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Athena v. Mayo: A Splintered Federal Circuit Invites Supreme Court or Congress to Step Up On 101 Chaos

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Print Article

"Unless one opposes the notion of patent protection entirely, it cannot be reasonably disputed that claims to diagnostic kits and techniques, like pharmaceuticals, which require enormous initial investments in terms of both time and money, are the reason we suffer the promise of a monopoly." – Federal Circuit Judge Kimberly Moore

On July 3, the Court of Appeals for the Federal Circuit denied *en banc* rehearing in *Athena Diagnostics v. Mayo Collaborative Services*. The 86-page order from the Federal Circuit includes eight separate opinions—four concurring with the *en banc* denial and another four dissenting from the decision. The separate opinions reflect 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 this case up on appeal in order to clarify *Mayo*'s judicial exception to laws of nature and its impact on patent claims covering medical diagnostics.

Judge Dyk's Concurrence, Joined by Judge Hughes and, In Part, by Judge Chen

The concurrence by Judge Timothy Dyk, which was fully joined by Judge Todd Hughes, spoke approvingly of the *Mayo*/*Alice* subject matter eligibility framework, which has been "valuable and effective" at invalidating overly broad claims in a way that cannot be accomplished by Section 102 novelty, Section 103 obviousness or Section 112 enablement or written description. Dyk shared his colleagues' concerns that the *Mayo* test should leave room for diagnostic patents that are sufficiently specific, but found that "it is the Supreme Court, not this court, that should reconsider the breadth of *Mayo*." That decision didn't make all diagnostic claims patent-ineligible, but it "left no room for us to find typical diagnostic claims patent eligible, absent some inventive concept at *Mayo* step two," Dyk wrote.

Judge Raymond Chen joined Judge Dyk's concurrence at Parts VI, V and IV. In this portion, Dyk pointed out that there is tension between *Mayo* and the Supreme Court's holding in *Association for Molecular Pathology v. Myriad Genetics* (2013), which

supports the patentability of discoveries under Section 101 as long as the claims aren't drafted overbroadly. Judge William Bryson's concurrence in *Myriad* noted claims unchallenged in the lower court's decision, recognizing that the potential eligibility of those claims led to the notion that "an inventive concept can sometimes come from the discovery of an unknown natural phenomenon and its application for a diagnostic purpose." While Judge Dyk felt that the Supreme Court should refine *Mayo*, such refinement should be limited to preventing the claiming of natural laws by tying those laws to a specific and useful application at *Mayo* step one, which could serve as the determination of the "inventive concept" in *Mayo* step two. Under that approach, Athena's claims could be determined to be patent eligible, as they don't claim a natural law itself but rather specific methods of diagnosing a neurological disorder by detecting certain antibodies. Unlike *Mayo*, this case involved the discovery of that relationship and "not mere determination of the precise correlations of a known natural law using prior art processes."

Judge Chen's Concurrence

Judge Chen wrote his own concurrence in the *en banc* denial in which he spent time discussing the different Supreme Court holdings in *Parker v. Flook* (1978) and *Diamond v. Diehr* (1981). In *Flook*, the Court required an inventive concept in claims beyond the recitation of an algorithm or law of nature after analyzing the claims on an element-by-element basis. By contrast, the Court in *Diehr* required the analysis of the challenged patent claim as a whole. *Diehr* served as the guiding precedent on the Section 101 inquiry for three decades until *Mayo*, which employed reasoning that tracked both *Flook* and Justice John Paul Stevens' dissent in *Diehr*. Chen argued that *Alice Corp. v. CLS Bank International* (2014) marked a further reversion to *Flook*'s analytical framework of considering elements of patent claims individually.

Judge Chen did note that *Mayo*'s analytical framework is harder to apply consistently than *Diehr* "and more aggressive in its reach." Further, *Mayo* didn't expressly overturn *Diehr*'s limitation on *Flook* that emphasized the need to consider the invention as a whole. Chen's discussion of this point clearly invites Supreme Court review of this case:

Through it all, there is a serious question today in patent law as to what extent *Diehr* remains good law in light of *Mayo*. We are not in a position to resolve that question, but the Supreme Court can. Resolution of the present confusion is important because if *Mayo* in fact overruled the principles in *Diehr*… then that would be a significant incursion on the settled expectations that had existed for 30 years since *Diehr*.

