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, AND MAYO CLINIC,
Respondents.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

BRIEF OF THE INTELLECTUAL PROPERTY LAW ASSOCIATION OF CHICAGO AS AMICUS CURIAE ON PETITION FOR WRIT OF CERTIORARI IN SUPPORT OF PETITIONERS

DAVID L. APPLEGATE
Counsel of Record
WILLIAMS MONTGOMERY & JOHN LTD.
6800 WILLIS TOWER
233 SOUTH WACKER DRIVE
CHICAGO, IL 60606
(312) 443-3200
DLA@WILLMONT.COM

OF COUNSEL
CHARLES W. SHIFLEY, PRESIDENT
THE INTELLECTUAL PROPERTY LAW ASSOCIATION OF CHICAGO
P.O. BOX 472
CHICAGO, IL 60690

OF COUNSEL
LAURA LABEOTS, PH.D.
LATHROP GAGE LLP.
155 NORTH WACKER DRIVE
SUITE 3000
CHICAGO, IL 60606-1787

BRYAN G. HELWIG, PH.D.
MCDONNELL BOEHNEN HULBERT & BERGHOFF LLP.
300 S WACKER DRIVE
SUITE 3100
CHICAGO, IL 60606

ROBERT H. RESIS
BANNER & WITCOFF, LTD.
10 SOUTH WACKER DRIVE
SUITE 3000
CHICAGO, IL 60606

October 31, 2019

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

Cases

Statutes and Constitutional Provisions

Other Authorities

I. INTEREST OF *AMICUS CURIAE*[1]

Founded in 1884 in Chicago, a principal forum for U.S. technological innovation and intellectual property litigation, the Intellectual Property Law Association of Chicago ("IPLAC") is the country's oldest bar association devoted exclusively to intellectual property matters. IPLAC's over 1,000 voluntary members include attorneys in private and corporate practices in the areas of copyrights, patents, trademarks, trade secrets, and the legal issues they present before federal courts throughout the United States, as well as before the U.S. Patent and Trademark Office and the U.S. Copyright Office. IPLAC's members represent innovators and accused

---

[1] Pursuant to Supreme Court Rule 37.2(a), proper notice was given and written consent to the filing of this brief has been provided by counsel of record for each party.

Pursuant to Supreme Court Rule 37.6, no counsel for a party authored this brief in whole or in any part or made a monetary contribution intended to fund preparation or submission of the brief, and no person other than the *amicus curiae*, its members, or its counsel, made such a monetary contribution.

In addition to the required statement, IPLAC adds that after reasonable investigation, IPLAC believes that (a) no member of its Board or Amicus Committee who voted to prepare this brief, or any attorney in the law firm or corporation of such a member, represents a party to this litigation in this matter, (b) no representative of any party to this litigation participated in the authorship of this brief, and (c) no one other than IPLAC, or its members who authored this brief and their law firms or employers, made a monetary contribution to the preparation or submission of this brief.

infringers in approximately equal measure and are split nearly equally between plaintiffs and defendants in litigation.

As part of its central objectives, IPLAC is dedicated to aiding in developing intellectual property law, especially in the federal courts.[2]

II. SUMMARY OF ARGUMENT

IPLAC supports Petitioners' request to grant *certiorari.* This Court should clarify whether, and by what measure, a new and specific method of diagnosing a medical condition is patent-eligible subject matter. Here, the method detects a molecule never previously linked to the condition being treated using novel man-made molecules and a series of specific chemical steps never previously performed. If these facts do not at least demonstrate potential patentable subject matter, then following *Mayo Collaborative Services v. Prometheus Laboratories, Inc.,* 566 U.S. 66 (2012), no medical diagnostics patent is ever likely to be granted in a field of critical importance to the future healthcare of Americans. As the *en banc* opinions below amply demonstrate, this case is an appropriate and timely vehicle for clarifying the standards for patentability of process patents in the field of medical diagnostics under 35 U.S.C. § 101 in the wake of *Mayo.*

---

[2] Although over 30 federal judges are honorary members of IPLAC, none of them was consulted or participated in any way regarding this brief.

