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Legal Sidebar

Judges Urge Congress to Revise What Can Be Patented

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What can be patented? A series of Supreme Court decisions beginning nearly a decade ago catapulted that question to the forefront of patent law. Since then the U.S. Court of Appeals for the Federal Circuit (Federal Circuit)—the only federal appeals court that hears patent law appeals—has issued a number of decisions limiting patent eligibility. Some stakeholders, however, view the current law as discouraging important innovations like medical diagnostic tests. One commenter has lamented that "thanks to the Supreme Court the most exciting scientific discoveries, technological advances[,] and innovations of the twenty-first century are no longer patent eligible in America." Supporters contend, however, that current law weeds out bad patents and "facilitates the early resolution" of patent infringement cases.

This issue has attracted significant interest from the 116th Congress. For instance, in early June, the Senate Judiciary Committee held three days of hearings (Part I; Part II; Part III) on "[t]he State of Patent Eligibility in America" and draft amendments to the relevant statutory provisions. And the debate over patent eligibility has extended beyond Capitol Hill. In July, in *Athena Diagnostics, Inc. v. Mayo Collaborative Services*, the Federal Circuit denied full-court review of a decision holding that a diagnostic method was patent-ineligible. In eight separate opinions, all of the active judges of the Federal Circuit called for the law to be changed to allow for the patenting of diagnostic methods. In light of this debate both in and outside of Congress, this Sidebar provides a brief overview of the current law of patent eligibility, before discussing the opinions in *Athena* and the importance of the issue for Congress.

The Law of Patent Eligibility

Patent eligibility is governed by, among other provisions, 35 U.S.C. § 101, which reads that "[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of" the Patent Act. (Section 101 is not the only requirement for patentability; an invention must also be novel and nonobvious, and the application must describe and set forth the invention in a manner clear enough for others to make it.) Despite section 101's seemingly broad language, the Supreme Court has long held that laws of nature, natural phenomena, and abstract ideas are not patentable. For example, the Court has opined that "a new mineral discovered in the earth or a new plant found in the wild is not patentable subject matter," nor is Albert Einstein's "celebrated law that $E=mc^2$." The basis for

this limitation on patentability is the belief that allowing "the basic tools of scientific and technological work" to be patented "might tend to impede innovation more than it would tend to promote it." The Court has recognized, however, that interpreting these judicially-created exceptions too broadly "could eviscerate patent law" because "all inventions at some level embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas."

The Supreme Court has articulated a two-part test to determine whether a patent impermissibly encompasses a law of nature, natural phenomenon, or abstract idea. First, a court must "determine whether the [patent] at issue is directed to one of those patent-ineligible concepts." If it is, then the court must consider whether the patent contains additional elements that "'transform the nature of the [invention]' into a patent-eligible application"—what is referred to as a search for an "inventive concept."

The Supreme Court first used that analysis in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.* The patents at issue in that case involved a method for treating a gastrointestinal disorder based on a measurement of a certain metabolite in a patient's blood. Specifically, the patent claimed the method of administering a drug based on the metabolite level in the patient's blood, as the metabolite level correlated with the effectiveness of a particular dosage of the drug in question. The Court held that the invention was patent ineligible. First, the *Mayo* Court viewed the patents to be directed at a law of nature—the relationship between metabolite levels and dosage of the drug. Second, it concluded that the patent did not transform the invention into a patent-eligible application because aside from the relationship itself, the other steps in making the diagnosis were "well-understood, routine, conventional activity already engaged in by the scientific community."

Shortly after deciding *Mayo*, the Supreme Court extended its analysis to abstract ideas and computer-implemented inventions. For instance, in *Alice Corp. v. CLS Bank*, the Court held that a patent directed to performing a transaction using a computer as an intermediary was a patent-ineligible abstract idea.

Mayo and the related section 101 decisions have had a profound effect on patents and the practice of patent law. In the 14 months following the *Alice* decision, the courts invalidated more patents under section 101 than they had in the five years preceding *Alice*. Between June 2014 and March 2017, district courts invalidated more than 60% of the patents challenged on section 101 grounds. On appeal, the Federal Circuit invalidated more than 90% of the patents challenged under section 101, including new methods of detecting an increased risk of cardiovascular disease and methods of diagnosing fetal genetic defects using maternal blood samples that had previously been discarded as medical waste.