Athena provides ample proof of this present confusion. Judge Chen noted that the dissents and *amici* raise several valid concerns but, under *Mayo*, Athena's patent claims involving the association of an antibody and a medical disorder is deemed to be a law of nature and not an application of that law. Additional claim elements such as label-adding steps, immunoprecipitating steps or the use of a particular label are all conventional and add nothing to the underlying technology. While new diagnostic methods "intuitively seem to be the kind of subject matter the patent system is designed for," the claims don't stand under *Mayo*'s scrutiny, but Chen indicated that they could be patentable if read "as a whole" under *Diehr*. Chen also noted that Athena's claims arguably cover a new use of a known composition of matter, which the Patent Act contemplates as a patentable discovery; the Supreme Court hasn't addressed the meaning of "discovers" separately from "invents" in Section 101.

Judge Moore's Dissent, Joined by Judges O'Malley, Wallach and Stoll

Judge Kimberly Moore'd dissent, the lengthiest opinion in the *en banc* denial, started by noting that none of the judges of the Federal Circuit agree that the claims should be ineligible. The only disagreement is whether *Mayo* requires that outcome. Since *Mayo*, Moore noted that the Federal Circuit has invalidated every diagnostic claim that has come before the court in eight separate cases. "We have turned *Mayo* into a per se rule that diagnostic kits and techniques are ineligible," Moore wrote. When reading *Mayo* in light of *Myriad*, Moore felt it was clear that the Supreme Court didn't intend for the Federal Circuit to extend *Mayo* as far as it has.

Like Judge Chen, Judge Moore agreed that diagnostic kits and techniques "are precisely the type of innovation the patent system exists to promote" and help to reduce healthcare costs through early disease detection. Diagnostic tests cost millions of dollars to develop and can be easily reproduced, making patent protection crucial.

Unless one opposes the notion of patent protection entirely, it cannot be reasonably disputed that claims to diagnostic kits and techniques, like pharmaceuticals, which require enormous initial investments in terms of both time and money, are the reason we suffer the promise of a monopoly.

Judge Moore would put a finer point on the issue a few pages later:

The math is simple, you need not be an economist to get it: Without patent protection to recoup the enormous R&D cost, investment in diagnostic medicine will decline. To put it simply, this is bad. It is bad for the health of the American people and the health

of the American economy. And it is avoidable depending on our interpretation of the Supreme Court's holding in *Mayo*.

Moore reconciled *Mayo* with her belief that Athena's claims were patent eligible by noting that the claimed invention in *Mayo*, involving a relationship between the concentration of metabolites in the blood and dosage levels of thiopurine drugs, was not a new discovery of that relationship. By contrast, the claims in *Athena* involved the discovery of a type of antibody that binds to a particular receptor transmitting signals from neurons to muscles, leading to a completely new method for diagnosing a particular neurological disease that was capable of diagnosing about 20% of the patient population that had been previously undiagnosed. This was a new and useful discovery of a previously unknown relationship that should pass muster under Section 101, Moore opined.

Interestingly, even a cursory reading of Judge Moore's dissent reveals that her opinion was informed a great deal by the recent patent eligibility hearings held by the Senate Intellectual Property Subcommittee. Given that Moore was part of the Federal Circuit panel in this April's *Cleveland Clinic II* decision, which expressly rejected the notion that the U.S. Patent and Trademark Office's guidance on patent eligibility could impact the appellate court's case law, this would seem to underscore the need for Congressional action on Section 101 patent eligibility to give any weight to USPTO Director Iancu's efforts on subject matter eligibility.

Judge Newman's Dissent Joined by Judge Wallach

Judge Pauline Newman, the Federal Circuit's "great dissenter" who also issued a dissent in the *Athena* panel decision, wrote another one "because of the importance of medical diagnosis and the critical role of the patent system in achieving new diagnostic methods." Like Judge Moore, Newman said she believes that the Federal Circuit has "mistakenly enlarged" the Supreme Court's *Mayo* holding.

