No. 19-430

IN THE
Supreme Court of the United States Court

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

BRIEF OF AMICUS CURIAE NEW YORK INTELLECTUAL PROPERTY LAW ASSOCIATION IN SUPPORT OF PETITIONER

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INTEREST OF *AMICUS CURIAE*[1]

The New York Intellectual Property Law Association ("NYIPLA") is a bar association of approximately 1,000 attorneys who practice in the area of patent, copyright, trademark and other intellectual property ("IP") law.[2] It is one of the largest regional IP bar associations in the United States. Its members include in-house counsel for businesses and other organizations, and attorneys in private practice who represent both IP owners and their adversaries (many of whom are also IP owners). Its members represent inventors, entrepreneurs, businesses, universities, and industry and trade associations. Many of its members are involved in research, patenting, financing and other commercial activity across industries.

The NYIPLA's members and their clients regularly participate in patent litigation on behalf of both plaintiffs and defendants in federal court and in proceedings before the United States Patent and Trademark Office ("PTO"). They also actively engage in licensing matters representing both patent

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[1] Pursuant to Sup. Ct. R. 37.6, the NYIPLA and its counsel represent that they have authored the entirety of this brief, and that no person other than the *amicus curiae* or its counsel has made a monetary contribution to the preparation or submission of this brief.

[2] Pursuant to Sup. Ct. R. 37.2(a), both Petitioners and Respondents have consented to the filing of any amicus curiae brief in support of either or neither side's position on this petition for certiorari. Petitioners' consent letter was filed in a docket entry dated October 3, 2019. Respondents consented on October 15, 2019.

licensors and licensees. The NYIPLA thus brings an informed perspective to the issues presented.

The NYIPLA's members and their respective clients have a strong interest in the issues in this case because their day-to-day activities depend on the consistently-applied and longstanding broad scope of patent-eligible subject matter under the Patent Act. Moreover, because of the vital and increasing importance of biotech and medical innovation to public health and the economy, the NYIPLA and its members have a particularly strong interest in ensuring that those principles continue to be consistently and flexibly applied in those important areas.[3]

SUMMARY OF THE ARGUMENT

This petition for a writ of certiorari presents issues fundamental to patent eligibility that are of exceptional importance to patent owners, to patent challengers, and to innovation across all industries. These issues are particularly important in the life

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[3] The arguments made in this brief were approved by an absolute majority of the NYIPLA's officers and members of its Board of Directors, but do not necessarily reflect the views of a majority of the members of the Association, or of the law or corporate firms with which those members are associated. After reasonable investigation, the NYIPLA believes that no officer or director or member of the Amicus Briefs Committee who voted in favor of filing this brief, nor any attorney associated with any such officer, director or committee member in any law or corporate firm, represents a party to this litigation. Some officers, directors, committee members or associated attorneys may represent entities, including other amici curiae, which have an interest in other matters that may be affected by the outcome of this litigation.

sciences and medical fields where inventions relate to advancements in public health, including the diagnosis and treatment of life-threatening, chronic, and debilitating illnesses.

This case involves taking such a medical innovation out of the realm of patent eligibility even though all twelve active judges of the Federal Circuit agreed that diagnostic tests, such as the one at issue here, *should* be patent eligible under Section 101. App. 96a (Moore, J., dissenting from denial of the petition for rehearing en banc) ("This is not a case in which the judges of this court disagree over whether diagnostic claims, like those at issue in *Athena*, should be eligible for patent protection. They should.").

The inventors of Athena's patent discovered that 20% of patients who have myasthesnia gravis ("MG"), a rare neurological disorder where patients experience muscle weakness and symptoms including drooping eyelids, double vision, and slurred speech, did not produce acetylcholine receptor autoantibodies, but, instead, produced autoantibodies to a membrane protein called MuSK. "Prior to the[] discovery [by the inventors], no disease had been associated with MuSK." App. 3a (citation omitted). Based on this discovery, the inventors developed and patented methods of diagnosing neurological disorders such as MG by, *inter alia,* detecting autoantibodies that bind to MuSK.

