No. 19-430

IN THE

Supreme Court of the United States

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

Petitioners,

v.

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

Respondents.

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

BRIEF OF *AMICUS CURIAE* THE CHARTERED INSTITUTE OF PATENT ATTORNEYS IN SUPPORT OF THE PETITIONERS

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INTEREST OF *AMICUS CURIAE*

The Chartered Institute of Patent Attorneys (CIPA) respectfully submits this *amicus curiae* brief in support of Petitioners.[1]

CIPA is the professional and examining body for patent attorneys in the United Kingdom (UK). The Institute was founded in 1882 and was incorporated by Royal Charter in 1891. It represents over 2,000 chartered patent attorneys, whether they work in industry or in private practice. Total membership is over 3,500 and includes trainee patent attorneys and other professionals with an interest in intellectual property.

Almost all chartered patent attorneys are members of the Institute of Professional Representatives before the European Patent Office. Further, most UK patent attorneys have substantial experience with the U.S. patent system as a result of filing and prosecuting applications before the United States Patent and Trademark Office (USPTO) with the assistance of local counsel, and many have experience with U.S. patent litigation, again with the assistance of local counsel.

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1. Pursuant to Rule 37.2(a), all parties received timely notice of the intent to file this brief, and consent was granted by all parties.

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

CIPA's educational activities include organizing conferences, seminars and meetings on patent law, frequently with the assistance of U.S. practitioners, publishing a monthly journal featuring articles on patent law and recent decisions, publishing books in-house on patent law, publishing through Sweet and Maxwell the *CIPA Guide to the Patents Acts* (now in its 8th Edition), the *European Patents Handbook*, and the *European Patents Sourcefinder*, and publishing other titles relating to trademarks and designs.

The scope of patent-eligible subject matter in the United States and its inconsistency with international treaties and practice is of fundamental concern to CIPA members and their clients. Patent protection is particularly important for inventions in the life sciences, especially for pharmaceutical, biotechnological, and medical testing inventions where research, product development, and commercial activities depend upon eligibility criteria that are consistent and predictable. CIPA is concerned that this Court's decision in *Mayo* has been interpreted and applied by the Federal Circuit, district courts, and the USPTO in a way that is unnecessarily restrictive as to the scope of patent-eligible subject matter in the life sciences, which has placed an undue burden on patent applicants and internationally discordant restrictions on long-established and widely accepted eligibility criteria. The situation affects many members of the UK (and international) public having patent applications undergoing examination by the USPTO. CIPA filed an *amicus* brief in this case at the

Federal Circuit[2] and in April 2016 filed an *amicus* brief to this Court in support of the Petition for Certiorari in *Ariosa v. Sequenom*[3].

SUMMARY OF ARGUMENT

This case raises significant issues under both international and U.S. domestic patent law. Internationally, since 2012 the repeated denial by the U.S. Court of Appeals for the Federal Circuit of eligibility for all medical diagnostic patents that have come before it has created a categorical exclusion contrary to Article 27 of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), diagnostic methods of the present kind being held patentable in many countries and, for example, under the PCT International Search and Preliminary Examination Guidelines. Under U.S. domestic law, the most representative claims at issue here relate to subject matter falling unequivocally and not merely through the draftsman's art within three of the four eligible categories of Section 101, namely composition of matter, manufacture and process. The claimed subject matter therefore exhibits unusually strong positive statutory eligibility, which should not be denied by judicial exception as a claim to a natural law without issues arising concerning the balanced construction of Section 101 and the doctrine of separation of powers.

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2. Downloadable from https://cdn.patentlyo.com/media/2018/10/ATHENA.AmicusCIPA.pdf.

3. Downloadable from https://www.scotusblog.com/wp-content/uploads/2016/04/15-1182.amicus.final_.pdf.

ARGUMENT

I. The Federal Circuit decision conflicts with international treaties to which the United States is a party, as well as established international practice.

In their dissenting opinion concerning the petition for rehearing *en banc* of the panel decision, Judge Moore (joined by Judges O'Malley, Wallach, and Stoll), wrote that the Federal Circuit has turned this Court's decision in *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66 (2012), into a *per se* rule that diagnostic methods are ineligible under 35 U.S.C. § 101, citing eight successive Federal Circuit decisions denying the eligibility of such claims, including *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371 (Fed. Cir. 2015), *cert. denied*, 136 S.Ct. 2511 (2016). Although the same finding was not expressly made in the opinions of the other judges, in view of the consistency of approach adopted by the United States courts there can be little doubt that the application of this Court's *Mayo* decision has had a practical effect equivalent to such a *per se* rule.