The claimed methods at issue in U.S. Patent No. 7,267,820 for diagnosing neurotransmission or developmental disorders are not directed to, in the words of *Mayo*, a "natural law" or "law of nature." Instead they are directed to specific applications of "natural laws" claiming detailed specified processes. Even following *Mayo*, such processes that rely on applications of so-called natural laws should remain patentable subject matter under *Diamond v. Diehr*, 450 U.S. 175 (1981).

Petitioners' patent claims specify a chemical process for creating and detecting new molecules that previously neither existed nor were detected in nature, all for the useful purpose of diagnosing a previously undiagnosable variant of a debilitating disease. Under *Association for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576 (2013), these novel manmade molecules themselves are patent eligible, and the process for making them falls squarely within the language of 35 U.S.C. § 101.

As shown below on denial of the petition for rehearing *en banc*, this Court's references in *Mayo* to "natural laws" or "laws of nature" are at best confusing to the lower courts. *See, e.g., Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC*, 927 F.3d 1333, 1335 (Fed. Cir. 2019)(Lourie, J., concurring, joined by Reyna and Chen, JJ.); 1337 (Hughes, J., concurring, joined by Prost, C.J., and Taranto, J.); 1339 (Part III of Dyk, J., concurring, joined by Hughes, J.); at 1340 (Dyk, J., concurring, joined by Hughes and Chen, JJ.); 1349 (Chen, J., concurring); 1363 (Moore, J., dissenting, joined by O'Malley, Wallach, and Stoll, JJ.); 1370-1371 (Stoll, J., dissenting, joined by Wallach, J.); (Fed. Cir. 2019) (*Athena II*).

Every patentable invention under the sun relies in part upon "laws of nature" or "natural phenomena." A patent on a mechanical wrench, for example, would rely on laws of physics, materials science, and principles of geometry dating back at least to Archimedes. A patent on a slide rule would necessarily rely upon the application of logarithms. But neither would claim unpatentable subject matter under § 101. See, e.g., U.S. Patent No. 9030x, August 17, 1835, to P. Merrick for an "Improvement in Screw Wrench," and U.S. Patent No. 460,930 to William Cox for an "Engineer's Duplex Slide Rule." Einstein's famous equation $E=mc^2$, see *Mayo* at 711, or the speed of light may be unpatentable, but a process for measuring the distance between the earth and the moon that relies upon the speed of light may be.

Accordingly, this Court's language in *Mayo* on the unpatentability of "laws of nature" needs further clarification. Neither "laws of nature" nor "natural phenomena" may be patentable, but the specific application of such "laws" and phenomena through detailed process claims – as in the present case – most certainly should be.

The current confusion about patentable subject matter in light of *Mayo* is particularly distressing in the field of medical diagnostic techniques. Since *Mayo*, for example, the Federal Circuit has found every diagnostic method it has addressed unpatentable under Section 101. *E.g., Cleveland Clinic Found. v. True Health Diagnostics LLC*, 760 F. App'x 1013 (Fed. Cir. 2019) ("*Cleveland Clinic II*"); *Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC*, 915 F.3d 743 (Fed. Cir. 2019) ("*Athena* I"); *Roche Molecular Sys., Inc. v.* CEPHEID, 905 F.3d 1363 (Fed. Cir. 2018); *Cleveland Clinic Found. v.*

True Health Diagnostics LLC, 859 F.3d 1352 (Fed. Cir. 2017) ("*Cleveland Clinic I*"); *Genetic Techs. Ltd. v. Merial L.L.C.*, 818 F.3d 1369 (Fed. Cir. 2016); *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371 (Fed. Cir. 2015); *In re BRCA1- and BRCA2-Based Hereditary Cancer Test Patent Litig.*, 774 F.3d 755 (Fed. Cir. 2014); *PerkinElmer, Inc. v. Intema Ltd.*, 496 F. App'x 65 (Fed. Cir. 2012).

Yet such diagnostic techniques are at the core of medical science, which cannot begin to treat or cure a disease without first detecting and diagnosing it. Such medical diagnostic techniques fit squarely within the intent of the Framers in authorizing Congress to grant letters patent "to promote the progress of science and the useful arts." U. S. Const., Art. 1, Sec. 8, cl. 8. They fit just as squarely within the Congressional language of 35 U.S.C. § 101. The present case provides an appropriate and timely opportunity for this Court to restore some balance in the field of diagnostic method patents by clarifying the language of *Mayo*.

