No. 19-430

IN THE

Supreme Court of the United States

ATHENA DIAGNOSTICS, INC., *et al.*,

Petitioners,

v.

MAYO COLLABORATIVE SERVICES, LLC, *et al.*,

Respondents.

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

BRIEF OF THE CHICAGO PATENT ATTORNEYS AS *AMICI CURIAE* IN SUPPORT OF PETITIONERS

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INTEREST OF *AMICI CURIAE*

The *amici curiae* are patent practitioners who regularly prosecute and litigate U.S. patents. The *amici curiae* are concerned with preserving the integrity of a patent system that fosters innovation, and the companies that commercialize such innovation in the marketplace.[1,2]

SUMMARY OF THE ARGUMENT

The pending petition for writ of certiorari identifies issues that fundamentally affect the patent eligibility of all medical diagnostic tests under 35 U.S.C. § 101 and impact the proper application of this Court's jurisprudence. These issues are of particular importance to advancements in the medical and healthcare fields that contribute to early diagnosis, treatment, and prevention of disease.

This *amici curiae* brief underscores the Federal Circuit's struggle to properly interpret and consistently apply this Court's holdings in *Mayo/Alice*. This brief also illustrates how, despite unanimous agreement among Federal Circuit judges that the present claims at issue *should* be patentable, the lower court feels compelled by its misinterpretation of this Court's jurisprudence to consider an entire class of diagnostic method claims as being ineligible.

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1. No party's counsel authored this brief in whole or part; no party or party's counsel contributed money intended to fund preparing or submitting the brief; and no person other than *amici* or counsel for *amici* contributed money intended to fund preparing or submitting the brief. Sup. Ct. R. 37.6.

2. Counsel for the respective parties were provided timely notice and consented to the filing of this brief. Sup. Ct. R. 37.2(a).

In their decision denying Athena's petition for rehearing *en banc*, the judges of the Federal Circuit demonstrated their deep division regarding proper application of this Court's test for determining patent eligibility under 35 U.S.C. § 101. Several judges expressly called for guidance from this Court (many reiterating prior pleas) on the correct eligibility standard. In addition, the differing opinions among the judges resulted in only seven of the Federal Circuit judges agreeing with the *per curiam* decision to deny rehearing *en banc*, with the remaining judges dissenting, producing no fewer than *eight* separate opinions to enunciate their divergent views. There is consensus among the Federal Circuit judges that sufficiently specific diagnostic method claims with proven utility ***should*** be patentable. However, they differ on whether this Court's directive in *Mayo Collaborative Services v. Prometheus Labs., Inc.*, 566 U.S. 66 (2012), prevents them from so finding. The majority opinions held that the Federal Circuit was foreclosed from finding patent eligibility for Athena's claims based on *Mayo* and for them to hold to the contrary would require refinement of the test by this Court. Pet App., 61a (Laurie, J., concurring in denial of rehearing *en banc*); 62-63a (Hughes, J., concurring); 68-69a (Dyk, J., concurring); 90a and 95a (Chen, J., concurring). The minority, however, believes that it is the Federal Circuit itself that has misinterpreted and misapplied the eligibility test. Pet App., 99-101a (Moore, J., dissenting in denial of rehearing *en banc*); 121a (Newman, J., dissenting); 136a (Stoll, J., dissenting); 138a (O'Malley, J., dissenting).

The eight opinions demonstrate the sharp divide in the Federal Circuit's understanding of how this Court's decision in *Mayo* should be interpreted. These opinions

also represent a desperate plea for guidance and clarity from this Court as to how the patent eligibility test should be applied, particularly as to diagnostic method claims.

Amici curiae submit that the minority is correct that the Federal Circuit has both misapprehended and misapplied the legal standard for patent eligibility of diagnostic method claims, including those of Athena's claimed invention. Under this misunderstanding, the Federal Circuit has (as has been its wont) rigidly applied this Court's *Alice* and *Mayo* decisions. As a result, the Federal Circuit has imposed a bright-line ineligibility rule that ignores the fundamental purpose behind the patent-eligibility framework established by this Court: if a claim does not threaten to entirely preempt the public's use of a judicial exception (herein, a "law of nature"), the claim does not constitute patent-ineligible subject matter. Further compounding its errors, the Federal Circuit has often misapplied the *Alice/Mayo* test, as here, by failing to consider the claims as a whole in determining whether a specific claimed technique is more than "routine, well-known, and conventional" and thus patent eligible.