As explained in our earlier brief (noted by Judge Newman in her dissenting opinion in the original panel decision), in its focus on judicial exception rather than substantive eligibility the Federal Circuit decisions have rendered ineligible many diagnostic method inventions considered eligible under the Patent Cooperation Treaty (PCT), the European Patent Convention (EPC), and the laws of many other countries. Hence, the scope of patent-eligible subject matter has become inconsistent with the obligations of the United States under Article 27 and

Note 5 of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) administered by the World Trade Organization (WTO).

Article 27.1 of TRIPS, entitled "Patentable Subject Matter," provides a complete code for patent eligibility that WTO member countries, including the United States, have agreed to respect. It states that "patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step, and are capable of industrial application." It further provides that patent rights should be enjoyed without discrimination as to the field of technology. In negotiating TRIPS, care was taken to ensure consistency with U.S. domestic law. Thus, Article 27 is to be read together with Note 5, which provides that the term "capable of industrial application" may be deemed to be synonymous with the term "useful".

Exclusions from patentability are covered by Articles 27.2 and 27.3 of TRIPS. They include the protection of "*ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment." Other exclusions also exist, but there is no provision for the exclusion of laws of nature, natural products, or processes involving natural products.

Patent-eligible treatment and diagnostic methods are discussed in the Patent Cooperation Treaty International Search and Preliminary Examination Guidelines ("Guidelines"), published by the World Intellectual Property Organization and last revised in June 2019. In the Guidelines, Chapter 9 is entitled: "Exclusions from, and Limitations of, International Search and International

Preliminary Examination." Paragraph 9.10 cites PCT Rules 39.1(iv) and 67.1(iv), which provide that international search and international preliminary examination are excluded for diagnostic methods but only when practiced on the human or animal body. The Guidelines explain that the treatment of blood for storage in a blood bank or diagnostic testing of blood samples is not excluded.

The patent-in-suit here, U.S. Patent No. 7,267,820 ("the '820 patent"), issued to inventors Vincent and Hoch, concerns a diagnostic method carried out on serum or plasma from patients and unequivocally complies with the Guidelines. Subject-matter eligibility for the same invention during its international search and examination was therefore never disputed. *See* International Publication WO 01/96601, subsequently granted in Europe as patent EP-B-1327147, and granted in Canada as patent 2,455,271. Likewise, the patent-in-suit in *Ariosa v. Sequenom* concerned a blood test that was deemed subject-matter eligible under these Guidelines.

There exists an urgent need for clarification and reconsideration of the scope of the *Mayo* decision, as evidenced by the views of Judges Moore, O'Malley, Wallach, and Stoll of the *per se* exclusion rule, and its conflict with recent foreign court decisions that consider such subject matter to be patent-eligible. For example, the Federal Court of Australia in *Sequenom, Inc. v. Ariosa Diagnostics, Inc.* [2019] FCA 1011, held that Sequenom's patent for methods of prenatal testing was both valid and infringed. The decision confirms that diagnostic methods involving the practical application of a natural phenomenon remain patent-eligible in Australia. The court reasoned that the claims of Sequenom's patent were not directed to a

natural phenomenon *per se*. Rather, the court determined that the claims defined the *practical application* of a natural phenomenon, namely, the presence of cffDNA in maternal blood. *See id.* at [485]. The opinion clearly answered the question of whether the claims resulted in something "made" by human action, finding that cffDNA could not be detected in maternal blood without human action. The discordant outcome in the corresponding case in the United States can be attributed to several factors, including the effective *per se* rule discussed above and the inappropriate claim construction that dissected the claims into their constituent parts, rather than considering the claim in its entirety, and that is also contrary to Australian practice. *See id.* at [522]. The Australian approach to determining patent-eligible subject matter is reflected in Judge Linn's concurring opinion in the Federal Circuit's panel decision in the corresponding U.S. case. *See Ariosa*, 788 F.3d at 1380.

Reconsideration of the ambit of the *ratio decidendi* in *Mayo* is needed to bring it within the canon of construction suggested by Justice Marshall in *Murray v. Schooner Charming Betsy*: Section 101 "ought never to be construed to violate the law of nations if any other possible construction remains." 6 U.S. 64, 188 (1804). This is especially compelling in relation to TRIPS, an international agreement for which the United States was a principal advocate. Therefore, the Court should seize upon this opportunity to explain that the *ratio decidendi* in *Mayo* is less broad than how it has been applied, and return the state of U.S. law regarding subject-matter eligibility closer to its position in 1995 when the TRIPS agreement came into effect.