III. PERTINENT FACTS[3]

Antigens are foreign substances that make their own way or can be artificially introduced into the human body to stimulate production of corresponding antibodies by the body. Antigens and antibodies generally combine into larger, more complex molecules that can be detected and measured through a variety of means. By detecting

---

[3] IPLAC assumes the Court's familiarity with the underlying facts and chemistry and describes the process here only in general terms. See generally, *Athena II*, *supra*, p. 3.

the existence of and measuring the concentration of these antigen-antibody complexes, a diagnostician determines the presence of a disease associated with the complex molecule.

Petitioners do not claim to have patented this general antigen-antibody phenomenon. Petitioners instead claim as patentable a unique process for detecting a previously unknown man-made antigen-antibody complex associated with a rare form of myasthenia gravis ("MG"). MG is a long-term autoimmune disease that leads to skeletal muscle weakness, often manifesting itself in double vision, drooping eyelids, and difficulty walking or talking.[4] MG is estimated to affect 50 to 200 million people worldwide.[5]

The form of MG that Petitioners' claimed invention detects had previously gone undiagnosed and was therefore difficult to treat. Petitioners' unique process for detecting this new man-made molecule – not the antigen-antibody process in general or even the new, man-made molecule itself – is Petitioners' claimed patentable subject matter.

More specifically, Petitioners' process claims involve producing a peptide sequence pertaining to the extracellular N-terminal domain of the MuSK

---

[4] Kaminski, Henry J., Myasthenia Gravis and Related Disorders (2 ed. 2009), Springer Science & Business Media. p. 72. ISBN 978-1597451567; archived from the original on 8 September 2017.

[5] Adams, James G. (2012). Emergency Medicine: Clinical Essentials (2 ed. 2012), Elsevier Health Sciences. p. 844. ISBN 978-1455733941; archived from the original on 8 September 2017.

protein with a covalent linkage to one or more radioactive iodine atoms in the histidine or tyrosine residues of the peptide.[6] This peptide process step does not occur naturally in the human body but instead is man-made. The sequence dramatically modifies the physical, chemical, and structural properties of the original MuSK peptide. Next the radioactive-iodinated-MuSK peptide antigen is introduced into a sample of a patient's bodily fluid. This forms a radioactive antigen-antibody complex when the autoimmune MuSK antibody is present in the bodily fluid. This step, too, does not occur naturally in the human body and is also man-made. The resulting radioactive antigen-antibody complex also does not exist in nature.

Detecting and quantifying the radioactivity of the resulting antigen-antibody complex confirms the presence of the MuSK autoimmune antibody and thus the presence of this disease in a patient. None of the steps, nor the resulting antigen-antibody complex, occurs naturally in the human body or as part of a natural process.

---

[6] Hermanson, Greg T., *Pierce Biotechnology* (3rd edition 2013).

IV. ARGUMENT

A. The Patent in Suit Claims a Process, Not a Law of Nature.

The purpose of the Patent and Copyright Clause of the U. S. Constitution is to promote the progress of science and the useful arts. U. S. Const., Art. I. Sec. 8, cl. 8. To that end, current U. S. patent law provides a time-limited right to exclude others from using "any new and useful *process*, machine, manufacture, or composition of matter, or any new and useful improvement thereof ..." for which an applicant receives a patent. 35 U.S.C. § 101 (*emphasis added*). Only Section 101 – governing patentable subject matter – is pertinent to this Petition. Whether the claimed process is novel or nonobvious under 35 U.S.C. §§ 102 and 103, for example, or meets the requirements of § 112 or other conditions of patentability is not before the Court.

The first U. S. patent ever granted – in 1790 – was for a process of making potash, a naturally occurring class of salts that contain potassium in water-soluble form used in fertilizer, and Section 101 explicitly calls out processes as potentially patentable subject matter.[7] See "First U.S. Patent Issued Today in 1790," available at https://www.uspto.gov/about-us/news-updates/first-us-patent-issued-today-1790, visited October 9, 2019.

