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 IN OPPOSITION

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QUESTION PRESENTED

Whether patent claims to a method of diagnosis are ineligible under 35 U.S.C. § 101 where the claims employ admittedly "standard" and "known" laboratory techniques to detect the presence of an autoantibody that, when present, correlates to a particular disease.

RULES 24(B) AND 29.6 STATEMENT

All parties are identified in the caption of this brief. Respondent Mayo Collaborative Services, LLC, a subsidiary of Mayo Clinic, is a for-profit Minnesota corporation that provides reference laboratory services under the name Mayo Medical Laboratories. Respondent Mayo Clinic is a non-profit organization. No publicly held company owns 10% or more of the stock of either respondent.

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INTRODUCTION

Patent claims directed to a natural law that employ only conventional and routine activities to detect that law are not patent eligible. *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66, 73 (2012). That rule disposes of this case, as the district court, appellate panel, and *en banc* Federal Circuit each concluded.

After years of the lower courts neglecting this rule, this Court clarified this requirement just seven years ago in *Mayo*, endorsing "a bright-line prohibition against patenting laws of nature . . . ." *Id.* at 89. *Mayo* holds that "a process reciting a law of nature" is not patentable "unless that process has additional features that provide practical assurance that the process is more than a drafting effort designed to monopolize the law of nature itself." *Id.* at 77-78.

Mayo set forth a two-part framework for assessing eligibility that this Court endorsed again in *Alice Corp. v. CLS Bank Int'l*, 573 U.S. 208, 217-18 (2014). Under that framework, a court first determines if the claim is directed to a law of nature and, if so, then asks if the claim contains an "inventive concept," or patent-eligible application of the law of nature. *Id.* This framework reinforces that "[g]roundbreaking, innovative, or even brilliant discovery does not by itself satisfy the § 101 inquiry." *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576, 591 (2013).

Since that time, despite ample opportunity, Congress has not acted to change the *Mayo/Alice* framework, which, despite Athena's protestations, only allows patent challengers to assert what the law always had been—that natural laws are for all to use, and may not be patented, whether broadly or narrowly, by

appending the natural law to an otherwise conventional process.

Nothing about the facts of this case warrant revisiting this Court's eligibility framework or reversing the decision below.

Athena's '820 patent discloses the discovery of a natural law: a previously unknown reason why some patients suffer from disease—they generate autoantibodies that bind to a protein in the body called MuSK, which itself had previously been known to exist.

The patent fails, however, to claim any innovative application of that natural law. Rather, the patent generically claims any way of detecting the problem autoantibodies to diagnose disease, and then itemizes two particular but admittedly "known" techniques for doing so. One such known technique is described by the claims Athena emphasizes here. As the patent confesses, scientists had long used that technique to detect a different autoantibody already known to cause the very disease central to the inventors' newfound natural law.

The relevant patent claims thus do no more than enable diagnosis by swapping out one natural law for another in a well-defined, routine activity for detecting autoantibodies. In other words, they recite nothing more than conventional or obvious pre-solution activity, and so lack the type of inventive concept this Court has long required. The claims thus run afoul of *Mayo* and are not patent eligible.

Athena, amici, and various Federal Circuit judges disapprove of this outcome. They plead that all medical diagnostics *should* be patent eligible. They posit that patent claims making use of man-made materials; or that require multiple laboratory-based steps,

however conventional; or that detect something no one had previously looked for *should* be patent eligible. And they speculate, without any record support, that scientific research and the public health will suffer if all medical diagnostic methods are not patent eligible, even in the face of dramatically increased investment in diagnostics since *Mayo*.

But these are all policy concerns for Congress to examine and address; this Court's precedent, including *Mayo*, has already considered each one.

There is thus no work for this Court to do here. This Court has already interpreted § 101 of the Patent Act and laid down a clear boundary around what is and is not patent eligible. Athena's patent claims fall squarely on the ineligible side of that boundary. Any further action regarding the patentability of medical diagnostic claims such as Athena's that employ conventional, known techniques should and does rest with Congress.

STATEMENT

I. THE '820 PATENT COVERS OBSERVING A NATURAL LAW USING KNOWN TECHNIQUES

A. The Inventors Uncovered a Natural Law: The Correlation Between Autoantibodies to a Known Protein (MuSK) and a Known Disease (*Myasthenia Gravis*)

Myasthenia gravis, or MG, is a neuromuscular disorder characterized by the weakness and rapid fatigue of skeletal muscles. C.A.J.A. 43 (1:13-23); App. 3a. In the 1960s, decades before the '820 patent inventors filed their first patent application in 2000, re-

searchers found that a type of naturally occurring antibody directed against a protein called the acetyl choline receptor (AChR) caused MG. C.A.J.A. 35, 43 (1:24-36). These types of antibodies, which recognize naturally occurring bodily substances as foreign antigens, are known as autoantibodies. C.A.J.A. 43 (1:42-45). MG was thus identified as autoimmune in origin.

The '820 patent teaches that before the inventors' research project began, clinical diagnosis of MG could largely be confirmed by testing patient fluid samples for the presence of AChR autoantibodies. The patent describes using a technique known as immunoprecipitation to do so. That involves incubating AChR labeled with a radioactive isotope ("radiolabeled AChR") with a patient sample and then detecting whether the so-labeled AChR had bound to any AChR autoantibodies present in the fluid. The culprit AChR autoantibodies appeared in about 80% of patients with MG. C.A.J.A. 43 (1:34-36). This diagnostic work was done in the 1970s and 1980s. *See* C.A.J.A. 48 (at listed references 4 and 6); *see also* C.A.J.A. 44 (4:10-12 (citing references 4 and 6)).

Pinpointing the cause of the remaining 20% of MG cases was the research interest of the named inventors of the '820 patent. According to the patent, the inventors screened the plasma of patients who lacked AChR autoantibodies to look for alternative autoantibodies that might cause disease. C.A.J.A. 43 (1:36-53). Their research showed that many such patients had autoantibodies directed against a different protein receptor in the body called MuSK (muscle-specific tyrosine kinase). Though the MuSK protein receptor had been known since the mid-1990s, it had not yet been linked to disease. C.A.J.A. 43 (2:51-60).

