correct the Federal Circuit's expansion of judicial exceptions. Athena asserts that since the Federal Circuit did not perform statutory interpretation but rather applied the Supreme Court's judge-made law, it is appropriate for the Supreme Court to address the issue. Athena concludes its reply brief by characterizing the Federal Circuit's action as an expansion of the Supreme Court's exception without congressional mandate.

Will the Supreme Court take the bait and try to clarify its judicial exception to subject matter eligibility? Or will it decline and leave the discontented to the slower and less certain legislative process?