---

[7] The name "potash" derives from "pot ash," referring to plant ashes soaked in water in a pot, which was the primary pre-industrial era means of manufacturing the product. The word potassium, in turn, appears to have derived from potash. https://en.wikipedia.org/wiki/Potash, visited October 9, 2019.

That patent relied upon natural products and processes – so-called "laws of nature" – but claimed a new and useful process for making the product. U.S. Patent No. USx1, July 31, 1790, to S. Hopkins for "Potash". Indeed, Congress intended statutory subject matter to "include anything under the sun that is made by man." S. Rep. No. 1979, 82nd Cong., 2d Sess., 5 (1952); H.R. Rep. No. 1923, 82nd Cong., 2d Sess., 6 (1952).

Since that time, this Court has universally upheld the patentability of processes that employ well-understood and unpatentable machinery, mathematical formulae, algorithms, and so-called laws of nature.

In *Cochrane v. Deemer*, 94 U.S. 780, 787-788 (1877), this Court observed that "[t]he machinery pointed out as suitable to perform the process may or may not be new or patentable, whilst the process itself may be altogether new, and produces an entirely new result." In *Funk. Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948), the Court recognized that the application of a natural law or mathematical formula to a known structure or process may likewise be patentable. No particular machine need be involved. *Gottschalk v. Benson*, 409 U.S. 63 (1972) ("Transformation and reduction of an article 'to a different state or thing' is the clue to the patentability of a process claim that does not include particular machines."). In *Parker v. Flook*, 437 U.S. 584, 590 (1978), this Court made plain that "[a] process is not unpatentable simply because it contains a law of nature or mathematical algorithm." And in *Diamond v. Diehr*, 450 U.S. 175, 185 (1981), this Court stated that "we think that a physical and chemical process for molding precision synthetic

rubber products falls with the § 101 categories of possibly patentable subject matter."

The laws of thermodynamics also do not render unpatentable a method for making steel, see, e.g., U.S. Patent No. 902,052, October 27, 1908, to Frank D. Carney for a "Process For Manufacturing Steel From Cromiferous Pig-Iron," and the laws of aerodynamics did not render the airplane unpatentable. See U.S. Patent No. 821,393, May 22, 1906, to Wilbur and Orville Wright for "New and Useful Improvement in Flying Machines." Nor do the natural laws of biology render polymerase chain reaction ("PCR") patent claims out of bounds under Section 101. See, e.g., U.S. Patent No. 4,683,195, July 28, 1987, to Mullis, et al., for a "Process For Amplifying, Detecting, and/or Cloning Nucleic Acid Sequences." So, too, should the immunological reaction between antigens and antibodies not render new and non-obvious diagnostic techniques *per se* unpatentable. Each claimed invention in the field of medical diagnostics should instead be subject to the same Section 102, 103, and 112 tests as claimed inventions in other fields of science and technology, not automatically ruled out of bounds under Section 101. 35 U.S.C. §§ 102, 103, 112.

In *Mayo,* however, this Court unfortunately created uncertainty in the field of medical diagnostics patents by stating that "adding 'conventional steps, specified at a high level of generality,' to a law of nature does not make a claim to the law of nature patentable." 566 U.S. at 62. This characterization has not been particularly helpful in instructing inventors, practitioners, and the lower courts, including the Federal Circuit. In analyzing the patentability of potentially life-saving medical

diagnostic techniques, confusion reigns, as witness the multiple overlapping and sometimes contradictory *en banc* opinions in this case below. *Athena II* at 1335 (Lourie, J., concurring, joined by Reyna and Chen, JJ.); 1337 (Hughes, J., concurring, joined by Prost, C.J., and Taranto, J.); 1339 (Part III of Dyk, J., concurring, joined by Hughes, J.); at 1340 (Dyk, J., concurring, joined by Hughes and Chen, JJ.); 1349 (Chen, J., concurring); 1363 (Moore, J., dissenting, joined by O'Malley, Wallach, and Stoll, JJ.); 1370-1371 (Stoll, J., dissenting, joined by Wallach, J.); (Fed. Cir. 2019), *supra*.