Taking the patent at its word, the inventors thus discovered a pre-existing, natural relationship between a naturally occurring bodily substance—autoantibodies that bind to MuSK—and the incidence of MG and other MuSK-related disorders. That is a natural law.

B. The Patent Describes Only Known Ways to Observe the Natural Law

The '820 patent issued in 2007, well before *Mayo*. Perhaps because of this, the patent gives little consideration to that decision's inventive concept inquiry. Instead, the patent's goal is to monopolize the diagnosis of MG and other MuSK-related diseases based on use of the newfound natural law. How? By detecting the MuSK autoantibodies that are central to observing it. C.A.J.A. 43-44 (2:61-3:3, 3:25-32).

Importantly, the '820 patent describes only admittedly "known" ways to detect MuSK autoantibodies, including the same immunoprecipitation method previously used to detect AChR autoantibodies and diagnose MG. As the patent explains, "*[t]he actual steps of detecting autoantibodies in a sample of bodily fluids may be performed in accordance with immunological assay techniques* ***known per se in the art***." C.A.J.A 44 (3:33-35) (emphases added).

After directing the reader to use these "known" techniques, the patent describes two of them in detail: the ELISA and immunoprecipitation techniques. ELISA involves formation of a complex between MuSK, MuSK autoantibodies, and a secondary antibody that can be readily detected. C.A.J.A. 44 (3:36-65). Immunoprecipitation is the same technique as that used to detect AChR autoantibodies, except

MuSK replaces AChR. It involves formation of a complex between labeled MuSK and MuSK autoantibodies, separating (immunoprecipitating) the complex from solution, and then detecting the label on MuSK to signal the presence of the MuSK autoantibodies. C.A.J.A. 44 (3:66-4:12). The patent characterizes immunoprecipitation, together with a form of radioactive labeling using iodine called iodination, as "*standard techniques in the art, the details of which may be found in references*." C.A.J.A. 44 (4:10-12) (emphasis added).

Central to both disclosed techniques is the natural binding of MuSK autoantibodies to MuSK. That inherent physical relationship, which the petition wrongly characterizes (at 2) as a "chemical reaction[]," is part and parcel of the inventors' newfound natural law.

C. The Patent Covers All Diagnoses Involving the Newfound Natural Law

Collectively, the '820 patent claims cover all methods of diagnosing any MuSK-related diseases by detecting the presence of MuSK autoantibodies and thereby observing the newfound natural law.

Claims 1 and 12 are broadest and generically cover diagnosis of a MuSK-related disease by detecting MuSK autoantibodies in bodily fluid. C.A.J.A. 48-49. Claims 10 and 11 relate back to claim 1, and merely add a recitation of which particular diseases are diagnosed. *Id.* Claim 2 also relates back to claim 1, and adds detection of MuSK autoantibodies after incubating MuSK in a bodily fluid, thus implicating the natural, physical binding between the two. C.A.J.A. 48. Together, these five claims preempt all ways—known and unknown as of the patent's filing

date—of diagnosing MuSK-related disease by observing the MuSK autoantibodies central to the newfound natural law.

Claims 3 through 9 "narrow" these broad claims by covering the two "standard" and "known" techniques the patent describes. Claims 3 through 6 cover the previously used ELISA technique, C.A.J.A. 48; C.A.J.A. 44 (3:36-65), while claims 7 through 9 cover the immunoprecipitation technique, C.A.J.A. 48-49; C.A.J.A. 44 (3:66-4:12). Notably, for all of Athena's focus on MG, none of these claims is limited to just that disease; rather, they extend to diagnosis of any MuSK-related disease.

Claim 9, the focus of the petition, embodies the newfound natural law with the "known" immunoprecipitation technique. Specifically, the claim requires use of MuSK that is labeled with radioactive iodine, ^{125}I, and subsequent detection of any MuSK-autoantibody complexes that form after the iodine-labeled MuSK is mixed with a patient sample. C.A.J.A. 48-49. As noted, the patent describes both immunoprecipitation and iodination as "standard techniques in the art." C.A.J.A. 44 (4:10-4:12).[1]

All told, neither the '820 patent nor its claims offer any contribution to the field of medical diagnostics aside from reporting the newfound natural law. While Athena strains to argue otherwise, the record is estab-

[1] The petition describes (at 7) claim 9 as requiring the use of a secondary antibody to achieve immunoprecipitation. That is wrong; neither claim 9 nor the patent's description of immunoprecipitation is so specific. C.A.J.A. 44 (3:66-4:12); C.A.J.A. 48-49; *see also* App. 11a.

lished; the '820 patent employs only standard techniques scientists and clinicians had employed for decades to detect autoantibodies before the inventors uncovered their autoantibody-related natural law.

II. WITHOUT ANY EVIDENT "CONFUSION" OR DIFFICULTY IN APPLYING *MAYO*, THE LOWER COURTS FOUND ATHENA'S CLAIMS INELIGIBLE

A. The District Court Dismissed Athena's Complaint in Reliance on *Mayo*

Mayo offers medical diagnostic testing for Mayo Clinic and others through Mayo Medical Laboratories, a global reference laboratory that provides diagnostic tests across a wide range of health care subspecialties. Two of those tests relate to the diagnosis of MG. In the complaint, Athena accused these tests of infringing the '820 patent.

Mayo moved to dismiss the complaint under Fed. R. Civ. P. 12(b)(6), raising the § 101 eligibility issue for each claim in the patent. Mayo argued that the '820 patent's claims were directed to the inventors' newfound, but ineligible, natural law, and employed only techniques commonly used in the field, so lacked an inventive concept.

Citing *Mayo,* the district court granted that motion based on the pleadings, the patent, and Athena's additional admission that using labels, including ^{125}I, was known in the art. C.A.J.A. 5-12; C.A.J.A. 313-14. The district court's judgment reached only claims 6-9; apparently unwilling to defend their validity, Athena chose to drop claims 1-5 and 10-12 during the proceedings.

