No. 19-430

IN THE

Supreme Court of the United States

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

Petitioners,

v.

MAYO COLLABORATIVE SERVICES, LLC, DBA MAYO MEDICAL LABORATORIES, MAYO CLINIC,

Respondents.

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

BRIEF OF *AMICUS CURIAE* INTELLECTUAL PROPERTY OWNERS ASSOCIATION SUPPORTING PETITIONERS

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INTEREST OF THE *AMICUS CURIAE*[1]

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As owners of intellectual property, IPO members believe intellectual property rights promote the innovation, creativity, and investment necessary to address major global challenges and improve lives. IPO strives to maximize innovation across all industries and to improve lives throughout the world by fostering high quality intellectual property rights and effective, harmonized systems to obtain and enforce them on behalf of all IPO members.

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1. Pursuant to Rule 37.6, amicus affirms that no counsel for a party authored this brief in whole or in part, nor has any counsel, party, or third person other than amicus or its counsel made any monetary contribution intended to fund the preparation or submission of this brief. Pursuant to Rule 37.2, counsel of record for all parties received notice of amicus's intent to file this brief at least ten days before the due date. Both parties have consented to the filing of this brief.

2. IPO procedures require approval of positions in briefs by a two-thirds majority of directors present and voting

SUMMARY OF THE ARGUMENT

Section 101 of the Patent Act states: "Whoever 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 this title." 35 U.S.C. § 101. With that broadly worded statutory language, Congress intended patentable subject matter to "include anything under the sun that is made by man." *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980). However, the Court has long recognized an "important implicit exception" under which laws of nature, abstract ideas, and natural phenomena are not eligible for patent protection. *See Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66, 70 (2012). In *Mayo* and *Alice Corp. v. CLS Bank Int'l*, 573 U.S. 208 (2014), this Court established a two-step framework for determining whether a claim satisfies § 101 and is therefore patent eligible. First, a court must "determine whether the claims at issue are directed to one of [the three] patent-ineligible concepts." *Alice*, 573 U.S. at 217. If so, then the court must determine whether additional elements of the claim "transform" the claim into patent eligible subject matter such that the claim provides "more than" the ineligible concept itself. *Id.*

This test has proven to be inconsistent and unpredictable in its application. Different results have been reached in cases involving what appear to substantively similar patent claims. Even guidance from the U.S. Patent and Trademark Office has not ameliorated the uncertainty in this area of the law. Clear legal precedent is needed to ensure that patentees and potential accused infringers alike can better assess and predict the merits

of infringement and validity claims. This case presents an opportunity for the Court to settle this area of the law and introduce much-needed predictability back into § 101 jurisprudence, and therefore the Court should grant Petitioner's *certiorari* petition.

ARGUMENT

I. The *Mayo*/*Alice* Framework Has Been Applied Inconsistently Resulting in an Undesirable Lack of Predictability

The current *Mayo*/*Alice* framework has been applied inconsistently by panels of the Federal Circuit and in district courts around the country. The resulting unpredictability is at counter-purposes with the raison d'**ê**tre for the Federal Circuit— the development of a uniform and consistent body of federal patent law that can be applied by district courts nationwide in a predictable manner.[3] "If patent appeals are no more predictable than throwing darts, . . . the patent system suffers."[4]

In this case, both the panel majority and dissent seemed to agree that, as a general matter, the eligibility of diagnostic method claims benefits the public. Judge

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3. S.Rep. 97–275, 97th Cong., 1st Sess. 5, reprinted in 1982 U.S. Code Cong. & Ad. News 11, 15 ("The creation of the Court of Appeals for the Federal Circuit will produce desirable uniformity in this area of the law [patent law]."); *In re Cray Inc.*, 871 F.3d 1355, 1360 (Fed. Cir. 2017) (noting that the Federal Circuit "has a mandate to achieve uniformity in patent matters").

4. Gugliuzza, *The Federal Circuit as a Federal Court*, 54 Wm. & Mary L. Rev. 1791, 1835 (2013).

Newman, in dissent, explained that when patent eligibility standards disincentivize the development of diagnostic methods, "[t]he loser is the afflicted public, for diagnostic methods that are not developed benefit no one." *Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC*, 915 F.3d 743, 763 (Fed. Cir. 2019). Similarly, the majority noted that "providing patent protection to novel and non-obvious diagnostic methods would promote the progress of science and useful arts." *Id.* at 753 n.4. Despite this seeming agreement, the majority and dissent reached different conclusions as to the eligibility of the claims at issue. The majority explicitly named *Mayo* as the reason for this disparity: "[W]hether or not we as individual judges might agree or not that these claims only recite a natural law, . . . the Supreme Court has effectively told us in *Mayo* that correlations between the presence of a biological material and a disease are laws of nature purely conventional or obvious pre-solution activity is normally not sufficient to transform an unpatentable law of nature into a patent-eligible application of such a law." *Id.* (alterations and quotations omitted).