Athena v. Mayo

Athena, like *Mayo*, involved a diagnostic patent challenged under section 101. Athena Diagnostics (Athena) licensed U.S. Patent 7,267,820 (the '820 patent), which covered methods for diagnosing neurological disorders by detecting a particular protein. Specifically, the inventors of the '820 patent discovered that antibodies to the protein muscle-specific tyrosine kinase (MuSK) could be used to detect the neurological autoimmune disorder myasthenia gravis (MG). Although the relationship between MG and antibodies to MuSK was previously unknown, the techniques for testing and diagnosis were well-known in the field. Athena also sold a test kit that used the invention to diagnose MG. Mayo Collaborative Services, LLC (Mayo) developed two competing test kits, and Athena sued Mayo for allegedly infringing the '820 patent. Mayo moved to dismiss Athena's lawsuit on the basis that the '820 patent was invalid under section 101, and the district court granted the motion.

A three-judge panel of the Federal Circuit affirmed, with one judge dissenting. The court held that *Mayo* dictated that Athena's claims were invalid. The dissenting judge, while disputing whether *Mayo* was truly indistinguishable from the instant case, more broadly criticized the *Mayo* line of cases, arguing that

invalidating patents like Athena's disincentivized the creation and development of new diagnostic methods.

Following the decision, Athena asked for the full court (all twelve active Federal Circuit judges or the "en banc" court) to rehear the case. The court denied the request, with eight judges writing opinions either agreeing or disagreeing with the panel decision and, in so doing, discussing broader issues of concern over *Mayo* and its progeny.

Concurring Opinions

The judges concurring in the denial of rehearing felt bound by *Mayo*. For instance, Judge Alan Lourie, the author of the panel decision, argued that the Federal Circuit could "accomplish little" by rehearing the case because *Mayo* controlled. Judge Todd Hughes agreed, as did Judge Raymond Chen, who similarly opined that *Mayo* necessarily meant that Athena's claims were ineligible because both cases involved detecting a naturally-occurring correlation using conventional techniques.

Interestingly, however, the concurring judges all argued that Athena's new diagnostic method was the sort of invention that *should* be patent eligible. Several made suggestions for how the law could be revised to render Athena's invention eligible. For example, Judge Lourie argued that, in the absence of *Mayo*, he would have held that only patents directed to natural laws themselves—for example, $E=mc^2$—should be ineligible; using or detecting such natural laws would, however, still be eligible for a patent under his view. While arguing that section 101 is a valuable part of the patent laws, Judge Timothy Dyk similarly acknowledged that the *Mayo* test "should leave room for sufficiently specific diagnostic patents." Judge Chen concluded that diagnostics patents represent "a practical application of the discovered law of nature, that is, it is applied science in every sense of that term. And [they] should be patentable subject matter in a well-functioning patent system."

Accordingly, the concurring judges called for either Congress or the Supreme Court to revise the law. Judge Lourie opined that as long as *Mayo* remains good law, "the only possible solution lies in the pens of [patent] drafters or legislators." Judge Hughes contended that while the state of the law was "not a problem that [the Federal Circuit] c[ould] solve," he would "welcome further explication of eligibility standards." Notably, Judge Hughes suggested that such clarification "might come from Congress, with its distinctive role in making the factual and policy determinations relevant to setting the proper balance of innovation incentives under patent law." Other judges, however, thought the Supreme Court could further clarify the underlying law. For instance, Judge Dyk proposed that the Supreme Court could use *Athena* as an opportunity to refine *Mayo*'s framework. Similarly, Judge Chen opined that the Federal Circuit "would benefit from the Supreme Court's guidance" on patent eligibility.