II. Clarification is needed as to the relationship between the positive eligibility provisions of 35 U.S.C. § 101 and the judicial exceptions.

The urgency and importance of this need is demonstrated by substantial judicial inattention to the positive provisions of Section 101 in both the Federal Circuit's panel decision in this case and in the divided decision refusing rehearing *en banc*, in which all eleven judges unanimously conceded that the claimed subject matter ought to qualify as patent-eligible, but the six-judge majority considered itself bound by the sweeping scope of this Court's decision in *Mayo.* Indeed, only Judge Newman considered positive eligibility; the panel majority (Judges Lourie and Stoll) expressly declined to do so despite their knowledge that the claimed subject matter involved the binding of molecules during a sequence of chemical manipulations. *See Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC*, 915 F.3d 743, 750 n.3 (Fed. Cir. 2019). At least since *Mayo* the Federal Circuit has in its eligibility decisions focused exclusively on judicial exception and given no attention to the substantive provisions of the statute and its jurisprudence.

We submit that the over extension of the suggestion in *Mayo*, derived from earlier decisions of this Court, that laws of nature should be treated as "a familiar part of the prior art" has created much of the subsequent difficulty in determining the type of diagnostic claim that is eligible for patenting. The view is inconsistent with this Court's holding in *Diamond v. Diehr*, 450 U.S. 175 (1981), in which the Arrhenius equation, though not patentable in isolation, was held to contribute to a patent-eligible method. In that case, Justice Rehnquist quoted Justice Stone in *Mackay Radio & Telegraph Co. v. Radio Corp. of*

America, 306 U.S. 86, 94 (1939): "While a scientific truth, or the mathematical expression of it, is not a patentable invention, a novel and useful structure created with the aid of knowledge of scientific truth may be."

To illustrate the problem, and as discussed in more detail in the section below, the law of nature forming the basis of the '820 patent was the relationship between the presence of autoantibodies to the protein muscle specific tyrosine kinase (MuSK) in bodily fluid and neurotransmission or developmental disorders. While that discovery is not, in itself, patent-eligible, it was not part of the prior art, as it was unknown to science until the publication by Professors Vincent and Hoch and described in the '820 patent. Similarly, the formation of an antibody/^{125}I-labelled MuSK epitope was not "a familiar part of the prior art" or "well-understood, routine, conventional activity previously engaged in by researchers in the field," and neither was the further step of precipitating the antibody/^{125}I-labelled MuSK/Sheep IgG triple complex. Instead, these manipulations were new to science, involving new molecules and forming part of a novel and useful diagnostic method. Although immunoassay techniques such as ELISA and radioimmunoassay were known, as disclosed in the '820 patent, the individual steps employed were novel.

III. The fact pattern in this case is consistent with substantive eligibility, and provides an opportunity for restoration of balance.

Athena Diagnostics is the exclusive licensee of the '820 patent, directed to methods for diagnosing neurological disorders by detecting autoantibodies to a protein called muscle-specific tyrosine kinase (MuSK). *Athena*, 915 F.3d

at 746. In particular, the methods are useful for diagnosing myasthenia gravis (MG), which is a neurological disorder in which patients experience muscle weakness and symptoms including drooping eyelids, double vision, and slurred speech.

The facts of this case provide an opportunity for this Court to clarify that the analysis of subject-matter eligibility under Section 101 should focus on the question of what is eligible under the language of the statute, rather than what may be ineligible under a judicial exception. The claims at issue in this case touch on three of the four types of patent-eligible inventions recited in the statute.