The term "law of nature" itself is open to interpretation,[8] and all inventions and discoveries, patentable or not, must rely on some level and in some sense on "laws of nature" to be workable. (A "perpetual motion" machine would be neither workable nor patentable, for example, because it would violate the laws of thermodynamics. *See Newman v. Quigg*, 681 F.Supp 16 (D. D.C. 1988); MPEP 2107.01, General Principles Governing Utility Rejections (R-5) - 2100 Patentability. II. Wholly inoperative inventions; "incredible" utility.)

A careful examination of claims 6-9 of the patent in suit, U.S. Patent No. 7,267,820, reveals

---

[8] Gravity and the speed of light, for example, may be considered "laws of nature," while "natural phenomena," on the other hand, include such things as lightning, tornadoes, and rainbows. See Robert R. Sachs, "Punishing Prometheus: The Supreme Court's Blunders in *Mayo v. Prometheus,*" March 26, 2012, at https://patentlyo.com/patent/2012/03/punishing-prometheus-the-supreme-courts-blunders-in-mayo-v-prometheus.html, visited October 9, 2019.

that the claims are not directed to a "law of nature"; like all claims of all inventions, they merely *rely* on "laws of nature." The patented claims recite a chemical process for creating and detecting new and useful chemical molecules, which molecules had neither previously existed nor been previously detected anywhere in the world. U.S. Patent No. 7,267,820 at col. 12, ln 57 to col. 13 ln 9.

As such, even after *Mayo*, the claims in suit fall within the patentable subject matter of 35 U.S.C. § 101 under *Diamond v. Diehr*. Before development of the patented process, scientists didn't even know that the rare MuSK autoantibodies existed, let alone that their presence could be detected and would indicate an MG disease state. U.S. Patent No. 7,267,820 at col. 1, ln 34-61.

In *Mayo*, in contrast, the Federal Circuit held that measuring metabolites of a drug and tying changes in dosage regimens to threshold limits were mental steps that constituted unpatentable subject matter under 35 U.S.C. § 101. But in *Mayo* the measured metabolite was not transformed into a new chemical entity as part of the diagnostic method, and scientists already understood that the levels of certain metabolites in a patient's blood correlated with the likelihood that a particular dosage of a thiopurine drug could cause harm or prove ineffective. 566 U.S. at 72-73. Instead, the "conventional step, specified at a high level," *id.* at 82, was measuring a naturally occurring metabolite in the blood.

Whether the radiolabeling process that the claims in suit here employ, or the nature of antigen-antibody reactions themselves, is old or new

therefore has no bearing on whether Petitioners' discovery is potentially patentable under § 101. Petitioners simply maintain, in the very words of Section 101, they have discovered a "new and useful process … or a new and useful improvement thereof." That is the very definition of patentable subject matter, and this Court should grant *certiorari* to clarify *Mayo* to make that plain.

B. The Federal Circuit's Manifest Confusion Cries Out for Ceriorari Review.

As Petitioners have noted, on Athena's petition for rehearing *en banc* the Federal Circuit broadly agreed that Athena's claims should be patent-eligible. *See Athena II.* Yet the court was divided on the solution, some judges appearing to believe that the Federal Circuit could correct course because the problem lies in the Federal Circuit's own extensions of *Mayo*. *Id.* at 1370-1371 (Stoll, J., dissenting, joined by Wallach, J.) ("Our inflexible following of *Mayo* has created flawed decisions that are inconsistent with the precepts of *Mayo* and our patent system as a whole.")