Amici curiae believe that if permitted to stand, this misapplication of the proper understanding of this Court's jurisprudence on patent eligibility now entirely precludes, and will continue to preclude, protection of any claim directed to medical diagnostic inventions in the manner of a *per se* rule against patenting such inventions. Indeed, as set forth in Judge Newman's dissent from denial of rehearing *en banc*, the Federal Circuit has upheld invalidation of each and every diagnostic method claim that has come before it. *Id.* at 128a-129a; *see also infra* FN 4. Left unchecked, this practice will severely curtail

innovation in diagnosis of human disease and will slow development of medical diagnostic devices in America, shifting further advances and innovation (and their benefits that inure to the public) to patent- and innovation-friendlier jurisdictions. For at least these reasons, *amici curiae* urge this Court to grant the petition for a writ of certiorari.

ARGUMENT

I. The Federal Circuit Has Misapprehended the Fundamental Purpose of This Court's Patent Eligibility Framework: Preventing Preemption of the Public's Use of Natural Laws and Phenomena

To promote the progress of science and useful arts, inventors of "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof," may obtain a patent - a limited right to exclude others from practicing the claimed inventions. U.S. Const. art. I, § 8, cl. 8; 35 U.S.C. § 101.

While generally accepting the rule that "anything under the sun made by man" is eligible for patenting, this Court has carved out certain exceptions from the genus of "new and useful" patent-eligible inventions. *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980). Specifically, the Court considers laws of nature, natural phenomena, and abstract ideas (hereinafter collectively "the judicial exceptions") to be outside the scope of what is patent eligible. *Diamond v. Diehr*, 450 U.S. 175, 185 (1981); *see also Bilski v. Kappos*, 561 U.S. 593, 601 (2010); *Diamond v. Chakrabarty*, 447 U.S. at 309; *O'Reilly v. Morse*, 15 How. 62, 112–120 (1854); *Le Roy v. Tatham*, 14 How. 156, 175 (1853).

In *Alice Corp. Pty. Ltd. v. CLS Bank Int'l.*, 573 U.S. 208, 217-18 (2014), this Court set forth a two-part test designed to distinguish between patent-eligible subject matter and these patent-ineligible judicial exceptions. The first part of the test requires a determination of whether a claim is "directed to one of [the] patent-ineligible concepts," *i.e.*, the judicial exceptions. *Id.* If the answer to this initial determination is "yes", then the second part of the test asks whether the claim elements contain an "inventive concept" sufficient to "'transform the nature of the claim' into a patent-eligible application." *Id.* at 217 (quoting *Mayo*, 566 U.S. at 72-73, 79). To be patent-eligible, the "inventive concept" must be "sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the [ineligible concept] itself." *Id.* at 72-73 (citing *Parker v. Flook*, 437 U.S. 584, 594 (1978). In determining the "sufficiency" of the inventive concept, this Court directed the lower courts to look to specific claim elements that add more than what is merely "well-understood, routine, conventional activity, previously engaged in by those in the field." *Mayo*, 566 U.S. at 71.

As the Federal Circuit recognized in *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, the purpose of the two-part framework is to exclude from patentability those claims to otherwise useful inventions that do nothing more than claim a law of nature and thereby preempt the public's use thereof. 788 F.3d 1371, 1379 (Fed. Cir. 2015), cert. denied, 136 S. Ct. 2511 (2016). But this Court recognized that overly broad interpretations of this exclusionary principle 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." *Mayo*, 566 U.S. at 71. Accordingly, this Court's

two-part framework was crafted (and should be applied) narrowly to serve its legitimate purpose—preventing preemption of the judicial exceptions. This Court has warned that "a process is not unpatentable simply because it contains a law of nature or a mathematical algorithm ... and an application of a law of nature or mathematical formula to a known structure or process may well be deserving of patent protection." *Diehr*, 450 U. S. at 187 (quoting *Flook*, 437 U.S. at 590); *see also Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948) ("If there is to be invention from [a discovery of a law of nature], it must come from the application of the law of nature to a new and useful end."). Further, this Court has instructed that claims must be viewed as a whole, including any ordered combination, to properly determine patent eligibility. *Mayo*, 566 U.S. at 79-80 (citing *Diehr*, 450 U.S. at 187). This Court has not diminished or abandoned these long-standing precedents, and in accordance with them the two-part analytical framework should not be applied in a manner that prevents patenting of useful subject matter that would not entirely preempt the judicial exception.