B. The Federal Circuit Affirmed, Also Relying on *Mayo*

The Federal Circuit affirmed the district court's judgment dismissing Athena's complaint in a 2-1 decision. The court faithfully applied the two-step framework set forth in *Alice* and *Mayo* to reach that decision.

Under the first part of the test, the Federal Circuit found the claims were "directed to" a law of nature. The court first identified the relevant natural law as "the correlation between the presence of naturally-occurring MuSK autoantibodies in bodily fluid and MuSK related neurological diseases like MG." App. 9a. It then reviewed claims 7-9 and concluded they "involve[d] both the discovery of a natural law and certain concrete steps to observe its operation." App. 11a. But, it found the claims' steps "only apply conventional techniques to detect the natural law." *Id.* Accordingly, applying *Mayo*, the court concluded "that claims 7-9 are directed to a natural law because the claimed advance was only in the discovery of a natural law, and that the additional recited steps only apply conventional techniques to detect that natural law." *Id.*

The court relied on the specification in making that finding, noting that the inventors described their discovery only in terms of the natural correlation between autoantibodies and presence of MuSK-related disease. App. 12a. And when discussing the "claimed concrete steps for observing the natural law," the specification describes them as "known per se in the art" and "standard techniques in the art." *Id.* (quoting '820 patent at 3:33-37, 4:10-12). The court concluded that the patent itself "describes the claimed invention principally as a discovery of a natural law, not as an

improvement in the underlying immunoassay technology." *Id.*

The court took pains to distinguish Athena's claims, "which recite a natural law and conventional means for detecting it," from other claims that may recite "applications of natural laws, which are patent-eligible," such as new methods of treating a disease. App. 14a. The court explained that "[c]laiming a natural cause of an ailment and well-known means of observing it is not eligible for patent because such a claim in effect only encompasses the natural law itself." *Id.* In contrast, "claiming a new treatment for an ailment, albeit using a natural law, is not claiming the natural law." *Id.*

Having found Athena's claims directed to a natural law, the court moved on to the second part of the framework—"whether the limitations of the claim apart from the law of nature, considered individually and as an ordered combination, 'transform the nature of the claim into a patent-eligible application.'" App. 8a (quoting *Mayo*, 566 U.S. at 78). It readily found they did not, because the claimed steps "only require standard techniques to be applied in a standard way." App. 16a.

For this analysis, the court again relied on the patent's description of the claimed iodination and immunoprecipitation steps as "standard techniques." *Id.* The court concluded that, "[b]ecause the specification defines the individual immunoprecipitation and iodination steps and the overall radioimmunoassay as conventional techniques, the claims fail to provide an inventive concept." *Id.* Put another way, "the recited steps here were conventional both as an ordered combination and individually." App. 17a.

The Federal Circuit also rejected Athena's arguments that the "newness" of the claimed methods, and that the use of man-made materials in the claimed methods, are enough to make them eligible. As to the first argument, the court invoked *Mayo* to explain that, "to supply an inventive concept the sequence of claimed steps must do more than adapt a conventional assay to a newly discovered natural law; it must represent an inventive application beyond the discovery of the natural law itself." App. 18a. As to the second argument, the court concluded that "appending labeling techniques to a natural law does not provide an inventive concept where, as here, the specification describes 125I labeling as a standard practice in a well-known assay." *Id.*

The Federal Circuit's opinion thus applied *Mayo* in a straightforward manner to reach the conclusion that Athena's claims "recite only a natural law together with conventional steps to detect that law, [so] they are ineligible under § 101." App. 22a.

C. The Federal Circuit Denied Athena's Petition for Rehearing

The Federal Circuit then denied Athena's petition for rehearing by a 7-5 vote. The *en banc* majority, like the panel majority, properly recognized that this case represents a straightforward application of *Mayo*.

As the opinion authored by Judge Lourie succinctly explained, the ineligibility outcome under this Court's precedent is clear:

> Under Supreme Court precedent, I do not believe that specific yet purely conventional detection steps can impart eligibility to a claim that otherwise only sets forth what the Court

> has held is a natural law. That is the situation presented in *Ariosa*, *Cleveland Clinic*, and now *Athena*. Accordingly, as long as the Court's precedent stands, the only possible solution lies in the pens of claim drafters or legislators. We are neither.

App. 61a (Lourie, J., concurring).

Judge Lourie's opinion also correctly pointed out that the Federal Circuit's case law post-*Mayo* has been consistent, echoing the panel majority's analysis: "However, our cases are consistent. They have distinguished between new method of treatment claims and unconventional laboratory techniques, on the one hand, and, on the other hand, diagnostic methods that consist of routine steps to observe the operation of a natural law." *Id.*

The other opinions supporting denial of rehearing also recognize that under this Court's precedent Athena's claims cannot stand. For example, Judge Chen's opinion states that "the Supreme Court has made clear that detecting a law of nature (without more than conventional steps for accessing the law of nature) does not qualify as a patent-eligible application of a law of nature." App. 90a. His opinion goes on to explain that Athena's claims do exactly that—recite an "association between the antibody and the disorder" along with "label-adding and immunoprecipitating steps [that] are conventional, standard techniques in the art of detecting the presence of a law of nature such as a protein." App. 92a.

To be sure, the opinions in favor of denying rehearing express reservations about this Court's *Mayo* decision, and their authors suggest they may have ruled differently if they could have written on a "clean

slate." App. 59a. But they recognize that precedent plainly controls, and that any attempt to change the result in this case would be asking this Court to "reconsider" the breadth of the decision that it made—with full understanding of the issues and ample amicus participation—just seven years ago. App. 68a.

Indeed, even many of the dissenting judges recognize that *Mayo* has been applied consistently. They are just dissatisfied that this consistent application has found certain "diagnostic" claims to come before the court ineligible. App. 96a-99a. They set forth various purported policy justifications for changing the law to allow for the eligibility of these types of claims. But notably, nothing in the record of this case substantiates the expressed concerns, particularly in relation to stifling innovation.