In a divided decision, the panel majority held that the claimed diagnostic methods were patent ineligible under this Court's two-part test in *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566

U.S. 66 (2012). Ignoring the claims as a whole, the panel held that the claims were directed to a natural phenomenon—the correlation between MG and the MuSK autoantibodies—under step 1 of *Mayo*. The majority then found that the additional steps of the claims were routine and conventional apart from their application to diagnosing MG, and that the claims were therefore not patent eligible subject matter.

Significantly, the panel majority agreed that the claims "involve both the discovery of a natural law and certain concrete steps to observe its operation." App. 11a. Further, it found that the claims left "open to the public other ways of interrogating the correlation between MuSK autoantibodies and MuSK-related disorders" without practicing the claims. App. 13a. Nevertheless, the Federal Circuit held that the fact that the invention did not preempt other uses of the natural law was not determinative of patent eligibility. *Id.*

The Federal Circuit's decision in *Athena* turned this Court's precedent on its head by ignoring the analysis of preemption of other diagnostic methods in the field. In doing so, it created a cloud of uncertainty over the patent eligibility of inventions that have limited scope and do not preempt other diagnostic methods that might apply the same natural law using different concrete steps. The Federal Circuit incorrectly interpreted the *Mayo* test as a bright-line, exclusive test—regardless of whether there is preemption. This Court has made clear that the *Mayo* test is meant to assist courts in distinguishing patent claims that preempt natural laws, natural phenomena and abstract ideas from those that do not. This case presents the Court with the needed

opportunity and a proper vehicle to clarify that the *Mayo* test is not meant to be exclusively or rigidly applied, and preemption is an important and necessary consideration of patent eligibility.

The Federal Circuit also erred in interpreting *Mayo* to require divorcing the natural phenomenon from the other steps of the claim. This Court's precedents have long recognized that claims must be considered as a whole and that a claim should not be dissected into new and old elements in assessing patent eligibility. As recognized by the Federal Circuit, the consequences for medically important diagnostic patents would be devastating if *Mayo* required such dissection of claims into new and old elements.

The Federal Circuit denied review of Athena's petition for rehearing *en banc* 7:5, with the majority explaining that the Court's direction in *Mayo* left the Federal Circuit with no choice but to invalidate medical diagnostic claims similar to those in *Athena*, and asking for guidance from this Court. Multiple opinions from Federal Circuit judges reflect the pressing need for this Court's guidance in order to avoid the anomalous and likely unintended results that the majority of the Federal Circuit believes are required by *Mayo*. The panel majority emphasized that *Mayo* "[left] no room for a different outcome here," although the majority agreed with Judge Newman's dissenting opinion that "the public interest is poorly served by adding disincentive to the development of new diagnostic methods." App. 14a n.4. Further highlighting the need for the Court's intervention are "[t]he multiple concurring and dissenting opinions regarding the denial of *en banc*

rehearing in this case [which] are illustrative of how fraught the issue of § 101 eligibility, especially as applied to medical diagnostics patents, is." App. 62a (Hughes, J., concurring in the denial of the petition for rehearing en banc).

This Court's intervention is crucial to clarify the standard for patent eligibility "to promote the Progress of Science and the useful Arts." U.S. Const. art. I, § 8, cl. 8.

ARGUMENT

I. The Intra-Circuit Split in the Federal Circuit and Plea for Guidance

The denial of rehearing *en banc* in this case demonstrates that the Federal Circuit judges are split 7 to 5 on whether diagnostic patents, such as the one at issue in *Athena*, are patent eligible under *Mayo*. The majority of the judges (Judges Lourie, Chen, Dyk, Reyna, Taranto, Hughes, and Chief Judge Prost) supported denial of Athena's petition, concluding under protest that the court had no choice but to hold the claims patent ineligible because of this Court's broad language in *Mayo*, even though they agreed with the dissenting judges that this was a disservice to public health and innovation. In four opinions denying *en banc* review, these seven Federal Circuit judges explain the need for the Court's intervention.

Judges Moore, Newman, O'Malley, Wallach and Stoll dissented from the denial of *en banc* review, explaining that the Federal Circuit incorrectly has "turned *Mayo* into a per se rule that diagnostic kits and techniques are [patent] ineligible." App. 99a (Moore, J.). In four opinions, these judges of the

Federal Circuit stress the need for the Court's intervention given the majority's sweeping interpretation of *Mayo*, leaving diagnostic patents out in the cold and chilling innovation of new diagnostic methods needed by the afflicted public.