As Judge Newman noted in her dissent, the problem centers on the inconsistency that has resulted from the application of *Mayo/Alice*. "This court's decisions on the patent-ineligibility of diagnostic methods are not consistent." *Id.* at 757. For example, Judge Newman argued, the panel decision below "is not consistent with . . . *Rapid Litigation Management [Ltd. v. CellzDirect, Inc.]*, 827 F.3d [1042, 1048 (Fed. Cir. 2016)], where the court held that although the general type of cell was known, and the manipulation of these specific cells was conducted in a conventional manner, the overall method was eligible under Section 101." *Id.* at 762. With inconsistency

comes unpredictability, Judge Newman explained, and "a disincentive to the development of new diagnostic methods." *Id.* at 763. As she concluded, "[t]he judicial obligation is to provide stable, consistent application of statute and precedent, to implement the legislative purpose." *Id. Mayo/Alice* is currently hampering that prerogative.

Other Federal Circuit decisions have highlighted the inconsistency and unpredictability of § 101 decisions since this Court announced the *Mayo/Alice* framework half a decade ago. For instance, in *Interval Licensing LLC v. AOL, Inc.*, 896 F.3d 1335 (Fed. Cir. 2018), the claims were directed to a method of displaying images on a computer screen in a way that does not interfere with the user's primary activity. Under *Mayo/Alice* step one, the court found that "the recited claims are directed to an abstract idea because they consist of generic and conventional information acquisition and organization steps that are connected to, but do not convert, the abstract idea—displaying a second set of data without interfering with a first set of data—into a particular conception of how to carry out that concept." *Id.* at 1346. After finding under step two that "nothing in the claim converts the abstract idea to an inventive concept," the court held the claims ineligible under § 101. *Id.* at 1346-48. Judge Plager filed a separate opinion, beginning with reference to the *Mayo/Alice* test: "Today we are called upon to decide the fate of some inventor's efforts, whether for good or ill, *on the basis of criteria that provide no insight into whether the invention is good or ill.*" *Id.* at 1348 (emphasis added). Although Judge Plager concurred in the "carefully reasoned opinion by [his] colleagues in the majority," he noted that "the state of the law is such as to give

little confidence that the outcome is necessarily correct" because it "renders it near impossible to know with any certainty whether the invention is or is not patent eligible." *Id.* Judge Plager therefore dissented from the Federal Circuit's "continued application" of what he referred to as "this incoherent body of doctrine." *Id.*

II. The Claims in a Recent Federal Circuit Decision as Compared to Those in *Mayo* Highlights the Inconsistency of Results Under *Mayo*/*Alice*

The fine line between patent eligible and ineligible claims under *Mayo*/*Alice* is illustrated by comparing this Court's decision in *Mayo* and the Federal Circuit's decision in *Vanda Pharm. Inc. v. West-Ward Pharm. Int'l Ltd.*, 887 F.3d 1117 (Fed. Cir. 2018). The claims in *Vanda* and *Mayo* were both directed toward methods of treatment involving examining a patient's ability to metabolize a drug and using that information to adjust the patient's treatment plan accordingly.

In *Mayo*, this Court considered the eligibility of claims for methods of treatment, which included determining the level of a drug in the patient and adjusting the dosage administered accordingly. The Court held that the claims were directed toward a patent ineligible concept, and that the claims did not pass what is now referred to as step two of the *Mayo*/*Alice* test because "[t]he process that each claim recites tells doctors interested in the subject about the correlations that the researchers discovered." *Id.* at 78. In particular, the Court found, "[t]he 'administering' step simply refers to the relevant audience, namely doctors who treat patients with certain diseases with thiopurine drugs." *Id.* The other steps "simply tell a doctor about

relevant natural laws" and "to determine the level of the relevant metabolites in the blood, through whatever process the doctor or the laboratory wishes to use." *Id.* at 78-79. Summarizing, the Court found that "the three steps simply tell doctors to gather data from which they may draw an inference in light of the correlations." *Id.* at 79. Accordingly, the Court held that the claims "add nothing significant beyond the sum of their parts taken separately" and "are not sufficient to transform unpatentable natural correlations into patentable applications of those regularities." *Id.* at 80.