REASONS FOR DENYING THE PETITION

I. THE COURT SHOULD DECLINE ATHENA'S INVITATION TO CHANGE HOW IT INTERPRETS § 101

The crux of Athena's petition is that because its patent claims cover medical diagnostics they deserve special treatment. They do not. This Court's recent decisions on the judicial exceptions to patent eligibility wisely lay out a framework that applies to all patents regardless of technology area. The Court set forth that framework against the backdrop of over 150 years of precedent, and with due knowledge of the policy considerations in play. The Federal Circuit has applied *Mayo* consistently, so no intervention by this Court is warranted.

A. This Court Has Already Clarified the Eligibility Considerations for Claims Involving a Natural Law

This Court in *Mayo* and *Alice* confirmed its longstanding interpretation of § 101 of the Patent Act as including implicit exceptions: laws of nature, natural phenomena, and abstract ideas are not patentable. *Alice*, 573 U.S. at 216; *Mayo*, 566 U.S. at 70-71. It also set forth a two-part framework to distinguish patents that claim a law of nature from those that claim patent-eligible applications of it. *Alice*, 573 U.S. at 217.

Step one asks whether the claim is directed to an ineligible law of nature. *Id.* If the answer is yes, step two asks whether, considered both individually and as an ordered combination, "the additional elements 'transform the nature of the claim' into a patent-eligible application." *Id.* (quoting *Mayo*, 566 U.S. at 78). The step two analysis looks for an "inventive concept," or some claim element or elements "'sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the [ineligible law of nature] itself." *Id.* at 217-18 (quoting *Mayo*, 566 U.S. at 72-73) (alteration in original). "[S]imply appending conventional steps, specified at a high level of generality" to a law of nature will not make it patentable. *Mayo*, 566 U.S. at 82; *see also Alice*, 573 U.S. at 222.

This Court applied the two-part framework in *Mayo* to process claims involving a natural law and found them ineligible. There the claims involved the steps of administering a thiopurine drug and later determining the level of the drug's metabolite (the substance formed by the body in digesting the drug) in the patient, and additionally recited precise correlations between the metabolite level observed and a need to

change drug dose. *Mayo*, 566 U.S. at 74-75. This mattered because people metabolize drugs at different rates, so the level of metabolite in the blood was the important measurement. The claims stated that *if* the level of metabolite after dosing exceeds a certain level, "*then* the administered dose is likely to produce toxic side effects." *Id.* at 77. The Court explained that although "it takes a human action (the administration of a thiopurine drug) to trigger a manifestation of this relation in a particular person, the relation itself exists in principle apart from any human action." *Id.* The relation resulted from the natural process by which the human body metabolizes thiopurine drugs, and constituted a natural law. *Id.*

Having concluded the claims involved a natural law, the *Mayo* Court asked, "What else is there in the claims before us?" *Id.* at 78. Beyond the correlations, the claims recited "an 'administering' step, a 'determining' step, and a 'wherein' step." *Id.* Although those steps are not natural laws, the Court concluded "neither are they sufficient to transform the nature of the claim" beyond ineligible subject matter. *Id.* The Court crisply explained the rationale:

> To put the matter more succinctly, the claims inform a relevant audience about certain laws of nature; any additional steps consist of well-understood, routine, conventional activity already engaged in by the scientific community; and those steps, when viewed as a whole, add nothing significant beyond the sum of their parts taken separately. For these reasons we believe that the steps are not sufficient to transform unpatentable natural correlations into patentable applications of those regularities.

Id. at 79-80.

Mayo thus makes clear that claims in which a natural law is merely observed using established techniques are not patent eligible. This was not new law.

In *Parker v. Flook*, 437 U.S. 584 (1978), the Court found ineligible claims that recited a process for updating an alarm limit for use in common chemical processes, employing a mathematical formula. The method consisted of three steps: measuring a variable in the chemical process, such as temperature; using an algorithm to calculate what the alarm limit should be; and adjusting the alarm limit to the new value. The algorithm was new, but the other steps were "well known." *Id.* at 585-86, 594. The Court explained that, to allow "conventional or obvious" post-solution activity to make a process based on natural laws patentable would "exal[t] form over substance." *Id.* at 590. Because "the application, considered as a whole, contain[ed] no patentable invention," consisting only of "well known" steps plus a natural law, it did not satisfy § 101. *Id.* at 594; *see also id.* (a natural phenomenon "cannot support a patent" absent "some other inventive concept in its application"); *Alice*, 573 U.S. at 222; *Mayo*, 566 U.S. at 81-82.

The fact that a claim involves a natural law is not in and of itself fatal, as *Mayo*'s framework makes clear. This Court's decision in *Diamond v. Diehr*, 450 U.S. 175 (1981), illustrates why not. There, this Court found eligible claims to a detailed step-by-step method that used the Arrhenius equation to solve a significant industrial problem with curing rubber. The claimed method required continuously monitoring temperature inside a mold and using that data to open the mold only when the rubber was perfectly cured, which amounted to "a result heretofore unknown in the art."

Id. at 177-79, 184, 193 n.15. The method confined use of the known Arrhenius equation in a "process which, when considered as a whole, is performing a function which the patent laws were designed to protect"—transforming raw rubber into precision molded products. *Id.* at 184, 192. Put another way, the *Diehr* claims used a natural law to achieve an improved outcome with particularized features (*e.g.*, continuously monitoring temperature); they were not simply directed to the equation itself. *Alice*, 573 U.S. at 223; *Mayo*, 566 U.S. at 80-81.

The Court's decision is *Bilski v. Kappos*, 561 U.S. 593 (2010), is consistent with these principles. The Court again emphasized that the addition of "token postsolution components" to an unpatentable concept do not "make the concept patentable," or demonstrate that the inventor created a "new and useful process" within the language of § 101. *Id.* at 612. Process claims that recite an unpatentable concept and tack on only conventional activities are not eligible.

