No. 19-430

IN THE

Supreme Court of the United States

ATHENA DIAGNOSTICS, INC., OXFORD UNIVERSITY INNOVATION LTD., and MAX-PLANCK-GESELLSCHAFT ZUR FORDERUNG DER WISSENSCHAFTEN E.V.,
Petitioners,

v.

MAYO COLLABORATIVE SERVICES, LLC, DBA MAYO MEDICAL LABORATORIES, and MAYO CLINIC,
Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

REPLY BRIEF FOR PETITIONERS

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Mayo's contention that there is no confusion in the lower courts collapses under the weight of the Federal Circuit's 7-5 split. The Federal Circuit explained at length, across multiple opinions, its struggle to apply the judge-made exceptions to 35 U.S.C. § 101 in a clear and consistent manner. The 7-5 split was not a disagreement over policy; there was broad consensus that Athena's claims should be patent-eligible. Rather, it was a fundamental disagreement over how to interpret this Court's decisions, in particular how to apply the prior *Mayo* decision beyond its unusual facts while reconciling perceived tensions among this Court's opinions.

The United States agrees that the legal confusion surrounding the "framework articulated in the Court's recent Section 101 decisions … warrants review in an appropriate case." U.S. Br. 8, *Hikma Pharms. USA Inc.* v. *Vanda Pharms. Inc.*, No. 18-817 (U.S. Dec. 6, 2019) ("U.S. Br."). Indeed, while advising against a grant in *Hikma*, the government highlights *this case* as one in which "further guidance from this Court is amply warranted." *Id.* at 22-23.

Eleven amicus briefs further amplify the need for this Court's review. As the former Chief Judge of the Federal Circuit explained, in his "twenty-two years on the bench," he never saw a legal issue that "created such disharmony, disagreement, and inconsistency," creating an "unsustainable" inability to "distinguish eligible subject matter from ineligible, with any reasonable certainty." Michel Br. 4. Other amici have similarly attested to the difficulty of consistently applying this Court's prior *Mayo* decision and the resulting chilling effect on medical investment and innovation.

Mayo's response only reinforces the need for this Court's guidance. Mayo's central argument that because Athena's claims adapt techniques known *in the abstract*, they are patent-ineligible—notwithstanding the use of novel man-made molecules in specific laboratory steps never previously performed—tees up multiple points of doctrinal uncertainty identified by the Federal Circuit, amici, and government. Those legal questions include the role of novel man-made molecules in method claims, the level of abstraction at which to view claims, the Federal Circuit's one-sided approach to preemption, and what it means to view the claims as a whole. Clarification on even one of these points would revive Athena's claims and help rein in the Federal Circuit's misinterpretation of this Court's precedent.

Mayo's attempt to argue the facts loses sight of the procedural posture. Mayo moved to dismiss under Rule 12(b)(6) on the theory that, without any factual development, the asserted claims were categorically ineligible for patent protection as a matter of law. This case thus presents a pure question of law, with no factual disputes to resolve because the record must be viewed in the light most favorable to Athena. In short, it provides a perfect vehicle to clarify the law.

Finally, Mayo gets things backwards when it argues that Congress should correct the Federal Circuit's expansion of the judicial exceptions to § 101. The Federal Circuit did not interpret the statutory text; it misapplied this Court's decisions creating exceptions to that text. If Mayo wants those exceptions expanded, it is the one that should take its policy arguments to Congress. The Court has a special responsibility to ensure that the lower courts do not unduly expand judge-made law by misinterpreting the framework it created.

I. THE COURT SHOULD REVIEW THIS CASE TO CLARIFY THE JUDICIAL EXCEPTIONS TO SECTION 101

A. The Federal Circuit Is Divided On How To Interpret This Court's Precedent

Mayo's assertion (at 18) that "the Federal Circuit has had no problems applying *Mayo* consistently" ignores the 7-5 split in the Federal Circuit. The court did not split based on disagreement about what the law *should* be—in fact, the Federal Circuit broadly agreed that Athena's claims *should* be patent-eligible. Rather, the court split based on genuine disputes about how to apply the framework this Court established in *Mayo Collaborative Services* v. *Prometheus Laboratories, Inc.*, 566 U.S. 66 (2012).