Amici curiae respectfully submit that the Federal Circuit's decision affirming the invalidity of the asserted claims of U.S. Patent No. 7,267,820 ("the '820 patent") is in direct contradiction of this Court's jurisprudence under 35 U.S.C. § 101. Namely, the Federal Circuit's misapprehension of the guiding principle behind this Court's two-part analytical framework and the narrow application intended by this Court have led to considerable confusion by the Federal Circuit as to how to apply this framework, as it has recognized itself. *See infra* FN 4.

Accordingly, the Federal Circuit has ignored this Court's intent to deny patent eligibility only to claims that entirely preempt use of a judicial exception. Instead, the Federal Circuit has rigidly applied its own version of the patent-eligibility test as a bright-line rule, effectively condemning all diagnostic method claims to the pit of patent ineligibility.

A. Preventing preemption of judicial exceptions is the overarching purpose behind the *Alice/Mayo* analysis

This Court should seize this opportunity to clarify that the purpose behind its patent-eligibility test set forth in *Alice/Mayo* is to ensure that only those claims that entirely preempt a judicial exception deserve to be deemed patent-ineligible subject matter under 35 U.S.C. § 101. This Court has made clear that "the concern that drives this exclusionary principle [is] one of preemption." *Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 573 U.S. 208, 216 (2014); *see also Mayo*, 566 U.S. at 85 ("The Court has repeatedly emphasized ... a concern that patent law not inhibit further discovery by improperly tying up the future use of laws of nature").

If preemption is indeed the primary concern underlying the *Alice/Mayo* test and the basis for finding the judicial exceptions to be ineligible under 35 U.S.C. § 101, in instances where claims do not threaten to entirely preempt the public's use of a judicial exception, they should not be considered patent-ineligible subject matter. *Mayo*, 566 U.S. at 87. Indeed, in *Mayo*, this Court found those claims patent-ineligible because the claims did "not confine their reach to particular applications of [the natural] laws"

and preemption of such laws is "the basic underlying concern" regarding patent eligibility. *Id.* Conversely, in *Diehr*, this Court held the claims to be patent-eligible because the patentees did not "seek to pre-empt the use of the [Arrhenius] equation," but "only to foreclose from others the use of that equation in conjunction with all of the other steps in their claimed process." 450 U.S. at 187.

The Federal Circuit has fundamentally misunderstood the importance of preemption in its application of the *Alice/Mayo* patent-eligibility test. As a result, the Federal Circuit has developed a rigid application of the test, all but ignoring preemption and its effect on patent-eligibility. As applied by the Federal Circuit, the question of preemption merely serves to confirm the Federal Circuit's finding of patent-ineligibility[3], amounting to the "tail wagging the dog." In so doing, the Federal Circuit ignores the fundamental reason that the eligibility question arises in the first place. Now, even narrowly claimed inventions that do not entirely preempt use of the judicial exception can be, and have been as in this case, held to be ineligible. The Federal Circuit's analysis has relegated preemption to an afterthought, where even the lack of preemption carries no weight in the patent-eligibility determination. This misunderstanding has resulted in every single diagnostic method claim the Federal Circuit considered since this Court's *Mayo* decision being found patent-ineligible.[4]

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3. *See, e.g., Ariosa*, 788 F.3d at 1379 ("Where a patent's claims are deemed only to disclose patent ineligible subject matter under the Mayo framework, as they are in this case, preemption concerns are fully addressed and made moot.").

4. *See, e.g., Cleveland Clinic Found. v. True Health Diagnostics LLC*, 760 F. App'x 1013 (Fed. Cir. 2019) (diagnostic test that can be

In view of the Federal Circuit's inability to properly appreciate the fundamental basis for the ineligibility standards enunciated in *Alice* and *Mayo*, this Court's timely direction and guidance is clearly necessary.