In *Vanda*, the Federal Circuit considered the patent eligibility of a treatment method under § 101. Similar to *Mayo*, the treatment method included a step in which the dosage given to the patient was adjusted based on the patient's ability to metabolize a certain compound. As the *Vanda* court explained, "[c]laim 1 requires specific steps: (1) determining the patient's CYP2D6 metabolizer genotype by (a) obtaining a biological sample and (b) performing a genotyping assay; and (2) administering specific dose ranges of iloperidone depending on the patient's CYP2D6 genotype." Thus, both sets of claims required correlating the ability of a patient to metabolize a drug with the proper dosage of treatment for that patient. Despite this similarity, the Federal Circuit found the claims in *Vanda* to be patentable, even though this Court had previously held in *Mayo* that the similar claims at issue there were not.

The similarity between the claims— and the inconsistency between the two decisions—is particularly evident when comparing the *Mayo* "wherein" clauses to the *Vanda* "if" and "wherein" clauses. Both tell a physician

performing the method how to adjust the patient's treatment based on the information obtained. In *Mayo*, the Court found these clauses to be a mark against the claims in terms of patent eligibility, reasoning that they "simply tell a doctor about the relevant natural laws, at most adding a suggestion that he should take those laws into account when treating his patient" by adjusting the dose. 566 U.S. at 78. In *Vanda*, the dose adjustment steps are the very reason the Federal Circuit distinguished *Mayo*: they "recite the steps of carrying out a dosage regimen based on the results of genetic testing." 887 F.3d at 1135.

III. The United States Patent and Trademark Office's Own Guidance Illustrates the Uncertainty and Unpredictability

Indicative of the unpredictability in assessing patent eligible subject matter in the diagnostic testing field are the examples provided by the United States Patent and Trademark Office (USPTO).

Since 2014, the USPTO has periodically issued guidance to examiners on the application of *Mayo/Alice*.[5] This guidance includes certain examples that "illustrat[e] exemplary subject matter eligibility analyses of claims." *Id.* In the set of examples issued between December 16, 2014 through December 15, 2016 (attached as Exhibit A), one example in particular highlights the unpredictability and arbitrary implementation of the framework. In

5. *See* United States Patent and Trademark Office, *Subject Matter Eligibility* (last visited Oct. 21, 2019), https://www.uspto.gov/patent/laws-and-regulations/examination-policy/subject-matter-eligibility.

example 29, the USPTO describes a fictional autoimmune disease called "julitis." Ex. A at 9-16. Of the seven example claims, two are instructive here. Claim 1 of the example recites:

> A method of detecting JUL-1 in a patient, said method comprising:
>
> a. obtaining a plasma sample from a human patient; and
>
> b. detecting whether JUL-1 is present in the plasma sample by contacting the plasma sample with an anti-JUL-1 antibody and detecting binding between JUL-1 and the antibody.

Id. at 10. Claim 2 of the example is identical to claim 1 but for one additional step:

> A method of diagnosing julitis in a patient, said method comprising:
>
> a. obtaining a plasma sample from a human patient;
>
> b. detecting whether JUL-1 is present in the plasma sample by contacting the plasma sample with an anti-JUL-1 antibody and detecting binding between JUL-1 and the antibody; and
>
> c. diagnosing the patient with julitis when the presence of JUL-1 in the plasma sample is detected.

Id. (emphasis added).

Claims 1 and 2 seem strikingly similar, the only difference being the additional "diagnosing" step of claim. Moreover, the transitional term "comprising," used in both example claims, is an inclusive phrase that does not exclude additional, unrecited elements or method steps. *See, e.g.*, *Mars Inc. v. H.J. Heinz Co.*, 377 F.3d 1369, 1376 (Fed. Cir. 2004) ("[L]ike the term 'comprising,' the terms 'containing' and 'mixture' are open-ended."); *Invitrogen Corp. v. Biocrest Mfg, L.P.*, 327 F.3d 1364, 1368 (Fed. Cir. 2003) ("The transition 'comprising' in a method claim indicates that the claim is open-ended and allows for additional steps."); *Genentech, Inc. v. Chiron Corp.*, 112 F.3d 495, 501 (Fed. Cir. 1997) ("'Comprising' is a term of art used in claim language which means that the named elements are essential, but other elements may be added and still form a construct within the scope of the claim."). Accordingly, claim 1 encompasses within its scope not only methods that include the delineated steps, but other unclaimed steps such as, for example, the diagnosing step of claim 2. In other words, claim 2 is narrower than but wholly encompassed within claim 1.

