IP Alert | Federal Circuit Punts to Supreme Court or Congress



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Athena Diagnostics, Inc. v. Mayo Collaborative Services

By Sarah A. Kagan, Ph.D.

On July 3, 2019, the U.S. Court of Appeals for the Federal Circuit issued an order denying a petition for rehearing en banc in the case of Athena Diagnostics, Inc. v. Mayo Collaborative Services, LLC (2017-2508). More interesting than the denial, however, are the eight separate opinions explaining the positions of the Federal Circuit judges on the issue.

Of the 12 judges participating in the consideration, eight wrote opinions. The opinions create a patchwork of ideas with overlapping portions and portions separately extending in multiple directions. Judge Raymond Chen wrote his own opinion and joined with another one and parts of a second; Judge Todd Hughes wrote his own and signed onto another; Judge Evan Wallach did not write his own but signed onto three others; and Judge Kathleen O'Malley wrote her own, joined another, and wrote that she agreed with two others. The groupings are summarized below.

Concurring in the denial	Dissenting to the denial
1. Lourie, Reyna, Chen	1. Moore, O'Malley, Wallach, Stoll
2. Hughes, Prost, Taranto	2. Newman, Wallach
3. Dyk, Hughes, and Chen (partially)	3. Stoll, Wallach
4. Chen	4. O'Malley

Even though the judges did not conduct an en banc hearing, they clearly engaged in a spirited exchange of ideas in their opinions. Not only did the opinions reference and respond to one another, but some of them referenced and seemed to communicate with the Senate Judiciary Committee's Subcommittee on Intellectual Property, which recently conducted hearings on a proposed revision to Section 101 of the Patent Act.

Briefly, the patent in dispute of Athena Diagnostics related to a method of diagnosing neurotransmission or developmental disorders such as Myasthenia Gravis by detecting autoantibodies to muscle specific tyrosine kinase (MuSK). The panel that heard the case consisted of Judges Pauline Newman, Alan Lourie, and Kara Stoll. For additional background on the underlying facts and dispute, see Banner Witcoff's previous coverage of the oral arguments and panel decision here and here.

Judge Lourie, who wrote the majority opinion for the panel, explained his denial of the petition for rehearing stating that his hands are tied by the Supreme Court's decision in Mayo Collaborative Services v. Prometheus Laboratories, Inc., 566 U.S. 66 (2012). If he were making the law of subject matter eligibility, ab initio, he would do it differently than the Supreme Court has done, he wrote. However, his reading of Mayo compels him to the conclusion that he expressed in the panel opinion. He reads Mayo as requiring something additional to a law of nature or natural phenomenon, and that something additional must not be mere routine steps but must be unconventional. Judge Lourie stated that the only possible solution to the problem of diagnostic methods lies with "the pens of claim drafters or legislators."[1] Since the court is neither, he voted for denial of rehearing.

Judge Todd Hughes, too, thought that Supreme Court precedent tied the court's hands. He recognized that the current state of the law was problematic for patenting of diagnostic methods. He articulated a need for a mechanism to distinguish between overly broad claims to laws of nature and claims to truly worthy, life-saving inventions. Judge Hughes indicated that fulfilling this need could come from either the Supreme Court or Congress.

Judge Timothy Dyk believes that Sections 102 (novelty), 103 (non-obviousness), and 112 (enablement and written description) are not sufficient to guard against overly broad claims. These sections of the patent statute do not address the problem of preemption of future innovation. Nor do they resolve quickly in litigation, as a threshold issue. Thus, in his view, Section 101 has a role to play in guarding against overbreadth. To the extent that Judge Dyk is critical of the Mayo jurisprudence, he believes that it should leave room for patentability of diagnostic methods that are specific. Judge Dyk recognizes a tension between the Supreme Court's statements in Mayo and Association for Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. 576 (2013), in that the former holds that essentially no claim containing a law of nature is patentable[2] and the latter indicates that a narrow claim containing a law of nature may be patentable. He also recognizes a tension between the Mayo jurisprudence and Section 101 itself ("Whoever invents or discovers…."). Judge Dyk discusses possible "fixes" that would address his concerns, such as permitting claims only to the extent that there is an established utility. Any fix to the standard for patentability of diagnostics, he thinks, must come from the Supreme Court.

Judge Chen, in the last of the concurrences, reviewed the Supreme Court jurisprudence on laws of nature and finds an inconsistency between cases that require analysis of the claim as a whole and cases that look for a point of novelty. He also criticized the analytical practice of treating the law of nature as part of the prior art, rather than treating it as part of the invention that could contribute to inventiveness. Finally, Judge Chen stated his belief that, in a well-functioning patent system, claims that embody a new discovery should be patentable subject matter. However, like the other judges denying rehearing en banc, Judge Chen believes that the change must come from the Supreme Court, rather than from the appellate court.