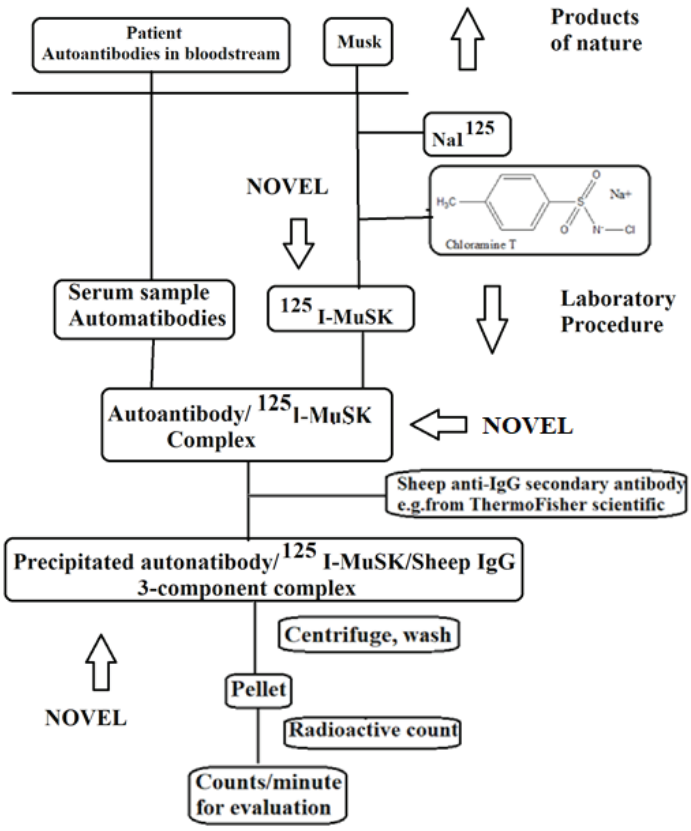
Dependent claim 9 of the '820 patent was the focus of the Federal Circuit's panel majority. For clarity, that dependent claim, when redrafted to include all the limitations of the claims from which it depends, would recite:

> 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, wherein said label is a radioactive label and is ^{125}I, 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).

The above method can be depicted with reference to the following diagram, which identifies the two molecules that occur in nature above the top-most horizontal line. All other molecules and products that are created by human intervention in a laboratory procedure are below the horizontal line:

METHOD OF CLAIMS 7-9



As illustrated, three molecular structures new to science are created by the following three chemical reactions:

> (1) MuSK + $Na^{125}I \rightarrow {}^{125}$I-MuSK;
> (2) Autoantibody + ^{125}I-MuSK → Autoantibody/^{125}I-MuSK; and
> (3) Autoantibody/^{125}I-MuSK + Sheep IgG → Autoantibody/^{125}I-MuSK/Sheep IgG.

The panel majority correctly identified the relevant natural law as the correlation between the presence of naturally-occurring MuSK autoantibodies in bodily fluid and MuSK-related neurological diseases such as MG. *See Athena*, 915 F.3d at 750. However, the panel majority ought to have identified the focus of the claim in terms of the procedural steps required to be carried out and new materials produced.

While the three novel structures were discussed at the district court and raised again during the Federal Circuit appeal, the panel majority dismissed their relevance to the question of subject-matter eligibility, stating:

> We note that the district court held that the "focus of the claims" was the binding of MuSK to MuSK antibodies in bodily fluid. Decision, 275 F. Supp. 3d at 310. Our cases have not described a claim to the binding of two molecules during a sequence of chemical manipulations (here, after MuSK labelling and before immunoprecipitation) as a claim to a natural law, even if such binding occurs according to natural laws. We need not resolve

> that issue here, as we agree with Mayo's identification of the natural law.

Athena, 915 F.3d at 750 n.10.

The panel decision correctly acknowledged that the claimed method starts with a sample of bodily fluid, implicitly in a laboratory reaction tube. The novel ^{125}I-MuSK molecule is added to the sample in the reaction tube. The ensuing reaction, which forms a labelled complex, is not a natural event occurring *in vivo*, but is brought about by the hand of man within the reaction tube.

Although immunoprecipitation was a known technique, it had not been reported in relation to MuSK prior to the '820 patent. The resulting molecular structure, consisting of IgG anti-MuSK-autoantibody/^{125}I-MuSK/ sheep IgG secondary antibody, which is recovered as a pellet by centrifugation and washing, is *prima facie* a novel, non-natural complex because its three chemically linked constituents, allowing the claimed method to be performed, had not been reported as having been brought together prior to the invention. Further, these elements of the claim are both useful, by virtue of radioactive labelling, and subject-matter eligible as a "composition of matter" under Section 101. Nothing in this claim can be considered a mere product of skilled claim drafting; rather, the claim utilizes several non-naturally occurring products of human ingenuity having a distinctive name, character, and use. Any contrary holding would conflict with Supreme Court authority. *See, e.g., Hartranft v. Wiegmann*, 121 U.S. 609, 615 (1887), quoted in *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980) and *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S.

576 (2013). Because the claim recites novel molecular structures such as ^{125}I-MuSK and the triple antibody, which are also patent-eligible compositions of matter, a method such as that recited in claim 9 that employs such molecules as part of an ordered combination of steps cannot logically be treated as ineligible subject matter. Moreover, detection of the radioactive label recited in the claims requires specific laboratory procedures involving sophisticated electronic apparatus.