B. The Federal Circuit's analysis fails to evaluate the claims as a whole in determining whether steps of a claimed method are routine, well-known, and conventional

When determining whether a claim is directed to patent-eligible subject matter under § 101, this Court requires consideration of the claim elements both individually ***and*** as a whole (*i.e.*, as an ordered combination of elements). *Alice Corp. Pty. v. CLS Bank Int'l*, 573 U.S. at 217 ("we consider the elements of each claim both individually and 'as an ordered combination'"); *Mayo*, 566 U.S. at 79-80. The holding that "claims must be considered as a whole" with regard to patent eligibility dates back at least to *Diehr*, 450 U.S. at 188, which mandates that

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used to determine whether an individual is at a lower risk or higher risk of developing or having cardiovascular disease found patent ineligible); *Roche Molecular Sys., Inc. v. CEPHEID*, 905 F.3d 1363 (Fed. Cir. 2018) (methods for detecting the pathogenic bacterium Mycobacterium tuberculosis (MTB) found patent ineligible); *Cleveland Clinic Found. v. True Health Diagnostics LLC*, 859 F.3d 1352 (Fed. Cir. 2017) (methods for assessing risk of cardiovascular disease found patent ineligible); *Genetic Techs. Ltd. v. Merial L.L.C.*, 818 F.3d 1369 (Fed. Cir. 2016) (method for amplifying and analyzing correlations between different regions of DNA sequence found patent ineligible); *Ariosa*, 788 F.3d 1371 (prenatal methods of detecting paternally inherited cffDNA in maternal plasma or serum found patent ineligible); *PerkinElmer, Inc. v. Intema Ltd.*, 496 F. App'x 65 (Fed. Cir. 2012) (screening methods to estimate the risk of fetal Down syndrome found patent ineligible).

"[i]t is inappropriate to dissect the claims into old and new elements." These requirements articulated by this Court recognize 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 72) and that "'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.* at 79 (quoting *Diehr*, 450 U.S. at 188). In *Mayo*, this Court expressly acknowledged that these directives from *Diehr* remain good law. *Id.*

However, the Federal Circuit, on its own initiative, has ignored this precedent and routinely dissects claim elements into new and old parts in assessing patent eligibility. For example, the Federal Circuit (and district courts below following, as they must, the Federal Circuit's application of patent ineligibility jurisprudence) has focused on whether the claim limitations ***could be*** practiced using routine and conventional means. This is error; the proper inquiry according to this Court is whether the claim limitations themselves were routine and conventional in the context of the claims as a whole.

The Federal Circuit's precedent prompted the district court decision to find Athena's claims ineligible. However, Athena's claims are demonstrably patent eligible because they are like the patent eligible claims in *Diehr*, and distinguishable from the patent-ineligible claims in *Mayo* on several grounds. First, Athena's claims, when viewed as a whole, are directed to a method for diagnosing myasthenia gravis ("MG") comprising novel, man-made reagents to detect a MuSK autoantibody complex. In particular, contacting bodily fluids with man-made, labeled

MuSK antigenic epitopes is novel and *not* a "routine, well-understood and conventional" process as contemplated by this Court's two-part *Alice/Mayo* analytical framework. Although making a labeled MuSK epitope and using it to detect MuSK antibodies could be practiced using conventional and routine methods (as Athena's □820 patent discloses and both the Federal Circuit and District Court noted), making a labeled MuSK epitope and using it to detect MuSK antibodies had never been done before the invention in the '820 patent. Thus, Athena's claimed process is not conventional or routine—it is novel. Whether a claim recites the practice of conventional and routine methods well-known in the art (as was the case in *Mayo*) when viewing the specific claim as a whole is a wholly different issue than whether separate claim limitations can be practiced *using* conventional and routine methods. The second part of this Court's two-part framework commands consideration of the former, not the latter.