As the United States notes, in the eight concurring and dissenting opinions, the twelve judges articulated "different understandings of *Mayo*" and sought "clarification from this Court" about which one is correct. U.S. Br. 22. For example, Judge Moore wrote in dissent that "§ 101 and *Mayo*, when read together and in their entireties, compel the holding that the claims [at issue here] are eligible." App. 109a-110a. In particular, Judge Moore explained, "[t]he concreteness and specificity of [Athena's] claims … moves them from reciting a law of nature to a particular application of a law of nature," and thus "[t]he claims are not directed to a natural law or phenomenon." App. 116a. Similarly, Judge Stoll explained that the Federal Circuit has applied *Mayo* broadly and "inflexibl[y]," resulting in "flawed decisions that are inconsistent with the precepts of *Mayo* and our patent system as a whole." App. 136a. In other words, the outcome in this case is a classic example of the "rote application" of *Mayo* "in a way that the *Mayo* Court clearly did not envision," U.S. Br. 14,

that has led to finding every diagnostic claim to come before the Federal Circuit patent-ineligible.[1]

The United States and numerous amici have confirmed that "the Federal Circuit, district courts, Patent Office, and inventors have struggled unsuccessfully to apply the *Mayo*/*Alice* decisions coherently and predictably." Lefstin & Menell Br. 4 (footnote omitted); *see also* U.S. Br. 16-17. The United States has explained that the "lack of clarity in judicial precedent" has constrained the Patent Office's "ability to provide direction" and that the judicial attempt to create a framework "decoupled … from the statutory text and context" has "proven problematic." U.S. Br. 16-17. Practitioners have bemoaned "the increased difficulty in predicting whether inventions will be found patentable despite the absence of preemption concerns." New York Intellectual Property Law Ass'n Br. 20. Patent Owners have explained that this Court's § 101 case law "has been applied inconsistently by panels of the Federal Circuit and in district courts around the country," and that the Federal Circuit has failed to "develop[] … a uniform and consistent body of … law that can be applied by district courts nationwide in a predictable manner." Intellectual Property Owners Association (IPO) Br. 3. In short, as former Chief Judge Michel explained, "[o]ne cannot distinguish eligible subject matter from ineligible, with any reasonable certainty." Michel Br. 4.

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[1] The sharp divide in the Federal Circuit has persisted in post-*Athena* cases expanding the judicial exceptions to Section 101. *E.g.*, *American Axle & Mfg., Inc.* v. *Neapco Holdings LLC*, 939 F.3d 1355 (Fed. Cir. 2019); *INO Therapeutics LLC* v. *Praxair Distribution Inc.*, 782 F. App'x 1001 (Fed. Cir. 2019).

B. Mayo's Arguments Reinforce The Need For This Court's Clarification

Mayo focuses on arguing the facts, contending that Athena's claims are not patent-eligible under this Court's two-part test because U.S. Patent No. 7,267,820 refers to certain techniques in the abstract as "known per se" (i.e., by themselves) or "standard." Mayo's argument, however, merely highlights the *legal* questions that the Federal Circuit has struggled with in applying this Court's cases.

First, as recognized by Judge Dyk, there is tension between the decision below and this Court's holding in *Association for Molecular Pathology* v. *Myriad Genetics, Inc.*, 569 U.S. 576, 594-595 (2013), that a "molecule that is not naturally occurring" is "not a 'product of nature' and is patent eligible under § 101." Pet. 17, 29-31; App. 69a-71a.

Mayo offers no good response. It implicitly concedes (at 25), as it must, that the prior *Mayo* case involved a drug routinely used before, not a *novel* man-made molecule as here. Further, its contention that the radioactive MuSK molecule in the claimed methods was created using known techniques ignores that the cDNA molecule this Court held patent-eligible in *Myriad* also could be created "through processes … well known in the field of genetics." 569 U.S. at 582. For purposes of evaluating the subject-matter eligibility of Athena's claims, it is the *presence* of a novel man-made composition that matters, not the manner of its creation. The remainder of Mayo's argument relies on the untenable premise that *radioactive* MuSK is not "markedly different" from naturally occurring MuSK. That is an argument Mayo cannot win under any circumstances, and especially not on a motion to dismiss. *See infra* § I.C.

In any event, the decision below did not turn on any of Mayo's points, as the majority held that the use of a novel man-made substance was simply irrelevant to the threshold issue of patent eligibility. App. 13a-14a. This Court's guidance is needed to resolve the tension between that holding and *Myriad*.