Judge Moore, joined by Judges O'Malley, Wallach, and Stoll, stated that the majority's refusal to reconsider their interpretation of *Mayo* leaves "no more options at this court for diagnostic patents." App. 118a. Judge Moore explained that "[w]hile we believe that such claims should be eligible for patent protection, the majority of this court has definitively concluded that the Supreme Court prevents us from so holding." App. 119a. Accordingly, she warned that the "only hope [for diagnostic patents] lies with the Supreme Court or Congress" and "hope[s] that they recognize the importance of these technologies, the benefits to society, and the market incentives for American business." *Id.*

Judge Lourie, joined by Judges Reyna and Chen, stated that the court could "accomplish little" in rehearing *Athena* as the Federal Circuit is "bound by the Supreme Court's decision in *Mayo*." App. 58a. Judge Hughes, joined by Chief Judge Prost and Judge Taranto, stated that while the "bottom line for diagnostics patents is problematic," this is "not a problem that the [Federal Circuit] can solve" as an inferior court "bound by the Supreme Court." App. 62a. Judge Hughes stated that "further explication of eligibility standards in the area of diagnostic patents" would be "welcome" as "[s]uch standards could permit patenting of essential life-saving inventions based on natural laws." App. 63a.

Similarly, Judge Dyk, joined by Judges Hughes and Chen, explained that "the development of new diagnostic methods is often based on researching complex biological systems. The inventive concepts in this area may lie primarily in the application of a natural law." App. 71a. Judge Dyk stressed that "patent eligibility should leave room for sufficiently specific diagnostic patents. But it is the Supreme Court, not this court, that must reconsider the breadth of *Mayo*." App. 68a.

The 7:5 intra-circuit split in the Federal Circuit on whether diagnostic patents are patent eligible under *Mayo*, the lack of any meaningful recourse with respect to diagnostic patents in view of the majority's interpretation of this Court's decision in *Mayo*, and the Federal Circuit's unanimous plea for guidance from the Court, require this Court's intervention.

II. The Role of Preemption in a Patent Eligibility Analysis Is an Issue of Exceptional Importance

A. Preemption Concerns are Fundamental to a Patent Eligibility Analysis

This Court should grant the petition for a writ of certiorari to clarify that *Mayo* does not trump a preemption analysis and that inventions posing no preemption concerns remain patent eligible under *Mayo*. This Court has long recognized that preemption concerns are central to a patent eligibility analysis. Section 101 sets out four broad statutory categories of inventions or discoveries that are eligible for protection. These statutory categories are subject to an "implicit exception: Laws of nature, natural phenomena, and abstract ideas are not patentable." *Alice Corp. v. CLS Bank Int'l*, 573 U.S. 208, 216 (2014)

(quoting *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576, 589 (2013)). As this Court has explained, the "concern that drives this exclusionary principle [is] one of pre-emption." *Alice*, 573 U.S. at 216. Laws of nature (like gravity), natural phenomena (like the DNA sitting in our chromosomes), and abstract ideas (like mathematical algorithms) are the "building blocks of human ingenuity." *Id.* (citation omitted). "'[M]onopolization of those tools through the grant of a patent might tend to impede innovation more than it would tend to promote it,' thereby thwarting the primary object of the patent laws." *Id.* (quoting *Mayo*, 566 U.S. at 71). This Court has "'repeatedly emphasized this . . . concern that patent law not inhibit further discovery by improperly tying up the future use of' these building blocks of human ingenuity." *Id.* (quoting *Mayo*, 566 U.S. at 85). As a result, this Court's Section 101 precedent "warn[s] . . . against upholding patents that claim processes that too broadly preempt the use of a natural law." *Mayo*, 566 U.S. at 72 (citation omitted).

At the same time, this Court has long recognized that "all inventions at some level embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas." *Mayo*, 566 U.S. at 71. It is therefore necessary to "distinguish between patents that claim the 'buildin[g] block[s]' of human ingenuity and those that integrate the building blocks into something more." *Alice*, 573 U.S. at 217 (quoting *Mayo*, 566 U.S. at 89). The former would "risk disproportionately tying up the use of the underlying natural laws, inhibiting their use in the making of further discoveries." *Mayo*, 566 U.S. at 73. "The latter pose no comparable risk of preemption, and therefore

remain eligible for the monopoly granted under [the] patent laws." *Alice*, 573 U.S. at 217.