The inventors of the '820 patent did not merely discover a new natural phenomenon (*i.e.*, the correlation between MuSK autoantibodies in bodily fluid and myasthenia gravis). Rather, they invented a new application of that discovery directed to a new method for detecting myasthenia gravis by employing novel, man-made reagents. The use of these novel reagents contributed "something more than" or "in addition to" any natural law upon which detection relied, making the methods steps not "routine, well-understood and conventional" as that phrase should be understood from *Mayo*. However, the Federal Circuit, like the district court, failed to consider the claims as a whole in analyzing the second step of the *Alice/Mayo* test. Rather, the Federal Circuit separated features of the claim and looked to whether the methods

underlying specific claimed steps were "routine" and "conventional." In other words, the Federal Circuit's analysis centered on whether immunoprecipitation and radiolabeling,[5] in general, were routine and conventional in the scientific arts. What this Court's *Alice/Mayo* test requires is for the Federal Circuit to determine whether immunoprecipitation and radiolabeling of these novel, man-made compounds in accordance with the claimed method were routine and conventional, when viewing the claims as a whole. Thus, both the Federal Circuit and the

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5. Claims 7–9 depend from claim 1 (not at issue in this Appeal), the language of which is inserted in italics for clarity:

> **7**. *A method for diagnosing neurotransmission or developmental disorders related to muscle specific tyrosine kinase (MuSK) in a mammal comprising the step of detecting in a bodily fluid of said mammal autoantibodies to an epitope of muscle specific tyrosine kinase (MuSK)*, comprising contacting MuSK or an epitope or antigenic determinant thereof having a suitable label thereon, with said bodily fluid, immunoprecipitating any antibody/MuSK complex or antibody/MuSK epitope or antigenic determinant complex from said bodily fluid and monitoring for said label on any of said antibody/MuSK complex or antibody/MuSK epitope or antigen determinant complex, wherein the presence of said label is indicative of said mammal is suffering from said neurotransmission or developmental disorder related to muscle specific tyrosine kinase (MuSK).
>
> 8. A method according to claim 7 wherein said label is a radioactive label.
>
> **9**. A method according to claim 8 wherein said label is ^{125}I.

'820 patent, col. 12, l. 62–col. 13, l. 9.

district court confused the fact that the claimed method could be used in a routine and conventional manner with the fact that the *method itself* was *not* routine or conventional.

This Court's guidance is critical to proper application of the proper test of patent eligibility by the Federal Circuit and district courts that will save important and useful diagnostic methods claimed with specificity from being "swallow[ed]" by improper and overbroad application of the judicial exceptions set forth by this Court. *Alice*, 573 U.S. at 217.

II. The Federal Circuit Judges Recognize the Importance of Diagnostic Methods and Agree That Properly Limited Diagnostic Method Claims Including Athena's Claims Should Be Patent-Eligible

Methods of diagnosing disease are "useful", as soundly recognized by the Federal Circuit judges. *See, e.g.*, Pet. App., 63a (Hughes, J., concurring in denial of rehearing *en banc*), 71a (Dyk, J., concurring), 94a (Chen, J., concurring), 96-97a and 102a (Moore, J., dissenting), and 120a (Newman, J., dissenting). But as they emphasize, diagnostic methods go far beyond "usefulness"; rather, they are of increasingly vital importance to our healthcare system, by both improving availability to rapid, accurate, and safe tests for diagnosis and treatment of life-threatening illnesses, and decreasing costs of treatment by reducing the need for more expensive treatments. As Judge Moore noted, diagnostic methods are "critical to treating illnesses and saving lives [and] money through early detection [reducing] the need for high cost

pharmaceuticals or curative procedures." Pet. App. 102a. In their dissents, both Judge Moore and Judge Newman emphasized the chilling effect within the diagnostic industry. Pet App., 102-104a, 106-109a ("[t]he math is simple . . . [w]ithout [dependable] patent protection to recoup the enormous R&D cost, investment in diagnostic medicine will decline"); *id.* at 131-133a ("the public interest is poorly served by adding disincentive to the development of new diagnostic methods" and such a "severe criticism . . . presented by the entire industry, and stressed by thoughtful scholars[ ] warrants judicial attention.'").