Second, courts have had difficulty applying this Court's holding in *Mayo* to less unusual facts than those in *Mayo*. Pet. 17-18; *see also* U.S. Br. 18 (*Mayo* framework is "ambiguous"). The differences between Athena's claims and the ones at issue in *Mayo* are not "cosmetic," Opp. 23. For example, by the time of the invention claimed in *Mayo*, doctors had long been administering the very same drug and adjusting its dose based on levels of the very same metabolite. 566 U.S. at 73-75, 78. The claims required no steps beyond those already engaged in by this "pre-existing audience" and thus added nothing other than the bare recitation of new information. *Id.* at 78. Here, in contrast, no one had ever assayed MuSK autoantibodies for any reason using any method, let alone with novel man-made, radioactive MuSK molecules or the specific steps of the claimed invention. The significance of this distinction split the Federal Circuit. *E.g.*, App. 117a (Moore, J.) (claimed discovery was inventive, unlike the claim in *Mayo*).

Third, Mayo ignores the confusion about the level of abstraction at which to analyze whether the steps of a claim transform a law of nature "into a patent-eligible *application* of such a law." *Mayo*, 566 U.S. at 72. Instead, Mayo repeats the Federal Circuit's error, asserting (at 24) that the specific claim steps recited in the patent-at-issue "were standard and known." But that assertion is wrong, and the issue is the source of sub-

stantial confusion warranting this Court's review. Pet. 19-20; *see also* U.S. Br. 13-14.

Fourth, Mayo does not deny that the Federal Circuit has turned the "preemptive" scope of claims into a one-way ratchet. This Court described the risk of preempting the use of a natural law or abstract idea by others as "the concern that drives" the judicial exceptions to § 101. *Alice Corp.* v. *CLS Bank Int'l*, 573 U.S. 208, 216 (2014). But the Federal Circuit considered it irrelevant that Athena's claims leave open "other ways of interrogating the correlation between MuSK autoantibodies and MuSK-related disorders," declaring: "Preemption is sufficient to render a claim ineligible under § 101, but it is not necessary." App. 13a.

Mayo attempts to distract from the Federal Circuit's one-sided approach by pointing to five broader patent claims that are *not even at issue in this suit*. Opp. 6, 29. But those claims have no bearing on the validity of the far more specific claims asserted here. *See* 35 U.S.C. § 282 ("Each claim of a patent … shall be presumed valid independently of the validity of other claims.").

Fifth, Mayo ignores the tension between the Federal Circuit's mechanical application of *Mayo* and this Court's longstanding directive that claims should be viewed "as a whole." *Diamond* v. *Diehr*, 450 U.S. 175, 188 (1981). Judge Chen noted that there is now a substantial question whether prior Supreme Court cases that required considering claims as a whole remain good law. App. 83a-89a. Doubt on that question, the United States observed, "threatens the patent-eligibility of numerous valuable innovations that incorporate existing steps into [a] new and useful process[]." U.S. Br. 19.

* * *

The Federal Circuit's legal errors on these points—which Mayo merely repeats or ignores—have skewed its application of this Court's two-part test. Athena's claims (1) use multiple man-made molecules that never previously existed (2) as part of a series of specific laboratory steps never previously performed (3) to enable doctors to diagnose a serious medical condition in the 20 percent of patients for whom no lab test was previously available. Properly understood, such claims are directed to a novel method of in vitro testing at step one, not the underlying natural law. At minimum, the claims add enough to qualify as patent-eligible applications at step two. Indeed, if this Court's two-part test—as opposed to the Federal Circuit's misinterpretation of that test—truly barred Athena's claims, *Mayo* would warrant reconsideration. *Cf.* U.S. Br. 3-5, 14.

C. This Case Presents An Ideal Vehicle To Clarify The Law

This case presents an ideal vehicle to clarify the doctrinal questions on which the Federal Circuit seeks guidance. The United States has specifically identified this case as an "appropriate case" in which this Court should provide "additional guidance." U.S. Br. 8, 22-23. Mayo does not identify any vehicle problems. To the contrary, the specificity of Athena's claims and their use of novel man-made molecules provide the Court with flexibility to clarify the law, on one or more dimensions, as the Court sees fit. Pet. 28.

The case also arises in an ideal procedural posture for resolving questions of law. Mayo attempts to argue

the facts, reaching outside the record.[2] But this Court need not address any factual disputes. Mayo won dismissal under Rule 12(b)(6) on the premise that no fact-finding was needed to invalidate Athena's claims as a matter of law. Any factual disputes must therefore be resolved in Athena's favor. One of the reasons the stakes are so high in this case is that if Athena's claims to specific laboratory steps using novel man-made molecules cannot even survive a motion to dismiss, it will sound the death knell for most medical diagnostic patents.