B. The *Mayo* Test for Patent Eligibility Was Not Meant to Be Exclusive

In *Mayo*, this Court set forth a two-part test "for distinguishing patents that claim laws of nature, natural phenomena, and abstract ideas from those that claim patent-eligible applications of those concepts." *Id.* (citing *Mayo*, 566 U.S. at 77-78). The *Mayo* test asks (1) whether a patent's claims are directed to one of the patent-ineligible concepts, and if so, (2) whether the elements of those claims—both individually and as an "ordered combination"—"transform the nature of the claim[s]" into a patent-eligible application. *Mayo*, 566 U.S. at 77-79.

This Court previously rejected the notion of an exclusive test for patent eligibility, *see Bilski v. Kappos*, 561 U.S. 593 (2010). The Federal Circuit, however, has interpreted *Mayo* as the definitive test for patent eligibility to be rigidly applied to all future cases to the exclusion of any other inquiry. In this case, "the inventors did not patent their scientific discovery of MuSK autoantibodies" or the correlation between those antibodies and the neurological condition, MG. App. 24a. "Rather, they applied this discovery to create a new method of diagnosis, for a previously undiagnosable neurological condition." *Id.* In invalidating a patent that did not claim a patent-ineligible concept itself but the practical application of a discovery, the Federal Circuit held that "[p]reemption is sufficient to render a claim ineligible under § 101, but it is not necessary." App. 13a. In other words, according to the panel majority, preemption demonstrates that subject matter is not

patent eligible but the absence of preemption, as here, is of no consequence to patent eligibility. This is error.

Preemption is the hallmark of patent ineligibility under Section 101. *Mayo* and *Alice* discuss preemption at length, since it is the basis for the judicial exceptions to patentability and the driving force behind these exceptions. *Alice*, 573 U.S. at 216. This Court also made clear that upholding the patent in *Mayo* "would risk disproportionately tying up the use of the underlying natural laws, inhibiting their use in the making of further discoveries." 566 U.S. at 73. Similarly, in *Alice*, this Court stressed that its patent eligibility conclusion was in "accord[] with the pre-emption concern that undergirds [this Court's] § 101 jurisprudence." 573 U.S. at 223. The Federal Circuit's conclusion that subject matter is patent ineligible under Section 101—even when there is no risk of preemption—is at odds with this Court's precedent.

The Federal Circuit's wooden application of *Mayo* (much like the machine-or-transformation test, Freeman-Walter-Abele and technological arts tests that had been applied in the past) ignores the goal of the inquiry—to determine whether the claim preempts the building-block, patent-ineligible concept in question. This Court rejected this type of rigid analysis of its machine-or-transformation test in *Bilski*, and such an approach also is incorrect here. 561 U.S. at 604. Just as in *Bilski*, here the Federal Circuit has elevated the test in *Mayo* from a "useful and important clue" and "investigative tool" to the "exclusive test" or "sole test for deciding whether an invention is" patent eligible. *Id.* In doing so, the Federal Circuit untethered the *Mayo* test from the

analysis of preemption, despite the fact that the purpose of the overall test is to assist courts in distinguishing patents that claim laws of nature, natural phenomena and abstract ideas from those that do not improperly monopolize practical applications of such concepts. *Alice*, 573 U.S. at 217.

Indeed, here, the Federal Circuit denied patent eligibility in the absence of any concern that a law of nature or natural phenomenon was being improperly monopolized. The panel majority acknowledged that the claims at issue "involve both the discovery of a natural law and certain concrete steps to observe its operation" (App. 11a), agreeing that claim 9 "leaves open to the public other ways of interrogating the correlation between MuSK autoantibodies and MuSK-related disorders without practicing the claim's concrete steps." App. 13a; *see also* App. 116a (Moore, J.) ("The claims do not 'broadly preempt the use of a natural law,' and do not prevent any scientist from using the natural law in association with other common processes."); App. 137a (Stoll, J.) ("Certain diagnostic claims, such as the ones at issue in this case, are so narrowly tailored that preemption is not a reasonable concern."). But the panel majority held that the absence of preemption was not enough to "disturb" its conclusion under step one of the *Mayo* framework that the "claims here are directed to a natural law." App. 13a.