As with other technologies that require robust patent protection to spur investment and commercial development, medical diagnostic technologies require some term of exclusivity to enable a reasonable expectation of return on development costs. Research and development of novel diagnostic tests often take years, and associated costs can be tens or hundreds of millions of dollars, with no guarantee of success. It would be foolhardy to think that industry will undertake such risks without the availability of robust patent protection. The Federal Circuit's overly stringent application of this Court's eligibility criteria has foreclosed diagnostic method claims from patent eligibility, eliminating any reasonable expectation of recouping the extraordinary costs of development, an outcome foreseen by this Court and properly cautioned against in its patent eligibility decisions. *Mayo*, 566 U.S. at 71, 92. Excluding diagnostic testing methods from the ambit of patent protection creates financial disincentives to the development and commercialization of such tests, with attendant harm to public health and private well-being.

Almost all of the separate opinions in the Federal Circuit's denial of Athena's request for rehearing *en banc* recognize the importance of diagnostic method claims to affordable and rapid diagnosis and treatment of life-threatening illnesses. Perhaps most forthrightly, Judge Moore, in her dissent, makes this point clear:

> 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. None of my colleagues defend the conclusion that claims to diagnostic kits and diagnostic techniques, like those at issue, should be ineligible. The only difference among us is whether the Supreme Court's *Mayo* decision requires this outcome.

Pet. App. 96a; *also* 102-109a.

The Federal Circuit judges also agree that, when properly limited in scope, diagnostic method claims should be patent-eligible. However, as Judge Moore identifies, the Federal Circuit judges differ on whether this Court's precedent in *Mayo* forecloses a finding of patent eligibility. For example, in his concurrence of the denial of the petition for rehearing *en banc*, Judge Hughes, joined by Chief Judge Prost and Judge Taranto, acknowledged that "the bottom line for diagnostics patents is problematic" but laments that "further explication of eligibility standards" from this Court are necessary to "permit patenting of essential life saving inventions" of diagnostic patents. Pet. App. 62-63a.

Judge Dyk, in his concurrence, likewise acknowledges that "there is no doubt that determining the relationship between specific genetic abnormalities and specific diseases constitutes an important discovery with proven utility." Pet. App. 70a. Judge Dyk continues that some of Athena's claims "could be patent eligible" if this Court were "to refine the *Mayo* framework to allow for sufficiently specific diagnostic patent claims with proven utility." Pet. App. 69-71a, 76-77a.

Similarly, Judge Chen, in his concurrence, recognizes that new medical diagnostic methods:

> [I]ntuitively seem to be the kind of subject matter the patent system is designed for: to encourage the risky, expensive, unpredictable technical research and development that people would not otherwise pursue in the hope that if they discover something of great medical value, then they will be protected and rewarded for that successful effort with a patent.

Pet. App. 94a. Judge Chen goes on to conclude that "practical application[s] of the discovered law of nature . . . is applied science in every sense of that term" and "should be patentable subject matter in a well-functioning patent system." Pet. App. 94-95a.

In dissent, Judge Newman similarly found that Federal Circuit has "mistakenly enlarged the [holding in *Mayo*], in substance and in application." Pet. App. 121a. According to Judge Newman, proper interpretation and application of *Mayo*, together with statute, precedent, and policy, support finding of Athena's claims patent-eligible. Pet. App. 121-132a.

In her dissent, Judge Stoll was equally concerned with over-reach and the flawed bright-line rule of eligibility for all diagnostic claims adapted by the Federal Circuit after *Mayo*. Pet. App. 135-136a. However, Judge Stoll noted that "[c]ertain diagnostic claims, such as the ones at issue in this case, are so narrowly tailored that preemption is not a reasonable concern." Pet. App. 137a.

The Federal Circuit's pointed and conflicting opinions illustrate the judges' confusion when analyzing diagnostic method claims and reveal their growing frustration in feeling that their hands are tied. They plead for this Court's guidance as to the patent eligibility analysis for diagnostic method claims. *See, e.g.*, Pet. App., 119a (Moore, J., dissenting in denial of rehearing en banc) ("No need to waste resources with additional *en banc* requests. Your only hope lies with the Supreme Court or Congress.").

