https://www.law360.com/ip/articles/1226435/sg-says-justices-should-use-athena-case-to-redo-mayo

SG Says Justices Should Use Athena Case To Redo Mayo

By **Dani Kass**

Share us on: By **Dani Kass**

Law360 (December 9, 2019, 8:36 PM EST) -- The solicitor general has told the U.S. Supreme Court that its Mayo framework needs a do-over, but the two cases in which he was asked to weigh in are not the right vehicles. Instead, he pointed to a case over the eligibility of diagnostic test patents as a better candidate.

Solicitor General Noel J. Francisco and his team of U.S. Department of Justice and U.S. Patent and Trademark Office attorneys on Friday said the cases in which he was asked to give feedback aren't good for Supreme Court review, as HP v. Berkheimer is premature, and Hikma Pharmaceuticals v. Vanda Pharmaceuticals was decided correctly at the Federal Circuit.

However, that didn't stop him from calling for a clarification of the high court's 2012 ruling in Mayo v. Prometheus — which says natural laws without inventive concepts aren't eligible for patents — and suggesting Athena Diagnostics v. Mayo Collaborative Services as a possibility for the job. Mayo involves a two-step test, which first looks at whether the subject is a natural law and, if so, whether there's an inventive concept that makes it patent-eligible.

Namely, the solicitor general said courts are interpreting "law of nature" too expansively, undoing patent rights for inventions that have long been held patentable, like the medical treatment methods in the Hikma case.

"It is arguably unclear whether even a method of treating disease with a newly created drug would be deemed patent-eligible under a mechanical application of Mayo's two-part test," the brief in the Hikma case states. "The potential for rote application of the Mayo two-step framework to call into question such bedrock understandings of the patent system, in a way that the Mayo court clearly did not envision, suggests that the Mayo framework warrants reconsideration."

In an April 2018 decision, the Federal Circuit **ruled 2-1** that Vanda's patent, which covers the use of a patient's genotype to tailor the medication's dosage, doesn't cover a natural law. The court **refused to rehear** the case.

Hikma **appealed in December 2018**, telling the justices that the Federal Circuit essentially declared all medical treatment methods patent-eligible, undermining the requirements of Mayo. The justices **asked for the solicitor general's take** in March, and he said the Federal Circuit got

it right.

“The court of appeals majority reached the correct result in concluding that the method of medical treatment claimed in Vanda’s patent is patent-eligible subject matter,” Francisco said. “A decision from this court resolving the internal tension within Mayo and reaffirming that Section 101 [of the Patent Act] encompasses methods of medical treatment would have little practical effect in this case. Nor does the decision below cast doubt on the patent-eligibility of a wide swath of medical technologies.”

In the Athena case, the Federal Circuit **invalidated the company’s patent** in February, saying its test for diagnosing an autoimmune disease is invalid for claiming only a natural law.

But the decision wasn’t cut and dried, as proven during Athena’s failed rehearing bid. There, the judges filed eight different opinions spanning a total of 86 pages. They **voted 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.

Athena **appealed in October**, asking the Supreme Court to provide clear guidance on when medical diagnostic tests can be patent-eligible.

The solicitor general noted that the Hikma case didn't have any recorded dissents for a rehearing, as compared to the variety of voices speaking up in Athena.

"Those various opinions provide substantial grounds for inferring that, if the Federal Circuit were not bound by the current Section 101 framework, that court might have reached different outcomes in Athena itself and in other diagnostic-method cases," he wrote.

The HP case doesn’t involve Mayo, but the related Alice v. CLS Bank, which looks at whether patents are directed to abstract ideas implemented using a computer, rather than a natural law.

HP won **summary judgment** invalidating a patent owned by inventor Steven E. Berkheimer in 2016, but the Federal Circuit **vacated that decision** in February 2018, finding the Alice test couldn't be applied at that stage in the litigation.

HP’s **October 2018 petition** for a writ of certiorari is looking to undo that ruling. The justices asked the solicitor general **to weigh in** in January.

Francisco said this procedural question ties into the larger patent-eligibility framework, since the focus of HP’s petition is whether the patent-eligibility test requires a determination by courts, juries or both. Answering it while the framework is in flux would be “premature,” he said.

“As both petitioner and respondent acknowledge, although the question presented in this case focuses on the allocation of decision-making authority between judge and jury, that question is ‘deeply intertwined’ with the underlying legal standards that govern patent-eligibility under Section 101,” the solicitor general said.

The solicitor general said the Supreme Court should either deny both the HP and Hikma petitions, or hold them until the Mayo question is clarified through Athena.

Counsel for Berkheimer, Hikma and Vanda declined to comment. Representatives for the remaining parties didn't immediately respond to requests for comment Monday.

The solicitor general is represented by Noel J. Francisco, Joseph H. Hunt, Malcolm L. Stewart, Jonathan C. Bond, Mark R. Freeman, Scott R. McIntosh and Weili J. Shaw of the Solicitor General's Office and the DOJ's Civil Division, and Sarah T. Harris, Thomas W. Krause, Amy J. Nelson and Robert J. McManus of the USPTO.

Athena is represented by WilmerHale and Fenwick & West LLP.

Mayo is represented by Fish & Richardson PC.

Hikma is represented by Wilson Sonsini Goodrich & Rosati PC.

Vanda is represented by Paul Weiss Rifkind Wharton & Garrison LLP.

HP is represented by Morgan Lewis & Bockius LLP and Gibson Dunn & Crutcher LLP.

Berkheimer is represented by Jenner & Block LLP, Much Shelist PC and Skiermont Derby LLP.

The cases are Athena Diagnostics Inc. et al. v. Mayo Collaborative Services LLC, case number 19-430; Hikma Pharmaceuticals USA Inc. et al. v. Vanda Pharmaceuticals Inc., case number 18-817; and HP Inc. v. Steven E. Berkheimer, case number 18-415, all in the Supreme Court of the United States.

--Additional reporting by Ryan Davis. Editing by Jack Karp.