Judge Chen, concurring in the denial of *en banc* review of this case, highlighted the emergent problem in the analytical framework that discounts the recitation of patent-eligible steps or species and instead focuses solely on an underlying law of nature to render the result an ineligible combination:

> When it comes to applying the judicial exceptions, it bears noting that the *Mayo* analytical approach is considerably harder to apply consistently than the *Diehr* framework, and more aggressive in its reach. Consider the claim in *Mayo*. If that claim had recited just the single step of administering a synthetic drug to a patient, that single-step claim would be patent-eligible, but lack novelty under § 102. And if that claim added a second step for determining the subsequent level of a non-naturally occurring metabolite in a patient, that claim also would pass muster under § 101, but lack novelty. But when the claim further recites a relationship between a metabolite level and its efficacy in a patient, that claim suddenly would be invalid under § 101 for violating the

> law of nature exception. In other words, steps 1 and 2 now get pushed aside and declared insignificant, and the last step is designated as the "focus" of the claim, *i.e.*, the heart of the invention. The notion that adding claim language can convert an otherwise patent-eligible claim into a patent-ineligible claim is counterintuitive and a very difficult thing to explain to 8,000 patent examiners.

Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC, 927 F.3d 1333, 1348 (Fed. Cir. 2019) (Chen, J., concurring).

The problem shines brightly in this case because of the fundamental differences between Athena's method and the method at issue in *Mayo*. In *Mayo*, the claim was directed to analysed levels of a metabolite formed *in vivo* and that were applied to define upper and lower levels of a therapeutic window for thiopurine drugs, whereas Athena's claims include new materials formed *in vitro* as part of a multi-step laboratory test procedure providing new benefits for an identifiable (and previously non-diagnosable) group of patients suffering from myasthenia gravis. The claimed method in *Mayo* is more easily alleged to lack novelty in either its starting material or the chemical entities recited in the claim, and left to rely only on the novelty of the ineligible information relating to the newly defined therapeutic window.

It is apparent that the alleged conflict between positive statutory eligibility as composition of matter features and judicial exception as a claim to a natural law was a significant and highly relevant legal issue that cried out

for resolution, not least because it involved the doctrine of separation of powers. The need to interpret a statute as written and the inappropriateness of rewriting it were recently emphasized by Justice Kavanaugh in *Henry Schein, Inc. v. Archer & White Sales, Inc.*, 586 U.S. ___, 139 S.Ct. 524 (2019). But the need to take positive provisions into account can be traced to older authority. For example, in *Bilski v. Kappos*, Justice Kennedy explained: "Concerns about attempts to call any form of human activity a 'process' can be met by making sure the claim meets the requirements of § 101." 561 U.S. 593, 603 (2010).

In addition, the overall claimed method falls as a matter of substance and not mere outward appearance within the Section 101 category of "process," the water-soluble autoantibody starting material being transformed or reduced to the water-insoluble three-component complex, which is a different state or thing.

The majority in *Diehr* summarized its conclusion that the claimed rubber-curing method involving the Arrhenius equation was patent-eligible in the following terms:

> We view respondents' claims as nothing more than a process for molding rubber products, and not as an attempt to patent a mathematical formula. We recognize, of course, that, when a claim recites a mathematical formula (or scientific principle or phenomenon of nature), an inquiry must be made into whether the claim is seeking patent protection for that formula in the abstract . . . . On the other hand, when a claim

> containing a mathematical formula implements or applies that formula in a structure or process which, when considered as a whole, is performing a function which the patent laws were designed to protect (e.g., transforming or reducing an article to a different state or thing), then the claim satisfies the requirements of § 101. Because we do not view respondents' claims as an attempt to patent a mathematical formula, but rather to be drawn to an industrial process for the molding of rubber products, we affirm the judgment of the Court of Customs and Patent Appeals.

450 U.S. at 192-3.

No valid distinction can be discerned between the rubber molding process of *Diehr* and the diagnostic method of *Athena*. The claimed process equally transforms the initial autoantibody into a different state or thing. The method of claim 9 cannot be regarded as an attempt to patent the correlation that was held to be a natural law, especially as it covers only a preferred one of two alternative detection methods disclosed in the patent. The diagnostic method is equivalent to "an industrial process" because it is commercialized on a mass-scale by medical diagnostic companies.

CONCLUSION

For the reasons stated above, the petition for a writ of certiorari should be granted.

Respectfully submitted,

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