Dissenting Opinions

The judges dissenting from full-court rehearing primarily argued that this case gave the Federal Circuit the opportunity to reconsider its interpretation of *Mayo*. For instance, Judge Kimberly Moore contended that the Federal Circuit had "extended *Mayo* too far" and should use *Athena* as an opportunity to revisit and revise the law. Judge Pauline Newman similarly agreed that the Federal Circuit had "mistakenly enlarged" *Mayo*. Judge Kara Stoll likewise argued that the current law is "an over-reaching and flawed test for eligibility." Rather than read *Mayo* broadly, the dissenters felt *Mayo* could be distinguished on the grounds that Athena's claims recited a specific, concrete *application* of the natural law and therefore were patent eligible. For instance, Judge Newman, echoing her earlier panel dissent, contended that rather than being directed to a natural law, Athena's patent was instead directed to a new diagnostic method.

More broadly, the dissenting judges argued that the incentives provided by patents were important to the development of diagnostic methods. Judge Moore argued that because new diagnostic methods take a

long time to develop (nearly 10 years), are costly to develop (up to $100 million), and are relatively easy to reproduce once developed, they require patents as incentives for innovation. Without patent protection, companies would not see investing in developing new diagnostic methods as worth the time, expense, and risk. Judge Moore further pointed out that incentivizing such diagnostics are a public good. In support of her argument, she noted that the Federal Circuit, based on *Mayo*, has invalidated patents directed to early detection of cardiovascular disease, breast cancer, and tuberculosis that had the potential to save tens of thousands of lives per year.

Like many of their concurring colleagues, the dissenting judges also called for the law to be revised. Judge Moore argued that the Federal Circuit's precedents had rendered diagnostic patents per se ineligible. Thus, for her, the only hope for diagnostic patents "lies with the Supreme Court or Congress." Judge Kathleen O'Malley also encouraged Congress to intervene and amend the Patent Act.

Implications for Congress

The denial of full-court review in *Athena* is noteworthy for several reasons. Procedurally, it is unusual for *any* judge to write an opinion either agreeing or disagreeing with the decision not to hear a case en banc. En banc rehearing is "not favored and ordinarily will not be ordered." Such requests are generally denied without a single opinion, in a one-page order. A denial of a full-court rehearing accompanied by *eight* separate opinions has never occurred in the history of the Federal Circuit. The number of opinions in *Athena* indicates that although the judges are divided on what should be done in view of current Supreme Court precedent, they view the section 101 issue as extremely important.

Substantively, the opinions bear out the importance of the § 101 issue. All of the judges agreed that Athena's invention is the kind of subject matter that *should* be patentable. The invalidation of Athena's patent will stand only because a majority of the appellate court believed that there was no principled way to distinguish *Mayo* from the facts of *Athena*.

Accordingly, the judges argued for a change in the law from either the Supreme Court or Congress. The Supreme Court has not, however, signaled that it intends to restrict the import of *Mayo* going forward. Since its most recent section 101 decision in 2014, the Supreme Court has denied at least 43 petitions for certiorari on section 101 issues. The Court recently called for the views of the solicitor general in two section 101 cases, suggesting that it is seriously considering reviewing those cases. Notably, in both cases the Federal Circuit *upheld* the patent under review, indicating that the Supreme Court may be interested in further restricting, rather the broadening, what may be patented.

Given this, Congress may be the central avenue for revisions to section 101. And, as noted, there are some signals that Congress may be interested in doing so. Draft legislation that the Senate Judiciary Committee released would address some of the concerns that various Federal Circuit judges raised in *Athena*. Foremost, the current draft language would nullify *Mayo* and its progeny, stating that "[n]o implicit or other judicially created exceptions to subject matter eligibility, including 'abstract ideas,' 'laws of nature,' or 'natural phenomena,' shall be used to determine patent eligibility under section 101, and all cases establishing or interpreting those exceptions to eligibility are hereby abrogated."

Several judges in *Athena* also suggested a narrower approach than wholly abrogating the *Mayo* line of cases. Overruling the natural law exception entirely might lead to the patentability of true natural laws (for example, $E=mc^2$). Instead, as several of the *Athena* opinions suggested, section 101 could be amended to make specific applications of a natural law (e.g., a diagnostic method) patent-eligible, while keeping true natural laws ineligible. As a consequence, with reports that Congress will continue to contemplate revising section 101 this fall, the opinions in *Athena* could inform this debate going forward.

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