Still more judges concurred in *denying* a rehearing *en banc* because they believe that, broadly interpreted, *Mayo* binds their hands. *Id.* at 1335 (Lourie, J., concurring, joined by Reyna and Chen, JJ.) ("Some of us have already expressed our concerns over current precedent," but "we are bound by the Supreme Court's decision in *Mayo*."); *id.* at 1337 (Hughes, J., concurring, joined by Prost, C.J., and Taranto, J.) ("[T]his is not a problem that we can solve. As an inferior appellate court, we are bound by the Supreme Court."); *id.* at 1339 (Part III of Dyk, J.,

concurring, joined by Hughes, J.) ("[I]t is the Supreme Court, not this court, that must reconsider the breadth of *Mayo*."); *id.* at 1340 (Dyk, J., concurring, joined by Hughes and Chen, JJ.) ("[I]t would be desirable for the Supreme Court to refine the *Mayo* framework to allow for sufficiently specific diagnostic patent claims with proven utility."); *id.* at 1363 (Moore, J., dissenting, joined by O'Malley, Wallach, and Stoll, JJ.) ("No need to waste resources with additional *en banc* requests. Your only hope lies with the Supreme Court or Congress."); *id.* at 1349 (Chen, J., concurring) ("We are not in a position to resolve that question, but the Supreme Court can.")

This manifest confusion and disagreement even within the Federal Circuit surrounding Section 101 in view of *Mayo* constitutes an unprecedented cry for help. This Court should grant *certiorari*.

C. Countervailing Concerns Provide No Reason Not to Grant *Certiorari*.

Arguments to the contrary should not dissuade this Court from considering the issues raised in the decision below. That Athena did not claim as patentable its man-mode molecules and because Congress may amend Section 101 is not dispositive because it is the claimed process here – not the unclaimed molecule – that has been found unpatentable subject matter, and process claims fall squarely within the existing statutory language.

The current controversy therefore arises not from the statutory language of Section 101, but from misinterpretation by lower courts of this Court's use of the phrase "natural law" in *Mayo*, which the Federal Circuit relied upon and felt bound by below. *Athena Diagnostics, Inc. v. Mayo Collaborative*

Servs., LLC, 915 F.3d 743, 752, 757 (Fed.Cir. 2019) (*Athena I*); see *Athena II* at 1335, 1337, 1339, 1340, 1349. It is the province of this Court to clarify understanding of the Court's own language. Proper correction of interpretive errors by lower courts is warranted and well within the supervisory authority of this Court.

D. Granting *Certiorari* Manifestly Serves the Public Interest.

This Court does not decide issues in a vacuum. This Court's rulings have the power instead to help shape people's lives for generations to come. *See, e.g., Brown v. Board of Education*, 347 U.S. 483 (1954); *Roe v. Wade*, 410 U.S. 113 (1973); *Obergefell v. Hodges*, 576 U.S. ___ (2015).

As Justice Kagan noted in *Kimble v. Marvel*, "with great power there must also come great responsibility." 576 U.S. at ____ (2015), citing. S. Lee and S. Ditko, *Amazing Fantasy* No. 15: "Spider-Man," p. 13 (story p. 11) (1962). Sometimes, as in *Kimble*, that may mean choosing not to overturn four-decade-old precedent where reliance interests have been strong and the parties can contract around it. In other cases, it may mean acting to effectuate the intent of Congress even where that intent is poorly expressed. *Cf. National Federation of Independent Business v. Sebelius*, 567 U.S. 519, ___ (2012) (Roberts, C.J.); *King v. Burwell*, 576 U.S. ___ (2015), (Roberts, C.J.). In still others, it may mean protecting Constitutional rights previously known but unenforced, *Brown, supra;* or finding and protecting rights previously not believed to have existed. *Roe, supra; Obergefell, supra.*

In the present case, however, this Court need not consider whether to uphold or to overturn long-held precedent, interpret an ambiguous statute, nor discover or articulate a hitherto unknown right. Instead, it need only clarify its own recent language in the wake of subsequent experience. What the Court should not do, in Justice Kagan's phrasing, is to disregard the responsibility that comes with its great power by declining to grant *certiorari* here.

As Judge Moore observed below, in the seven years since this Court decided *Mayo*, the Federal Circuit has found unpatentable under Section 101 every single challenged diagnostic claim in every case that has come before it. *Athena II* at 1352 (Moore, J.). In just the one month after this Court decided *Mayo*, the Patent Office's rejection rate of patent applications for medical diagnostic techniques increased from 7% to 32%. Chien & Wu, *Decoding Patentable Subject Matte*r, 2018 Patently-O Patent L.J. 1, 15 (Oct. 21, 2018), https://bit.ly/2oBO1i5. Following *Alice Corp. v. CLS Bank International*, 573 U.S. 208 (2014) only two years later, the rejection rate for diagnostic claims grew to over 50%; it ultimately reached as high as 64%. *Id.* This evidences significant and likely unintended consequences in the potential patentability of new discoveries and inventions in a field with profound implications for human health and well-being.