What Athena seeks through *certiorari* is either a change in the settled eligibility framework that would make patent-eligible any use of a newly discovered natural law, or a reinterpretation of § 101 that guarantees eligibility for all medical diagnostic methods. But that has never been the law, as this Court has long recognized that "[g]roundbreaking, innovative, or even brilliant discovery does not by itself satisfy the § 101 inquiry." *Myriad*, 569 U.S. at 591. And there is a high bar for seeking to have this Court "reinterpret" a statute that it has already interpreted. "[C]onsiderations of *stare decisis* have added force in statutory cases because Congress may alter what we have done by amending the statute." *Patterson v. McLean Credit Union*, 491 U.S. 164, 175 n.1 (1989); *see also John R.*

Sand & Gravel Co. v. United States, 552 U.S. 130, 139 (2008). As noted in the petition and as discussed further below in Section III.A, Congress is already considering amending § 101, making the considerations of stare decisis even more sound.

B. The Federal Circuit Has Applied this Court's Eligibility Precedent Consistently Since *Mayo*

Not only has this Court already interpreted § 101, leaving no reason to "reinterpret" it, the Federal Circuit has had no problems applying *Mayo* consistently, despite Athena and amici's repeated suggestions otherwise. And while some Federal Circuit judges may not always be pleased with the outcome of each case, that dissatisfaction does not mean this Court's articulation of law is too confusing or difficult to apply. The Federal Circuit's decisions bear this out.

When faced with claims reciting the use of conventional steps to observe a natural law, the Federal Circuit has consistently found ineligibility, as *Mayo* requires. For example, in *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371 (Fed. Cir. 2015), *cert. denied*, 136 S. Ct. 2511 (2016), the Federal Circuit found ineligible claims directed to a method for detecting paternally inherited cffDNA in maternal plasma by an amplification procedure. Based on the *Mayo* standard, the court concluded that the claims were directed to a natural law—the presence of cffDNA in maternal plasma. *Id.* at 1376. The specification confirmed that the claimed steps of "preparation and amplification of DNA sequences in plasma or serum were well-understood, routine, conventional activities." *Id.* at 1377. The court thus explained that, under *Mayo*, "[t]he method at issue here amounts to a general instruction to doctors to apply routine, conventional techniques

when seeking to detect cffDNA," a natural phenomenon, and were ineligible. *Id.*

In *Genetic Technologies, Ltd. v. Merial, LLC*, 818 F.3d 1369 (Fed. Cir. 2016), *cert. denied*, 137 S. Ct. 242 (2016), the Federal Circuit found ineligible claims directed to detecting coding sequences of a gene and reciting the physical steps of DNA amplification and analysis. Again, the claims were directed to a law of nature—the relationship between coding and non-coding DNA sequences—and lacked an inventive concept because the specification confirmed that the claimed steps were "standard experimental techniques." *Id.* at 1375-77. The claims did nothing to apply the natural law; instead, they claimed a method for observing it, as in *Mayo* and *Ariosa*, and again here. *See also Roche Molecular Sys., Inc. v. Cepheid*, 905 F.3d 1363 (Fed. Cir. 2018) (finding ineligible claims reciting methods to use of DNA primers because use of the standard technique of PCR did not add inventive concept to natural law).

For similar reasons, in *Cleveland Clinic Foundation v. True Health Diagnostics, LLC*, 859 F.3d 1352, 1360-62 (Fed. Cir. 2017), *cert. denied*, 138 S. Ct. 2621 (2018), the Federal Circuit found ineligible claims directed to "methods for observing [a] law of nature" where all the steps related to known detection techniques.

But these outcomes of course do not mean that the Federal Circuit has interpreted *Mayo* as commanding that all methods that incorporate a natural law are *per se* ineligible. The Federal Circuit recognizes *Mayo* and *Alice* require application of the two-step framework to analyze how the natural law is used within a given claim. That court has painstakingly conducted

that analysis when faced with method claims that implicate a natural law. It has concluded in some cases that claims recite eligible subject matter where they did something other than recite the use of standard techniques to observe a natural law.

For example, in a situation where the claimed steps, taken together, recite a new laboratory technique that makes use of a natural law, the Federal Circuit found eligibility. Thus, in *Rapid Litigation Management v. CellzDirect, Inc.*, 827 F.3d 1042, 1046 (Fed. Cir. 2016), the Federal Circuit found eligible a "method of producing a desired preparation of multi-cryopreserved hepatocytes" that set out steps required to produce such a preparation, including the use of multiple freeze-thaw cycles. Although the claims included a newfound natural property of hepatocyte cells discovered by the inventors—"said hepatocytes being capable of being frozen and thawed at least two times"—the "end result" of the claims was "not simply an observation or detection of the ability of hepatocytes to survive multiple freeze-thaw cycles," but a "new and useful" method of preserving hepatocyte cells. *Id.* at 1046-48.

In addition, where a method recites a natural law, but goes beyond observing it and instead applies it in a particular treatment regime, the Federal Circuit has found eligibility under *Mayo*. In *Vanda Pharmaceuticals, Inc. v. West-Ward Pharmaceuticals, Inc.*, 887 F.3d 1117, 1120-21 (Fed Cir. 2018), the court found eligible claims to a method of treating schizophrenia patients using the drug iloperidone, which required dosing patients with an amount of iloperidone that was based on the results of a genotyping assay to determine the patient's ability to metabolize the drug.

The claims also required that this type of dosing regimen lead to a lower risk for QTc prolongation, a potentially serious cardiac side effect. *Id.* at 1121. The court explained that "[t]he inventors recognized the relationships between iloperidone, CYP2D6 metabolism, and QTc prolongation, but that is not what they claimed. They claimed an application of that relationship." *Id.* at 1135. The court distinguished the *Mayo* claims because the *Vanda* claims required a certain dose to be used based on the genotyping assay, which resulted in "'a new way of using an existing drug' that is safer for patients because it reduces the risk of QTc prolongation." *Id.* at 1135; *see also Mayo*, 566 U.S. at 87; *Endo Pharms., Inc. v. Teva Pharms. USA, Inc.*, 919 F.3d 1347, 1348, 1353-55 (Fed. Cir. 2019).

These cases demonstrate that the Federal Circuit has not struggled to apply *Mayo* in life sciences cases. As Judge Lourie described it, "our cases are consistent. They have distinguished between new method of treatment claims and unconventional laboratory techniques, on the one hand, and, on the other hand, diagnostic methods that consist of routine steps to observe the operation of a natural law." App. 61a. No further clarification from this Court is necessary.