Despite the fact that the procedure claimed by Athena had not been previously used to diagnose *myasthenia gravis* (MG), Judge Newman found that the *Athena* panel majority's determination of ineligibility misapplied both the patent statute as well as *Mayo*. Rather than a law of nature, Athena's claims cover a new multi-step method of diagnosis and it was incorrect for the majority to omit the steps to perform the method from the claims. Whereas Judge Chen saw *Alice* as a reversion to *Flook*, Newman noted *Alice* reiterated that "an invention is not rendered ineligible for patent simply because it involves an abstract concept." Newman argued that statute and case law required that the claimed invention is considered as a whole. Viewed under correct

law and precedent, Athena's claims meet Section 101's requirements and the appropriate patentability analysis should happen under Sections 102, 103 or 112.

Like Judge Moore, Judge Newman outlined several cases in which the Federal Circuit applied *Mayo* to invalidate claims covering methods of diagnosis. However, Newman further discusses several Federal Circuit cases in which methods of treatment have been found eligible under Section 101. These inconsistent rulings are incompatible with *Mayo*, which didn't create a Section 101 distinction between diagnostic methods and therapeutic methods. Newman also reviewed the concerns raised by *amici* in this case regarding the Federal Circuit's Section 101 rulings and their effects on the development of diagnostic methods. She wrote:

This case presents an opportunity for judicial review and judicial remedy. Although diagnostic methods are not the only area in which section 101 jurisprudence warrants attention, Federal Circuit precedent is ripe for reconsideration specific to diagnostic methods, to correct our application of the *Mayo* decision and to restore the necessary economic incentive.

Highlights From Other Concurrences and Dissents

Judge Lourie Concurring, Joined By Judges Reyna and Chen – "[W]e are bound by the Supreme Court's decision in *Mayo*… If I could write on a clean slate, I would write as an exception to patent eligibility, as respects natural laws, only claims directed to the natural law itself, e.g., $E=mc^2$, F=ma, Boyle's Law, Maxwell's Equations, etc. I would not exclude uses or detection of natural laws… But we do not write here on a clean slate…

"Amici and others have complained that our eligibility precedent is confused. However, our cases are consistent. They have distinguished between new method of treatment claims and unconventional laboratory techniques, on the one hand, and, on the other hand, diagnostic methods that consist of routine steps to observe the operation of a natural law, a clear line. Beyond that, I do not see a way clear to distinguish *Mayo* in a useful, principled, fashion."

Judge Hughes Concurring, Joined by Chief Judge Prost and Judge Taranto – "The multiple concurring and dissenting opinions regarding the denial of en banc rehearing in this case are illustrative of how fraught the issue of [Section] 101 eligibility, especially as applied to medical diagnostics patents, is… I, for one, would welcome further explication of eligibility standards in the area of diagnostics patents."

Judge Stoll Dissenting, Joined by Judge Wallach – "Federal Rule of Appellate Procedure 35 directs us to order rehearing en banc when 'the proceeding involves a

question of exceptional importance…' [A] wholesale bar on patent eligibility for diagnostic claims has far-reaching and long-ranging implications for the development of life-saving diagnostic methods. The eligibility of life-saving inventions is not only one of the most important issues of patent law, but of human health. Thus, the importance of the issue here mandates that we consider it en banc."

Judge O'Malley Dissenting – "I write separately…because I believe that confusion and disagreements over patent eligibility have been engendered by the fact that the Supreme Court has ignored Congress's direction to the courts to apply [the Patent Act] as written. Specifically, the Supreme Court has instructed federal courts to read into Section 101 an 'inventive concept' requirement—a baffling standard that Congress removed when it amended the Patent Act in 1952…

"Because the Supreme Court judicially revived the invention requirement and continues to apply it despite express abrogation, I dissent to encourage Congress to clarify that there should be no such requirement read into [Section] 101; to clarify that concepts of novelty and 'invention' are to be assessed via application of other provisions of the Patent Act Congress designed for that purpose."