III. This is an Appropriate Case to Provide Clarity and Guidance to Lower Courts

Since this Court's decision in *Mayo*, the Federal Circuit has held every diagnostic patent claim it has considered to be patent-ineligible subject matter under 35 U.S.C. § 101. *See supra* FN 4. However, *Mayo* was not a conventional diagnostic method case and differed in significant ways from the cases the Federal Circuit has invalidated in its name. For example, every limitation recited in the *Mayo* claims was known and practiced in the prior art; the only novelty in those claims was the natural law wherein detecting amounts of the administered drug below a certain threshold informed the skilled worker that too little of the conventional drug had been administered, and detecting amounts above another, higher threshold

informed that worker that too much of the conventional drug had been administered. None of the diagnostic method claims rendered patent-ineligible by the Federal Circuit, including *Athena*, have been "on all fours" with the facts in *Mayo*, and yet none of these earlier cases has provided the appropriate vehicle to clarify the patent eligibility framework as applied to diagnostic method claims.

A. Prior cases have constituted anomalies that would not provide the proper clarity for diagnostic method claims

The issue presented in *Mayo* was an anomaly because the claimed method and drugs were not new—they had already been in practice by physicians and the claimed steps added nothing new to this well-known and conventional method. Specifically, *Mayo* involved claims to a conventional process that preempted a law of nature (*i.e.*, the amount of thiopurine drug optimal for treatment of Crohn's disease and other inflammatory diseases and disorders). This Court determined that the claims involved "well-understood, routine, conventional activity *previously engaged in* by researchers in the field." *Mayo*, 566 U.S. at 73 (*emphasis added*). Indeed, doctors routinely administered thiopurine drugs to treat patients with autoimmune disorders at the time Prometheus's application was filed, and methods for measuring thiopurine metabolite 6-thioguanine levels were well known in the art and had been routinely used to investigate the efficacy and toxicity of thiopurine drugs. *Id.* at 78-79. There was no "inventive concept" recited in the "wherein" clauses in the *Mayo* claims, which merely set forth a natural law relating the amount of a metabolite

in a patient's red blood cells and therapeutic efficacy of treatment with the thiopurine drug. *Id.* As a result, this Court found the process claims ineligible subject matter or otherwise "risk disproportionately tying up the use of the underlying natural laws, inhibiting their use in the making of further discoveries." *Id.* at 73.

In *Mayo*, this Court determined that, aside from the correlation between 6-thioguanine metabolite levels and optimal thiopurine drug dose, the claims recited a combination of methods steps (administering a thiopurine drug and measuring the metabolites) that were known and had been practiced in the prior art, *i.e.*, the combination of steps lacked novelty. *Id.* at 78-79. As a consequence, in this Court's view, the claim sought to patent a prior art process by differentiating it based solely on the discovery of a natural phenomenon and the new knowledge derived from it. To make use of the natural phenomenon, the public would necessarily have to practice the claimed method. *Id.* at 79. The claimed invention thereby entirely preempted the public's use of the natural phenomenon, leading this Court to conclude that the claim was ineligible for patent protection under 35 U.S.C. § 101.

Claims directed to methods not previously practiced in the prior art have also been routinely invalidated by the Federal Circuit. For example, the claims in *Cleveland Clinic Found. v. True Health Diagnostics LLC* were directed to methods for assessing risk of cardiovascular disease in a patient by detecting myelopeoxidase ("MPO") in blood and correlating the presence of MPO to a patient's risk for cardiovascular disease. 859 F.3d 1352, 1362-63 (Fed. Cir. 2017), *cert. denied*, 138 S. Ct. 2621 (2018). The Federal Circuit held the claims in *Cleveland Clinic* to

be patent-ineligible because they "merely" detected a previously known link between MPO and cardiovascular disease, employing only naturally occurring products in a blood sample, and correlating the naturally occurring presence of MPO to cardiovascular disease using routine methods. *Id.* at 1362.

In *Ariosa*, the claims were directed to methods amplifying previously unknown cell-free fetal DNA ("cffDNA") in a plasma or serum sample obtained from a pregnant female and detecting the paternally-inherited cffDNA, which is naturally occurring in the maternal blood. 788 F.3d at 1376. The Federal Circuit found these claims patent-ineligible because they "merely" detected a natural phenomenon, employing only naturally occurring products in a blood or serum sample using routine methods of amplification. *Id.* at 1377. The court reached this conclusion despite the acknowledged novelty of finding cffDNA in maternal blood and the novel, beneficial methods that detection provided. *Id.* at 1377. *See also id.* at 1381.