The absence of preemption concerns in this case, unlike in *Mayo* and *Alice*, should have led to the conclusion that the claimed diagnostic method was patent eligible. The panel majority, however, took the position that preemption only works one way to signal patent ineligible subject matter, but that the lack of

preemption does not demonstrate patent eligibility. *Id.* The panel majority's position is contrary to this Court's precedent and is wrong as a matter of law. This Court's intervention at this juncture to clarify that absence of preemption is a reliable and conclusive indicator of patent eligibility is critically important.

The Federal Circuit's errors also stem from the misapprehension of *Mayo* as the exclusive test for patent eligibility. This Court has repeatedly cautioned against rigid application of generalized tests as exclusive ones. Justice Breyer, who authored *Mayo*, acknowledged that the facts of *Mayo* made it "an obvious case" and therefore could only "sketch an outer shell" of a test that would be developed in future cases since it was hard to "figure out how much . . . to go beyond . . . an obvious case." Tr. of Oral Arg. at 10-11, 28, *Alice*, 573 U.S. 208 (No. 13-298) (Breyer, J.). Indeed, this Court described the patent claims in *Mayo* as nothing more than "a drafting effort designed to monopolize the law of nature itself." *Mayo*, 566 U.S. at 77. This Court's guidance is needed to clarify that the *Mayo* test is a general tool, but it cannot be the exclusive test for patent eligibility and should not be rigidly applied in all circumstances.

III. Whether Claims Must Be Considered as a Whole in a Patent Eligibility Analysis Is Also an Issue of Exceptional Importance

This Court should also grant the petition for a writ of certiorari to clarify that claims must be considered as a whole in a patent eligibility analysis. This Court has warned that "too broad an interpretation of th[e] exclusionary principle could eviscerate patent law." *Id.* at 71. The panel majority in *Athena* dissected the claims into their individual

elements without considering the claimed invention as a whole, which resulted in denying patent eligibility to a novel diagnostic method.

This Court has long held that "claims must be considered as a whole" in a patent eligibility analysis. *Diamond v. Diehr*, 450 U.S. 175, 188 (1981). Indeed, it is "inappropriate to dissect the claims into old and new elements." *Id.* This Court emphasized that "[t]his is particularly true in a process claim because a new combination of steps in a process may be patentable even though all the constituents of the combination were well known and in common use before the combination was made." *Id.* *Mayo* neither addressed nor changed this well-settled rule. In *Mayo*, this Court reiterated that the steps of a claimed method must be considered as an "ordered combination." 566 U.S. at 79 (citing *Diehr*, 450 U.S. at 188); *see also Alice*, 573 U.S. at 218 n.3 ("Because the approach we made explicit in *Mayo* considers ***all claim elements***, both individually and in combination, it is consistent with the general rule that patent claims 'must be considered ***as a whole***.'" (quoting *Diehr*, 450 U.S. at 188)) (emphasis added).

Although *Mayo* did not change the "general rule that patent claims 'must be considered as a whole'" (*Alice*, 573 U.S. at 218 n.3), the majority of the Federal Circuit does not interpret or apply *Mayo* in this way (and the PTO and district courts have necessarily followed suit). This resulted in turning this Court's general and well-established rule on its head, and casting a cloud over an entire field of inventions that would otherwise unquestionably have been considered patent eligible under this Court's precedent.

This Court's guidance is essential to clarify that claims must be considered as a whole in a patent eligibility analysis and that *Mayo* does not require dissecting the claim into separate elements. As this Court previously explained, divorcing the natural principle from the other claim elements would, "if carried to its extreme, make all inventions unpatentable because all inventions can be reduced to underlying principles of nature which, once known, make their implementation obvious." *Diehr*, 450 U.S. at 189 n.12.

There is no reason why a new way of diagnosing a medical condition should not be patent eligible under this Court's precedent. Indeed, *Mayo* reiterates the well-established maxim that a "new way of using an existing drug" is patent eligible, 566 U.S. at 87. Similarly, this Court stated that a party that discovers a natural phenomenon is "in an excellent position to claim applications of that knowledge." *Myriad*, 569 U.S. at 596 (citation omitted).