II. THIS CASE IS NO DIFFERENT THAN THE OTHER § 101 DECISIONS THIS COURT HAS DECLINED TO HEAR SINCE *MAYO* AND DOES NOT WARRANT REVIEW

A. Far from Being an "Ideal" Case for Review, Finding Athena's Claims Eligible Would Require Substantial Revision of this Court's § 101 Precedent

The outcome of this case under *Mayo* is clear, as the district court and Federal Circuit each concluded. The claims cover methods of diagnosis by observing the natural relationship between MuSK autoantibodies and MuSK-related disorders using undisputedly standard techniques. The claims do not apply the natural law underlying them in an eligible way. They are the exact type of claims that precedent directs are ineligible.

Claim 9, which Athena treats as representative, covers diagnosing any MuSK-related disease through the steps of (1) putting MuSK (or a relevant portion of it) containing the radioactive iodine label ^{125}I into contact with a patient's fluid sample, (2) immunoprecipitating any resulting complex between MuSK and MuSK autoantibodies that naturally form, and (3) thereafter monitoring for the iodine label appended to MuSK. The claim further recites a "wherein" clause teaching that if the label is observed that is indicative of disease. C.A.J.A. 48-49. This teaching is a statement of the natural law because in the described assay technique the label is merely a surrogate for MuSK autoantibodies. As in *Mayo*, "[w]hile it takes human action" (mixing labeled MuSK with a patient sample) "to trigger manifestation of" the inventor's newfound natural law, the relation between MuSK

autoantibodies and disease "itself exists in principle apart from any human action." *Mayo*, 566 U.S. at 77.

True, the claim's plain language includes "concrete steps" in addition to the natural law, but those steps do not constitute any advance or improvement in existing laboratory techniques. As in *Mayo*, Athena's '820 patent states that the steps for detecting autoantibodies recited in the claims were "standard" and "known per se in the art." Given this, the Federal Circuit rightly concluded that the claims "are directed to a natural law because the claimed advance was only in the discovery of a natural law," and lack an inventive concept because they "apply[] standard techniques in a standard way." App. 11a; App. 16a.

Athena repeatedly tries to distance its patent from that at issue in *Mayo* but cannot. The only differences between them are cosmetic. Both patents recite conventional methods for observing a natural law. Although the claims at issue here use more words to describe those conventional steps with somewhat more specificity, that does not and cannot render them eligible. As *Mayo* explained, "our cases have not distinguished among different laws of nature according to whether or not the principles they embody are sufficiently narrow." *Mayo*, 566 U.S. at 88-89.

Accordingly, the result in *Mayo* would not have been different if the patentee had more specifically claimed the use of conventional steps. For example, if the claims had recited "administering" the drug *by mouth* and "determining" metabolite levels *by high pressure liquid chromatography*, the claims still would not have recited eligible subject matter. In fact, some dependent claims that were ultimately adjudged ineligible *did* recite high pressure liquid chromatography, a conventional technique that was well-known

in the art. *Prometheus Labs., Inc. v. Mayo Collaborative Servs.*, 628 F.3d 1347, 1351, 1357 (Fed. Cir. 2010).

Similarly, here, Athena's claims are no more eligible because they enumerate contacting labeled MuSK with a bodily fluid, immunoprecipitating antibody-MuSK complexes, and monitoring for the label in those complexes, than they would be if they only generically required autoantibody detection, which many of Athena's claims in fact do. *Cf. Alice*, 573 U.S. at 226 (finding system claims reciting particular computer components directed to ineligible subject matter for same reason as claims that generally recited a computer). Those enumerated steps were standard and known, as the patent itself admits. The process of claim 9 is not new; it just uses different types of known reagents that correspond to the newfound natural law.

This result is consistent with the long-standing precedent that an unpatentable abstract idea or natural law cannot be made patentable by attempting to claim its use in one type of technology. *Flook* found ineligible a patentee's attempt to claim an algorithm to calculate alarm limits, rejecting the argument that "if a process application implements a principle in some specific fashion, it automatically falls within the patentable subject matter of § 101." 437 U.S. at 593. According to the Court, such a rule "would make the determination of patentable subject matter depend simply on the draftsman's art and would ill serve the principles underlying the prohibition against patents for 'ideas' or phenomena of nature." *Id.*

Diehr also explains that "[a] mathematical formula does not suddenly become patentable subject matter" by "limiting the reach of the patent" to "a particular technological use." 450 U.S. at 192 n.14.

Bilski discussed and applied this same principle, relying on *Flook*'s rule that "limiting an abstract idea to one field of use" does "not make the concept patentable." 561 U.S. at 612. The Court again explained that when an "application's only innovation was reliance on a mathematical algorithm," embedding that algorithm in "a particular technological environment'" and adding conventional extra-solution steps did not satisfy § 101. *Id.* at 610-11.

To rule in favor of Athena here would thus require cabining this extensive precedent away from the business of diagnostics. But the patent law should not be about performing legal gymnastics in favor of a particular industry—its standards should apply to each industry equally. Under these long-standing rules, Athena's claims simply do not add "*enough* to their statements of the correlations to allow the processes they describe to qualify as patent-eligible processes that *apply* natural laws." *Mayo*, 566 U.S. at 77.

B. Under this Court's Precedent, Marked Differences Are Required Before a Natural Product May Impart Patentability, and None Are Present Here

Athena suggests, as it did below, that because the claimed methods involve the use of man-made materials, they must recite eligible subject matter. Not so.

First, the methods claimed in *Mayo* involved the administration of man-made drugs, and that did not make those methods eligible. *Mayo*, 566 U.S. at 74-75. Athena attempts (at 30-31) to distinguish *Mayo* by relying on the alleged "novel" nature of labeled MuSK, but this argument is belied by the admission in the specification that iodination (adding an iodine

label like ^{125}I) is a "standard" technique. App. 5a. Appending a customary label to the known protein MuSK by a standard technique does not add an inventive concept to the asserted claims such that they are directed to something more than the recited natural correlation. App. 18a.