These cases illustrate the Federal Circuit's confusion and failure to distinguish between those diagnostic method claims that are similar to those held patent-ineligible in *Mayo* and those that are dissimilar to the *Mayo* claims. The claims at issue in this case are yet another example of the consequences of the Federal Circuit's failure to identify the difference between the two.

B. This case represents an opportune vehicle to clarify the patent eligibility test for diagnostic method claims

The present claims recite method steps unknown in the prior art that rely on novel, man-made compositions. Practicing the claimed methods using these novel man-made compositions produces a new, different, more sensitive, and beneficial result unknown in the prior art that, while relying on natural laws (as all inventions must), does more than just recite a natural law and instruct the skilled man to "apply it." *Mayo*, 566 U.S. at 72. By using novel, man-made reagents in the method, the claims transcend merely applying a law of nature to what is "routine, well-understood and conventional"—the man-made reagents, being novel, are anything but routine, well-understood, or conventional, and their inclusion by itself should extricate the recited method steps from this Court's penumbra of judicial exceptions.

The inventors of the '820 patent discovered a previously unknown correlation between MuSK antibodies and myasthenia gravis and then applied that discovery through invention of a method to accurately detect that correlation, "employ[ing] their natural discovery to create a new and improved way of" determining a form of myasthenia gravis. *Rapid Litig. Mgmt. Ltd. v. CellzDirect, Inc.*, 827 F.3d 1042, 1048 (Fed. Cir. 2016). Such a discovery and implementation of knowledge to develop a new and useful tool is (and should be) patent eligible.

The claims before this Court do not entirely preempt the public's use of the natural phenomenon of the correlation between MuSK antibodies in bodily fluids

and myasthenia gravis. Indeed, implementation of such technique preempts neither the use nor detection of the discovered natural phenomenon, but only the combined technique using man-made components that are claimed. The claimed method is narrow and limited in scope. The scope of the claims does not encompass an unlabeled MuSK/antibody complex naturally formed in bodily fluid. If new methods of detecting either the naturally made MuSK/antibody complex are discovered at a later date, they can be freely practiced without infringing Athena's claims. If future research discovers that the presence of MuSK/antibody in body fluids correlates to a disease state other than myasthenia gravis, such an application is not preempted by the claims in the '820 patent. And if treatment for a disease is developed which is directed to the natural MuSK/antibody complex, the claims of the '820 patent do not preempt such a treatment.

Proper application of this Court's patent eligibility framework reveals that Athena's diagnostic method claims, like those in *Diehr*, that rely on a natural phenomenon (the correlation between myasthenia gravis and MuSK antibodies in bodily fluids) do not entirely preempt use of the natural phenomenon. These claims provide this Court with an opportunity to clarify the framework of patent eligibility and its proper application for lower courts.

CONCLUSION

The guiding principle of the *Alice/Mayo* two-part framework is to exclude claims that entirely preempt the public's use of a law of nature or natural phenomena because such claims impede progress in the useful arts. The Federal Circuit's application of the *Alice/Mayo* two-part framework disregards this purpose and has resulted in disincentives for skilled artisans to develop new and useful diagnostic inventions.

Diagnostic methods, such as the claims at issue, are at particular risk because they rely heavily and directly on laws of nature and natural phenomenon. While the Federal Circuit professes formal compliance with this Court's *Alice/Mayo* test with regard to patent-eligibility of diagnostic method claims, its incorrect, overreaching interpretation of this Court's framework has evolved into rigid application of a bright-line, *per se* rule that precludes patents from this entire technology area. The Federal Circuit's misapplication of this Court's mandate has resulted in invalidation of every diagnostic method claim considered by that court since *Mayo*.

The deep divide in the Federal Circuit over how to properly apply this Court's patent-eligibility test and that court's plea for guidance demonstrate that this issue will not be resolved without direct intervention by this Court. The proper balance can be achieved only by applying the *Alice/Mayo* two-part framework in a narrow fashion, as this Court did in *Mayo,* so that diagnostic methods that do not entirely preempt a law of nature or natural phenomenon may be patent eligible. Accordingly, the *amici curiae* urge this Court to grant Athena's petition for a writ of certiorari.

Respectfully Submitted,

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