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The Final Plea for 101 Sanity? *Athena Amici* Ask Supreme Court to Clean Up U.S. Patent Eligibility Mess

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November 5, 2019

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Print Article

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November 1 was the deadline for filing amicus briefs to the U.S. Supreme Court, which is considering whether to grant a petition for writ of *certiorari* to take up *Athena Diagnostics v. Mayo Collaborative Services* on appeal from the U.S. Court of Appeals for the Federal Circuit. Almost every *amicus* filing to the Supreme Court in this case supported granting the petition or backed up the position of petitioner Athena, who is asking the Supreme Court to clarify its patent-eligibility doctrine under the *Alice*/*Mayo* framework on the subject of medical diagnostic patent claims. The appeal to the Supreme Court follows a hotly contested denial of an *en banc* rehearing of the Federal Circuit's original panel decision in *Athena*, which produced eight opinions, including four dissents, with many judges agreeing that Athena's invention should be patent eligible even while they disagreed over whether Supreme Court precedent allowed for patent protection of diagnostic methods.

The Chartered Institute of Patent Attorneys in Support of Petitioners

The Chartered Institute of Patent Attorneys (CIPA), which is the professional and examining body for patent attorneys in the United Kingdom, filed this *amicus* brief based on their concerns that the Supreme Court's decision in *Mayo* has affected many members of the UK who have patent applications undergoing examination at the U.S. Patent and Trademark Office (USPTO). CIPA notes that the Federal Circuit's *en banc* denial in *Athena* and its focus on the judicial exception rather than substantial eligibility conflicts with patent eligibility standards under both the Patent Cooperation

Treaty (PCT) and the European Patent Convention (EPC), both of which consider diagnostic methods to be patentable subject matter. Further, the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), to which the U.S. is a signatory, provides a code for patent eligibility which doesn't exclude laws of nature or processes involving natural products. Patent rights for Athena's patent-in-suit here have been granted in both Europe and Canada. Australia has also upheld the eligibility of diagnostic method patents in infringement cases. Citing to the Supreme Court's 1804 decision in *Murray v. Schooner Charming Betsy*, CIPA states that Section 101 "ought never to be construed to violate the law of nations if any other possible construction remains."

CIPA contends that clarification is needed to determine the relationship between the positive eligibility provisions of Section 101 with the judicial exceptions identified by the Supreme Court. Further, CIPA argues that the fact pattern of this case is consistent with substantive patent eligibility as the claims-at-issue touch upon three of four types of inventions that are patent-eligible under the statute. While the majority panel at the Federal Circuit properly identified a natural law, in this case the correlation between the presence of muscle specific tyrosine kinase (MuSK) autoantibodies and MuSK-related neurological diseases, CIPA argues that the majority should have identified the focus of the claims in terms of the procedural steps to be carried out and the new materials produced by the process. As well, these new materials are formed *in vitro* in a laboratory test procedure, rather than *in vivo* within the human body as was the case with the claims invalidated in *Mayo*. CIPA also cites to the Supreme Court's 1981 decision in *Diamond v. Diehr*, arguing that no valid distinction can be drawn between the rubber molding process upheld in *Diehr* and the diagnostic method of *Athena*, which similarly transforms an initial material into a different state or thing.

The Honorable Paul R. Michel (Ret.) in Support of Petitioners

The Honorable Paul R. Michel, who served on the Federal Circuit for 22 years and was its Chief Judge from 2004 to 2010, begins his *amicus* brief, filed by Matthew Dowd of Dowd Scheffel, by pointing out that "[t]he Federal Circuit's menagerie of patent-eligibility decisions over the past decade are devoid of any semblance of consistency." This lack of consistency is underscored by his belief that the *Athena en banc* denial represents the greatest instance of disharmony on patent law at the Federal Circuit that he has ever seen.

"On one level, it is nearly impossible to overstate the level of judicial discordance in this case," Judge Michel wrote, noting that the *en banc* denial produced eight separate opinions that resulted in the invalidation of Athena's patent claims despite the fact

that the majority of Federal Circuit judges thought the invention was patent-eligible. Not only was the decision highly splintered, but Judge Michel points out that nearly every opinion asked the Supreme Court for further guidance on its Section 101 patent-eligibility doctrine. The Federal Circuit's doctrinal confusion was further underscored by its recent decision in *American Axle & Manufacturing, Inc. v. Neapco Holdings LLC* in which a Federal Circuit majority invalidated patent claims for a method of manufacturing a shaft assembly of a driveline system a law of nature was utilized by the method. This "gross misapplication of [Section] 101," as Judge Michel calls that decision, expands the statutory function of Section 101 in a way that will continue to lead to troubling decisions from the courts.

The confusion over the patent-eligibility doctrine extends well beyond the Federal Circuit, Judge Michel notes, as all three branches of the federal government have adopted inconsistent positions on the subject. Congress, in enacting the Patent Act, has authorized broad patent protection as is evidenced by its use of the word "any" in Section 101, which authorizes patent-eligibility for "*any* new and useful process, machine, manufacture, or composition of matter, or *any* new and useful improvement thereof." The Judicial Branch has given mixed treatment to medical diagnostics patents as the "natural law" and "abstract idea" judicial exceptions have worked to invalidate diagnostic claims in many cases while other cases have affirmed diagnostic claims without any clear method for delineating when a law of nature will be found. In the Executive Branch, the USPTO has issued guidelines on the patent eligibility of diagnostic inventions, but as the Federal Circuit's 2019 decision in *Cleveland Clinic Foundation v. True Health Diagnostics LLC* makes clear, the Federal Circuit isn't bound by the USPTO's subject matter eligibility guidance.