Second, the rationale in *Myriad* to which Athena clings is not applicable. There the Court considered the eligibility of complementary DNA (cDNA), which includes protein-coding regions of DNA called exons but excludes the non-coding regions called introns. *Myriad*, 569 U.S. at 580. The Court held cDNA patent eligible "except insofar as very short series of DNA may have no intervening introns to remove when creating cDNA." *Id.* at 595. Eligibility for such cDNA turned on the fact that its sequence does not exist in nature, and thus can be said to be "markedly different" from anything naturally occurring. *Myriad*, 569 U.S. at 594-95; *see id.* at 590-91. When eligible segments of cDNA are made, they are created as "something new" and "distinct from the DNA from which it was derived." *Id.* at 595. These very differences are what make cDNA useful.

There is nothing "markedly different" or "distinct" as between labeled MuSK and the non-labeled MuSK used to make it—there simply is an attached, admittedly conventional label that permits the laboratory technician to observe the MuSK, which functions the same as it always does. In this regard, labeled MuSK is similar to the fruit that was not deemed patentable in *American Fruit Growers, Inc. v. Brogdex Co.*, 283 U.S. 1 (1931), merely because the inventors had coated it with a mold-resistant chemical called borax. The borax-coated fruit was still considered a natural product because it was not "markedly different," or, as

the Court put it in that case, did not have a "new or distinctive form, quality, or property" as compared to the natural fruit. *Id.* at 11-12. So, too, does labeled MuSK lack any different properties than naturally occurring MuSK.

The rationale from *Myriad* more applicable here is that underlying the holding about the ineligibility of "isolated DNA." In addition to cDNA claims, Myriad had secured claims to "an isolated DNA coding for a BRCA1 polypeptide" made up of a particular amino acid sequence. 569 U.S. at 584. For those claims, this Court considered Myriad's contribution to the field and concluded that "Myriad did not create anything. To be sure, it found an important and useful gene, but separating that gene from its surrounding genetic material is not an act of invention." *Id.* at 591. The Court thus held Myriad's isolated DNA claims ineligible because isolated DNA is not "markedly different" from DNA found in nature, as precedent requires to confer eligibility on something involving a natural product. *Id.* at. 590-91 (discussing *Diamond v. Chakrabarty*, 447 U.S. 303 (1980) and *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127 (1948)).

Simply put, extending patent protection to conventionally labeled natural materials, or processes that use them, as Athena asks this Court to do, would gut the *Myriad* decision. Indeed, the "isolated DNA" of that case also did not exist in nature, but the difference between that and the intact DNA was considered too limited to warrant patent protection. *Id.* at 594-95. The same is true here of labeled MuSK.

Athena unsuccessfully relies on the Federal Circuit's finding below in *Myriad* that method claim 20, which was not part of the appeal to this Court, was patent eligible to suggest that any method involving a

man-made component is patent eligible. *See Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office*, 689 F.3d 1303, 1335-37 (Fed. Cir. 2012). Myriad's claim 20 is fundamentally different from Athena's claims because it, as this Court's precedent requires, involved man-made materials that were "markedly different" from their naturally occurring counterparts. Specifically, Myriad claim 20 required "growing a transformed eukaryotic host cell *containing an altered BRCA1 gene causing cancer*." *Id.* at 1310 (emphasis added); *see id.* at 1336. Normal eukaryotic host cells do not cause cancer. The cells recited in Myriad claim 20 therefore fit the requirements of this Court's precedent. They "are derived from altering a cell to include a foreign gene, resulting in a man-made, transformed cell with enhanced function and utility." *Id.* at 1336; *see also Funk Bros.*, 333 U.S. 127, 131 (claims to combination of bacteria not eligible because they "serve[d] the ends nature originally provided"); *Chakrabarty*, 477 U.S. at 310 (finding patentable the patentee's production of "a new bacterium with markedly different characteristics from any found in nature").

That the labeled MuSK recited in Athena's claims cannot and does not confer eligibility—even if considered a "novel" man-made material (although no such fact finding was ever made below)—is clear from the claims' operation and purpose. Athena's methods depend upon the physical binding of MuSK and MuSK autoantibodies. To be useful in Athena's methods, the form of labeled MuSK must be capable of this physical binding. Otherwise, the complexes the method is designed to detect could never form. Thus the entire point of Athena's claims is that the recited labeled

MuSK is *not* "markedly different" from naturally occurring MuSK. And indeed, there is nothing in the record to suggest it is.

In short, Athena's labeled MuSK must retain the same function, properties, and characteristics of natural MuSK to work as directed in the claimed methods. That means this man-made material cannot and does not bring Athena's claims within the bounds of eligibility drawn by this Court's precedent.

C. Athena's Preemption Argument Violates Precedent, and Seeks to Circumvent the Law of Eligibility Through "The Draftsman's Art"

Again harping on "specificity," Athena argues that eligibility is warranted because its claims do not preempt all potential uses of the inventors' newfound natural law.

But, as set forth above, the claims of the '820 patent, read as a whole, *do* improperly preempt use of the natural law. Claims 1 and 12 broadly cover diagnosis of any MuSK-related disease by detecting MuSK autoantibodies in bodily fluid, with no methods specified. The patents' other claims, including claim 9, relate back to those claims and add limitations directed to particular, "standard" laboratory methods for detecting the autoantibodies and particular diseases (though, notably, claim 9 itself it not limited to any particular disease). If a patentee could simply avoid preemption concerns by dividing up claims directed to observing a natural law into one group that covers all ways of doing so, and another group that recites more specific techniques, but still offers no improvement in the field, then the rule against preemption is entirely meaningless.

In effect, this would mean that Athena's choice to draft generic claims that do not specify any particular detection methods, as well as claims that specify unoriginal detection methods, would insulate it from adverse eligibility consequences. But this would flout *Flook*, which rejected the notion that a "competent draftsman" could impart eligibility merely by adding conventional activities to a natural law, and cannot be right. *See Flook*, 437 U.S. at 590.