Indeed, Judge Newman in dissenting from the panel majority emphasized that "[i]t is incorrect to separate the claim steps into whether a step is performed by conventional techniques, and then to remove those steps from the claims . . . for the purpose of Section 101 analysis." App. 32a. Judge Newman explained that "[c]laims 7-9 recite a combination of technologic steps, all of which are limitations to the claims and cannot be disregarded whether for patentability or patent-eligibility or infringement." *Id.*, App. 34a; *see also* App. 125a ("There is no support in the Court's precedent for our abandonment of the invention-as-a-whole in determining eligibility under section 101."). Judge Moore, joined by Judges

Wallach, Stoll, and O'Malley, also stressed that "[o]ur decision to entirely disregard the discovery incorporated in the claims is a misapplication of the statute." App. 117a.

Judge Chen, on the other hand, just as the panel majority, interpreted *Mayo* to require separating the discovery of the natural law from the other elements of the claims. But he explained that the Federal Circuit's interpretation is "in tension on its face with *Diehr*, which was equally clear in requiring that a patent claim be considered as a whole, without putting aside any natural law or otherwise dissecting a claim into new versus old elements." App. 88a. Judge Chen recognized that under *Diehr*, "which does not divide the claim into new versus old elements, Athena's claims, particularly claims 7 and 9, likely would have been found to be directed to a patent-eligible process comprising a set of technical, transformative steps to test a patient for a particular medical condition." App. 78a-79a. He also explained that "nothing in *Mayo* suggests that it sought to repudiate anything in *Diehr*; it instead suggests that it sought to maintain continuity with the Court's prior cases in this area." *Id.*, App. 88a.

Further, multiple Federal Circuit judges recognized that the *Mayo* test, as read by the majority of the Federal Circuit, is also in tension with this Court's decision in *Myriad*. For example, Judge Dyk stated that "*Myriad* [] recognized that an inventive concept can sometimes come from the discovery of an unknown natural phenomenon and its application for a diagnostic purpose," which is "in tension with *Mayo*." App. 70a. Similarly, Judge Chen explained

that "[*Myriad*] could be read as potentially maintaining an open door for diagnostic claims such as Athena's, because they may be regarded as applications of knowledge of discovered natural laws." App. 89a. Both, however, concluded that they saw no recourse without this Court's intervention due to "the direction of the Supreme Court" in *Mayo*. App. 95a; App. 68a (Dyk, J.) ("it is the Supreme Court, not this Court that must reconsider the breadth of *Mayo*.").

IV. This Case is an Ideal Vehicle for the Court to Resolve These Critical Issues

The issues presented in this petition for a writ for certiorari are critically important to patent owners, to patent challengers, and to innovation across all industries since "[a]t some level, all inventions . . . embody, use, reflect, rest upon or apply laws of nature, natural phenomena, or abstract ideas." *Alice*, 573 U.S. at 217 (quoting *Mayo*, 566 U.S. at 71)(internal quotation marks omitted). The proper role of preemption in a patent eligibility analysis and whether claims must be considered as a whole in that analysis are matters that impact innumerable patents and directly impact innovation, particularly in the areas of diagnosis and treatment of debilitating and critical illnesses.

These issues are squarely presented in this case and have been fully developed through extensive briefing of the parties and numerous *amici*, as well as multiple judicial opinions at the panel and rehearing stage requesting this Court's guidance. The divided panel opinion and 7-5 split on *en banc* review, demonstrate the intra-circuit split on how to interpret and apply the *Mayo* framework, and the need for review by the Court to clarify these critical issues.

A. The Record in this Case Calls for the Court's Clarification

The record in this case allows the issues to be presented precisely. It is undisputed that there is no preemption on the facts of this case and that the Athena patent does not monopolize all uses of a natural phenomenon. The precise question before the Court is then whether an otherwise meritorious invention can be denied patent eligibility in the absence of preemption. The panel agreed that the claim at issue here did not preempt any natural law and "leaves open to the public other ways of interrogating the correlation between MuSK autoantibodies and MuSK-related disorders without practicing the claim's concrete steps." App. 13a. The fact that the claim is to a concrete application of a new discovery also makes this case uniquely suited for the Court to clarify that *Mayo* requires consideration of the claims as a whole and that claims cannot be dissected into old and new elements in assessing patent eligibility. As the panel noted, "[p]rior to the[] discovery [by the named inventors], no disease had been associated with MuSK." App. 3a. Indeed, Judge Dyk, joined by Judges Hughes and Chen, pointed out that since "the claims here recite specific applications of the newly discovered law of nature with proven utility, this case could provide the Supreme Court with the opportunity to refine the *Mayo* framework as to diagnostic patents." App. 77a.