The rehearing-en-banc deniers implicitly invite the plaintiff-appellants to petition to the Supreme Court. The dissenters would have fixed the problem themselves by revisiting the court's own rulings en banc. However, having failed at that, the dissenters would also like the Supreme Court to fix the unintended consequences of its opinions. They are also open to Congress attempting to reorient the Section 101 jurisprudence.[3]

Judge Kimberly Moore provided a long argument in support of the economic benefits and social good of a functioning patent system for protection of diagnostics. She does not doubt that all members of the court agree on these. She, unlike the deniers, however, thinks that the Federal Circuit itself has created the current situation and could fix it. She believes that Mayo was not a per se ruling against diagnostic patents, but that the Federal Circuit has itself turned it into one. She reviewed the Federal Circuit's Section 101 law-of-nature cases since Mayo and found that the only claims that it held subject matter eligible were claims with at least an aspect of therapy. Like Judge Dyk, Judge Moore points out the inconsistency between the statute specifically mentioning people who "discover" things and the case law that finds discoveries per se ineligible as laws of nature. In a number of locations, Judge Moore cites to the testimony of the Senate subcommittee to support her characterization of the problem. Judge Moore differs from the rehearing deniers in her view that the appellate court itself could have solved the problem if it heard the case en banc. However, since the deniers won the poll, she now looks to either the Supreme Court or Congress to solve the problem. She has instructed them in the great importance of the issue to the nation.

Judge Newman, who dissented from the panel decision in the underlying appeal, hits many of the same points as Judge Moore. She discussed the economic rationale for patents, and noted that the rationale applies to diagnostic and therapeutic methods alike. Judge Newman, too, believes that the appellate court has misread and enlarged the Supreme Court's holding in Mayo. She stated that analyzing a claim's subject matter "as a whole" is established and Mayo did not disturb that. She also notes that the Supreme Court in Mayo did not set up the distinction between diagnostic claims and therapeutic claims. Judge Newman concludes that the public gains no benefit by the exclusion of diagnostics from patent protection. Like others, she noted that the panel decision contravenes both the constitution and the statutory intent.

Judge Stoll was a member of the panel that decided the Athena appeal. Interestingly, she stands by her decision, but also thinks that the bright line rule that the Federal Circuit applies should be revisited. She called the rule flawed and stated that it undermines the constitutional rationale for patents. Judge Stoll thinks that the question is exceptionally important and on that basis should have been considered en banc. Using very strong language that nonetheless failed sufficiently to mobilize her colleagues, she stated that avoiding en banc hearing was an abdication of the responsibility of the court on an issue that goes to the heart of its jurisdiction.

Judge O'Malley agreed with all the dissenters and calls on Congress to legislatively fix the problem. She sees the root of the problem in the Supreme Court's interjection of an "inventive concept" requirement into Section 101. She called this interjection "baffling" because Congress specifically removed this requirement in its overhaul of the patent laws in 1952. She quoted the late Judge Giles Rich as describing the inventive concept standard

as a subjective and personally idiosyncratic standard. Judge O'Malley wrote that the Supreme Court's continued use of the standard even after 1952 must be addressed by Congress.

Even though the appellate court will not formally deliberate en banc, the extensive set of opinions issued about the decision to deny such deliberation provides much guidance for the Supreme Court and Congress to consider. The Federal Circuit has mapped out multiple paths by which the Supreme Court or Congress can address the issue of patent eligibility of diagnostics. While the Senate's Subcommittee on Intellectual Property was taking testimony in June from former U.S. Patent and Trademark Office directors David Kappos and Q. Todd Dickinson and former Chief Judge of the Federal Circuit Paul Michel, someone in the audience murmured that he would like to hear from the current incumbents of those positions. That person has now had his wish fulfilled, at least with respect to the judges of the Federal Circuit. With regard to the current incumbent of the U.S. Patent and Trademark Office directorship, Judge Moore quotes Director Andrei Iancu as saying, "It's important for the judiciary to first recognize that there is a problem that needs to be addressed....101 remains the most important substantive patent law issue in the United States today. And it's not even close."

Click here to read the July 3 order in Athena Diagnostics, Inc. v. Mayo Collaborative Services, LLC.

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[1] The meaning of a solution in the hands of claim drafters is not readily apparent. Moreover, courts have repeated previously that patent eligibility should not be dependent on the craft of the claim drafters.

[2] Mayo requires the presence of a separate inventive element beyond the law of nature.

[3] Judge O'Malley described the 1952 Patent Act, in part, as an effort to reign in the judicial penchant to require "inventiveness."

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