This uncertainty over patent eligibility undermines investment in the U.S. biotech and medical diagnostics industries, investment which Judge Michel points out is incredibly costly. Judge Michel cites statistics showing that R&D and commercialization costs for a single diagnostic test average anywhere from $50 million to $75 million and can reach upwards of $100 million. The uncertainty posed by the Federal Circuit's application of the Supreme Court's patent-eligibility doctrine harms the ability of innovators to invest the money required to develop new diagnostic tests and are increasingly forcing innovators to seek patent protection in jurisdictions like China and Europe where eligibility doctrines are much more certain.

Intellectual Property Owners Association in Support of Petitioners

The Intellectual Property Owners Association (IPO), a trade association representing 175 companies and more than 12,000 individuals owning IP rights, argues in its

amicus brief that the Supreme Court's *Alice*/*Mayo* framework has been applied inconsistently, resulting in an undesirable lack of predictability in patent cases. This has undermined the Federal Circuit's "*raison d'être*," namely the development of uniform and consistent patent law. IPO leans heavily on Newman's dissent in *Athena*'s *en banc* denial, which argued that uncertain legal regimes that disincentivize innovation harm the public, "for diagnostic methods that are not developed benefit no one."

IPO contends that the inconsistency of results under *Alice*/*Mayo* is underscored by comparing the results of *Athena* with the Federal Circuit's 2018 decision in *Vanda Pharmaceuticals v. West-Ward Pharmaceuticals*. In both *Athena* and *Vanda*, patent claims-at-issue were directed towards methods of treatment involving an examination of a patient's ability to metabolize a drug and using that information to adjust the patient's treatment plan accordingly. While claims directed at correlating a patient's metabolism of a drug with a proper dosage treatment were invalid in *Athena* and *Mayo*, similar claims were upheld in *Vanda*.

Like Judge Michel, IPO discusses the USPTO's subject matter eligibility guidance, although IPO notes that the recommendations within that guidance points out the unpredictability of the *Alice*/*Mayo* framework. Analysis of examples of eligible and ineligible diagnostic claims disseminated by the USPTO between 2014 and 2016 show that, while one claim includes an additional diagnosing limitation and is thus wholly encompassed by the other example claim which meets Section 101 eligibility under the guidance, the narrower claim is actually ineligible under the USPTO's guidance because that diagnostic step is directed at a law of nature. "Common sense, and long-standing cannons of patent law, would dictate that if the broader claim is directed to patent eligible subject matter, so too should be the narrower claim," IPO states.

This uncertainty in diagnostic method patent-eligibility is even more troubling given the rate at which the biotech industry has been growing in recent years. IPO argues that the biotech sector will reach a global market size of $775 billion by 2024 while the number of patent grants in the sector have increased by 25 percent between 2010 and 2015. IPO also cites a 2019 investor survey by SMU Dedman School of Law Professor David O. Taylor which found that nearly three-quarters of investor respondents agreed that patent-eligibility is an important consideration for investment decisions. Sixty-two percent of investors surveyed said that they'd be less likely to invest in a technology company if their developments couldn't be patent-protected.

Pharmaceutical Research and Manufacturers of America in Support of the Petition

The Pharmaceutical Research and Manufacturers of America (PhRMA), which represents U.S. biopharmaceutical research companies that have invested $900 billion in R&D since 2000, argues in its *amicus* brief that the Federal Circuit, which has invalidated every diagnostic claim appealed to that court, has acknowledged that its application of Section 101 patent eligibility could eliminate all patent protection for diagnostics. While method-of-treatment claims have been largely upheld as valid, recent decisions like *INO Therapeutics LLC v. Praxair Distribution Inc.* have introduced the "natural phenomenon" exception into this area of biotech as well. In *Athena*, both the groundbreaking nature of the discovery about the association between biomarkers and neurological disease and the low preemption concerns caused by the narrow sequence of steps claimed by the patent gives the Supreme Court an ideal opportunity to clarify its precedent regarding diagnostic patent eligibility.

PhRMA notes that diagnostics play an important role in the public health system, guiding two-thirds of all clinical decisions in the U.S. while accounting for 2.3 percent of total healthcare expenses. Diagnostic tests are important for the growing field of personalized medicine, where diagnostic testing allows physicians to target treatments for optimal benefits and minimal side effects. Future innovation in diagnostics requires patent protections because of the cost of developing new tests, estimated at $100 million per new test as of 2011, and the relatively cheap way that those tests can be reproduced. PhRMA's brief concludes by traveling much of the same ground regarding the effects of uncertain patentability on R&D investment in biotech and other fields.

Eleven amicus briefs were filed in all. Read them all here and read a summary of the brief filed by Sherry Knowles and Meredith Addy on behalf of Freenome Holdings and New Cures for Cancers here.