B. The Federal Circuit's Application of *Mayo* Has Caused a Crisis of Patent Law and Medical Innovation

The issues are manifestly important and well elaborated as reflected by the participation of

numerous *amici* at the rehearing stage. Both the panel majority and the dissent agreed that "the public interest is poorly served by adding disincentive to the development of new diagnostic methods." App. 14a n.4; App. 34a. The majority further stated that "providing patent protection to novel and non-obvious diagnostic methods would promote the progress of science and useful arts." App. 14a n.4. A rigid application of *Mayo*, *i.e.*, one that denies patent eligibility in the absence of preemption concerns and fails to consider the claims as a whole, impedes precisely such valuable and significant applications of new discoveries.

The Federal Circuit judges, including those that concluded that they were bound to apply *Mayo* as the panel did, all expressed concern about the detrimental consequences of the decision to public health and scientific innovation. For example, Judge Chen stated that "[n]ew methods for diagnosing medical conditions" are "the kind of subject matter the patent system is designed for [in order] to encourage the risky, expensive, unpredictable, technical research and development that people would not otherwise pursue," and "should be patentable subject matter in a well-functioning patent system." App. 94a-95a. Judge Moore, joined by Judges O'Malley, Wallach and Stoll, noted that diagnostic techniques guide nearly 66% of clinical decisions, cost up to $100 million to develop over a period of approximately 10 years, and "are precisely the type of innovation the patent system exists to promote." App. 102a. Judge Moore further explained that: "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." App. 109a. Similarly, Judge Stoll stated that "a wholesale bar on patent eligibility for diagnostic claims [as a result of the majority's interpretation of *Mayo*] has far-reaching and long-ranging implications for the development of life-saving diagnostic methods." App. 136a. Judge Stoll emphasized that the "eligibility of life-saving inventions is not only one of the most important issues of patent law, but of human health." *Id.* And, as Judge Newman put it, "[t]he loser is the afflicted public, for diagnostic methods that are not developed benefit no one." App. 36a-37a.

Further, Congressional efforts to address these critical issues have failed. It is for this Court to intervene and clarify its precedent, foreclosing the Federal Circuit's rigid and erroneous application of *Mayo*.

C. Uncertainty Before the PTO Is Further Reason Why this Court's Intervention Is Needed

The NYIPLA's members also have observed first-hand in advising and representing their clients in patent matters before the PTO the increased difficulty in predicting whether inventions will be found patentable despite the absence of preemption concerns and when the claims were not directed to a law of nature. Following the Federal Circuit's lead, the PTO's guidance restates the two-part test of *Mayo* as an exclusive test. As Judge Chen notes, the *Mayo* framework is "considerably harder to apply than the *Diehr* framework" and "a very difficult thing to explain to 8,000 patent examiners." App. 87a-88a. Judge Chen explains that "the process of determining

what the claim is 'really about' when the claim is viewed in pieces, rather than as a whole, can be highly subjective and impressionistic." App. 88a. This is yet further reason that it is critically important for this Court to clarify that *Mayo* did not repudiate *Diehr* and that the *Mayo* test is only a helpful starting point, "a sketch [of] an outer shell," rather than an exclusive and fully developed framework for patent eligibility. Tr. of Oral Arg. at 28, *Alice*, 573 U.S. 208 (No. 13-298) (Breyer, J.).

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Thus, this case provides the Court an ideal vehicle for clarifying that *Mayo* is not an exclusive or rigid test, that claims must be considered as a whole, and that claims that do not preempt laws of nature are patent eligible under Section 101. Doing so would remove the cloud hanging over patent-eligible subject matter in the area of medical diagnostics, as well as all other industries.

CONCLUSION

This Court should grant the petition for a writ of certiorari on the Question Presented.

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Respectfully submitted,

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