II. MAYO'S ADDITIONAL ARGUMENTS ARE UNAVAILING

1. The Federal Circuit's expansive interpretation of the judicial exceptions to § 101 threatens important medical innovation, particularly the development of new diagnostics. Pet. 24-28; *see* U.S. Br. 15-16, 22. The United States and multiple amicus briefs confirm this point. *E.g.*, U.S. Br. 15-16; Pharmaceutical Research and Manufacturers of America Br. 14-22; Biotechnology Innovation Org. Br. 18-20; Chicago Patent Attorneys Br. 13-17; IPO Br. 12-13; Michel Br. 19. Academic literature has also made clear that "patent eligibility is an important consideration in deciding whether to invest in a company developing technology"; patent-eligibility case law has impacted many firms' investment behaviors; and these impacts have been felt most in the

[2] For example, Mayo asserts that the patented method simply replicates the assay for detecting AChR autoantibodies. In fact, it does not, and could not. C.A.J.A. 606, 622. The earlier assay relied on a radioactively labeled snake toxin, but no toxin was known to bind to MuSK as tightly and with the same specificity. *Id.* 607, 609. Pursuing a different approach, the inventors created radioactive ^{125}I-MuSK, avoiding the need for either snake toxin or the toxin inhibitor used in the prior art. *Id.* 607, 609, 615-616.

pharmaceutical, biotechnology, and medical device industries. Taylor, *Patent Eligibility and Investment* 31, 44-52, 62 (Feb. 24, 2019), Cardozo L. Rev. (forthcoming), https://bit.ly/2QXE1fq; Lefstin, et al., *Final Report of the Berkeley Center for Law & Technology Section 101 Workshop*, 33 Berkeley Tech. L.J. 551, 583-584 (2018) ("The shift in patent eligibility for diagnostics threatens research and development investment in medical diagnostics.").[3]

Mayo argues (at 33) that the Federal Circuit's § 101 framework leaves room for some (unspecified) innovation. But it notably cites no case upholding a diagnostic claim, where "*Mayo* has had particularly significant practical effects," U.S. Br. 22. Even if a narrow window might exist for a small subset of claims, the Federal Circuit's invalidation of the breakthrough methods in this case—which for the first time enabled "accurate and speedy" diagnosis (and thus treatment) of 20 percent of myasthenia gravis patients, C.A.J.A. 44—shows the far-reaching impact its decisions will have.

Athena is not asking for "a special rule for diagnostic patents" or seeking to "guarantee[] eligibility for all medical diagnostic methods." Opp. 17, 32. Athena merely seeks to restore balance by clarifying points of genuine confusion in the case law, which create uncertainty in a variety of technical areas. *E.g.*, U.S. Br. 15-16, 22. Federal Circuit's misapplication of those principles to broadly bar eligibility in a field of particular im-

[3] Mayo's statistics (32-33) are not to the contrary. It is unsurprising that investment in diagnostics, and the share price of Athena's parent company, have risen since the depths of the Great Recession. That says nothing about the overall impact of patent-eligibility law on innovation, or the impact of this case in particular.

portance to the health of the nation simply highlights the significance of that confusion and the urgent need for this Court to provide clarity.

2. The Court should not ignore the lower courts' confusion in the hope that Congress might intervene. Despite congressional hearings highlighting that confusion and the unsustainable state of the law, Pet. 22-24, there is no legislative solution in sight, Nayak, *IP Groups Developing Fresh Patent Eligibility Bill Proposal*, Bloomberg Law (Oct. 17, 2019), https://bit.ly/2ONFG4t ("lawmakers have not introduced a bill" in light of "disagreement among stakeholders").

In any event, this Court has a special responsibility to clarify patent-eligibility law and rein in the Federal Circuit's improper expansion of the exceptions to patent eligibility. As the United States explained, these exceptions are "atextual." U.S. Br. 8. Congress already spoke when it enacted § 101 as written, broadly defining patent-eligible subject matter while relying primarily on other statutory provisions (§§ 102, 103, and 112) to limit patent protection. *See* U.S. Br. 1-5, 20-21. If Mayo wants to expand the exceptions to § 101 beyond their historical scope, it should take those policy arguments to Congress. It is this Court's role to ensure that the Federal Circuit does not effect such an expansion in the absence of congressional action based on the misconception that this Court's precedent requires it.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted.

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