Investment in diagnostics goes to the very core of health care – and its concomitant costs – helping to improve patient outcomes before illnesses can become debilitating and prohibitively expensive to treat. See *Athena II* at 1356. As noted in this case below, "[d]iagnosis is the foundation of medicine." *Id.* at 1355 (Moore, J., dissenting, joined by O'Malley,

Wallach, and Stoll, JJ.). Diagnostic techniques may account for less than 2.5% of current healthcare expenses, but they guide approximately 66% of clinical decisions. *Id.* Proper diagnosis allows for early detection, which in turn permits more effective, less expensive, or more carefully targeted treatment. *See id.* at 1357-1358.

In an environment in which formerly conquered diseases like measles and malaria are now making comebacks,[9] diagnostics are also "'crucial in mitigating the effect of disease outbreaks.'" *Id.* at 1356. Where diagnostic techniques are novel and non-obviousness, and meet the other statutory requirements for patentability, this Court should clarify that Section 101 does not bar patentability. Simply because diagnostic techniques – like all scientific processes – rely upon naturally occurring phenomena or laws of nature should not present an absolute bar.

Allowing potential patent protection for specific diagnostic claims like Athena's is therefore not only correct as a legal matter but is also sound public policy. *See, e.g.*, *Athena II*, 927 F.3d at 1337, 1340, 1352, 1355-1359, 1368-1370 (various concurring and dissenting opinions discussing policy concerns). Because, as Judge Dyk noted below, "at least some of

---

[9] See CDC, *Measles Cases and Outbreaks,* CDC – Measles (Rubeola), available at https://www.cdc.gov/measles/cases-outbreaks.html, and Espinoza J.L., Malaria Resurgence in the Americas: An Underestimated Threat, *Pathogens*, 2019 Mar 8(1) PMC6471461, available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6471461/, last accessed Oct. 24, 2019.

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." *Id.* at 1343-1344. (Dyk, J., concurring, joined by Hughes and Chen, JJ.).

This Court should therefore grant *certiorari* because of its critical importance to doctors, patients, medical researchers, and the general public – as well as to patent practitioners and the lower courts.

V. CONCLUSION

The Court's language in *Mayo v. Prometheus* has left a wake of confusion and misunderstanding that only this Court can judicially rectify. This case provides an ideal opportunity for the Supreme Court to consider how its decision in *Mayo* has been extended and to help restore balance. Nothing in the patent in suit claims a monopoly on any naturally occurring phenomenon. Instead, the patent in suit purports to claim only a novel application of a novel process for diagnosing certain medical disorders. This Court should grant *certiorari* to clarify its patentability jurisprudence to clear the way for this and future beneficial medical diagnostics to come.

Respectfully submitted,

DAVID L. APPLEGATE
Counsel of Record
WILLIAMS MONTGOMERY & JOHN LTD.
6800 WILLIS TOWER
233 SOUTH WACKER DR.
CHICAGO, IL 60606
(312) 443-3200
DLA@WILLMONT.COM

OF COUNSEL
CHARLES W. SHIFLEY,
PRESIDENT
THE INTELLECTUAL PROPERTY LAW ASSOCIATION OF CHICAGO
P.O. BOX 472
CHICAGO, IL 60690

OF COUNSEL
LAURA LABEOTS, PH.D.
LATHROP GAGE LLP
155 NORTH WACKER DR.
SUITE 3000
CHICAGO, IL 60606-1787

BRYAN G. HELWIG, PH.D.
MCDONNELL BOEHNEN HULBERT & BERGHOFF LLP.
300 S WACKER DR.
SUITE 3100
CHICAGO, IL 6060

ROBERT H. RESIS
BANNER & WITCOFF, LTD.
10 SOUTH WACKER DR.
SUITE 3000
CHICAGO, IL 60606

October 31, 2019

Counsel for Amicus Curiae IPLAC