Notwithstanding the similarities between claims 1 and 2, the USPTO's guidance indicates that the broader claim 1 would be patent eligible, but the narrower claim 2 would not. *Id.* at 11-12. Specifically, under the *Mayo/Alice* test, the Patent Office concluded that claim 1 was *not* directed to a law of nature and thus was patentable based on step 1. *Id.* at 11. However, the USPTO concluded that the additional diagnosing step of claim 2 was directed to a law of nature, and therefore proceeded to step 2 of the analysis. *Id.* at 12. Under step 2, the USPTO determined that the additional elements of claims 2—that is, the very same elements that were found to be patent eligible

in claim 1—did not sufficiently transform the claim and therefore it was not patentable subject matter. *Id.*

The USPTO's differing recommendations with respect to these two claims is perplexing. Claim 2 adds a claim limitation, making it narrower than claim 1, yet the USPTO concluded that claim 2 would not be subject matter eligible under *Mayo/Alice*, seemingly just for its inclusion of the word "diagnosing," even though its scope falls within the broader, patent eligible claim 1. 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. *See, e.g.*, *Thales Visionix Inc. v. United States,* 850 F.3d 1343, 1349 n.1 (Fed. Cir. 2017) (stating that "[b]ecause we hold the independent claims patent eligible, we do not reach [the] issue [of eligibility of the dependent claims]"); *TQP Dev., LLC v. Intuit Inc.*, No. 2:12-CV-180-WCB, 2014 WL 651935, at *7 (E.D. Tex. Feb. 19, 2014) ("Because the Court finds that claim 1 is patent eligible under section 101, it follows that the rest of the disputed claims, which are dependent on claim 1, are patent eligible under section 101 as well."). Even more puzzling, claim 1 is patent eligible under the USPTO's guidance, yet the elements of claim 1 were found not to transform claim 2 into patent eligible subject matter.

Needless to say, this example highlights the challenges with the current *Mayo/Alice* framework. Even experts in the USPTO are having difficulty with the current test.

IV. Consistency in Patent Eligibility Standards for Diagnostic Claims Is an Important Issue to the Growing Biotechnology Industry in This Country

A 2019 Global Market Insights Report[6] reported that the biotechnology industry is expected to achieve a nearly 10% compound annual growth rate from 2018 to 2024, reaching a market size of over $775 billion. And based on statistics published by the USPTO, the biotechnology sector experienced a more than 25% increase in patent grants in just a five-year period between 2010 and 2015. As Judge Newman noted in her dissenting opinion, this growing life sciences industry is "plead[ing] for consistency in judge-made law." *Athena*, 915 F.3d at 762.

Many legal scholars and commentators have acknowledged the potentially detrimental impact patentability uncertainty can have on investment in technology and innovation.[7] For instance, a 2019 survey[8]

6. *See* Sumant Ugalmugale *et al., Biotechnology Market Size* (Jan. 2019), https://www.gminsights.com/industry-analysis/biotechnology-market

7. *See, e.g., The State of Patent Eligibility in America: Part 1 Before the S. Comm. On Intellectual Property,* 116th Cong. (2019) (statement of David Kappos, Former United States Patent and Trademark Office Director); Steve Brachman, *Patent-Ineligibility of Medical Diagnostics, Life Sciences Discoveries Arrests U.S. Progress* (Jan. 7 2018), https://www.ipwatchdog.com/2018/01/07/patent-ineligibility-medical-diagnostics-life-sciences-discoveries/id=90805/.

8. *See* David O. Taylor, *Patent Eligibility and Investment*, Cardozo L. Rev. (forthcoming), *available at* https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3340937; *see also* David O. Taylor, *Guest Post on Patent Eligibility and Investment: A Survey* (Mar.

by Professor David O. Taylor, SMU Dedman School of Law, found that 74% of the investors agreed that patent eligibility is an important consideration in firms' decisions whether to invest in companies developing technology. Professor Taylor further found that 62% of the investors agreed that their firms were less likely to invest in a company developing technology if patent eligibility standards would render patents unavailable. Overall, he concluded that the life sciences industry would be the most negatively affected as more investors in that space indicated that the elimination of patents would either somewhat decrease or strongly decrease their firms' interest in investing in life science companies.

Likewise, former USPTO Director David Kappos said before the U.S. Senate Sub-Committee on Intellectual Property:

> Our current patent eligibility law truly is a mess. The Supreme Court, Federal Circuit, district courts, and USPTO are all spinning their wheels on decisions that are irreconcilable, incoherent, and against our national interest … our current constricted approach to Section 101 is undermining investment.[9]

The message is clear: patent eligibility standards matter, and consistency is desperately needed.

6, 2019), https://patentlyo.com/patent/2019/03/patent-eligibility-investment.html.

9. *The State of Patent Eligibility in America: Part 1 Before the S. Comm. On Intellectual Property,* 116th Cong. (2019) (statement of David Kappos, Former United States Patent and Trademark Office Director).

CONCLUSION

The petition for a writ of *certiorari* should be granted.

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