Moreover, this Court has consistently recognized that the prohibition against patent-ineligible subject matter "cannot be circumvented" by limiting the claimed use "to a particular technological environment." *See Bilski*, 561 U.S. at 610-11 (quoting *Diehr*, 450 U.S. at 191-92); *Flook*, 437 U.S. at 593. So Athena's choice to draft its claims using one particular technological method that is "known per se in the art" as opposed to a different known technique does not avoid the preemption problem.

This Court heard all the same arguments that Athena makes here in the petitions for *certiorari* in the *Ariosa*, *Genetic Technologies*, and *Cleveland Clinic* cases discussed above, and denied all of them. The result should be no different here. Like those cases, this case is a straightforward application of this Court's precedent that does not warrant a grant of *certiorari*.

III. ATHENA'S POLICY CONCERNS ARE UNWARRANTED AND NOT THE PROVINCE OF THIS COURT

Dissatisfaction with this Court's patent eligibility framework and the outcomes it compels must be addressed by Congress, if at all. This Court in *Mayo* de-

clined to determine "whether, from a policy perspective, increased protection for discoveries of diagnostic laws of nature is desirable." 566 U.S. at 92. There is no reasoned basis to reverse course now.

A. There Is No Evidence that this Decision Will Negatively Impact Diagnostics Innovation

Athena, amici, and various Federal Circuit judges allege that allowing the Federal Circuit's decision below to stand, and its applications of *Mayo* to continue, will effectively ruin the diagnostics industry, but this hyperbolic claim is entirely speculative.

First, those issues were never addressed in this case, which was resolved on Fed. R. Civ. P. 12(b)(6) before any discovery took place, based on the plain admissions in the specification and by Athena's counsel that the techniques recited in the claims were well-known in the art. The record does not reflect what motivations drove the inventors, or what investment decisions were made, even though Athena claims (at 6) it was substantial. Given the inventors worked at research institutions abroad, it is difficult to believe that the incentives of the U.S. patent system drove their plans or do so today. *See* C.A.J.A. 35, 69.

Second, this Court already considered the same argument in *Mayo*, but was rightly not moved by it. 566 U.S. at 91-92. As properly recognized, there are two sides to the argument. The Court noted that it did not "find this kind of difference of opinion surprising. Patent protection is, after all, a two edged sword." *Id.* at 92. The Court explained that, "[o]n the one hand, the promise of exclusive rights provides monetary incentives that lead to creation, invention and discovery. On the other hand, that very exclusivity

can impede the flow of information that might permit, indeed spur, invention." *Id.* The Court cautioned that "we must hesitate before departing from established general legal rules lest a new protective rule that seems to suit the needs of one field produce unforeseen results in another." *Id.* Indeed, such caution is very prudent here. The Court should again decline the request to implement a special rule for diagnostic patents.

Third, available evidence suggests amici's concerns about diagnostics are unwarranted. Rather, evidence suggests that investment in diagnostics has increased tenfold since 2009. Alex De Winter, *Why It's a Good Year for Diagnostic Startups*, MedCity News (Aug. 24, 2017), https://perma.cc/NS8M-89YS. There has also been an increase in material biomarker transactions and FDA approvals of diagnostics since the *Mayo* decision, and an average of ten new genetic testing products were added to the market each day from 2015-17. Arti K. Rai & Colleen Chien, *Presentation at the Duke Center for Applied Genomics and Precision Medicine: Intellectual Property in Precision Medicine* 24–26 (Feb. 15, 2018), https://perma.cc/222C-PCQ9; Concert Genetics, *The Current Landscape of Genetic Testing* 1, 5 (Mar. 2017), https://perma.cc/K5KX-MST6.

This is certainly not indicative of a decrease in innovation or fewer advances being made in the medical diagnostic industry following *Mayo*. Moreover, the federal government funds much of the basic research in the gene disease, which is thus less affected by patent rights and potential profits in any event. *See* Sec'y's Advisory Comm. on Genetics, Health, & Soc'y, Dep't of Health & Human Servs., *Gene Patents and*

Licensing Practices and Their Impact on Patient Access to Genetic Tests 25–26 (Apr. 2010), https://perma.cc/XBC8-Q98D.

Indeed, Athena's own financial situation shows that it has not been harmed by the *Mayo* decision. The stock price of its parent company, Quest Diagnostics, has grown from around $57 per share at the beginning of 2013 to over $100 per share currently, with the price hitting an all-time high in mid-2018. *Quest Diagnostics Inc. (DGX, U.S.:NYSE)*, Wall St. J., https://perma.cc/CMC7-7X3X.

Finally, this Court's § 101 framework leaves room for patents on medical diagnostics. In this era with an increased focus on personalized medicine, diagnostics will no doubt play a key role. New diagnostics that are more accurate, more sensitive, more specific, and the like will no doubt be at the forefront of that shift in medical care. For such significantly *improved* diagnostic techniques, patent eligibility remains available. *See, e.g.*, *CellzDirect*, 827 F.3d at 1046-48. But merely plugging a new correlation between a naturally occurring bio-product and a disease into a known technique is not the type of activity the Patent Act protects.

B. Policy-Based Statutory Change Is the Province of Congress

The concerns of Athena, amici, and various judges about any potential effect of this Court's interpretation of § 101 on the field of medical diagnostics should be taken up with Congress.

In circumstances like this, "[c]ongressional processes are more accommodative, affording the whole industry hearings and an opportunity to assist in the formulation of new legislation. The resulting product

is therefore more likely to protect the industry and the public alike." *Radovich v. Nat'l Football League*, 352 U.S. 445, 452 (1957) (declining to hold professional football outside the scope of antitrust law, absent explicit Congressional exemption).

And, indeed, various industry groups, including some of the amici in this case, have been directing their concerns to Congress, as Congress has been considering proposed legislation to amend § 101 to loosen the requirements for eligibility. As part of the process, the Senate Subcommittee on Intellectual Property held multiple hearings to discuss the proposed changes, engaging interested parties on both sides of the debate.

Athena and its amici cite to testimony from those hearings claiming that the current rules set by this Court are harmful to medical innovation, but there was also plentiful testimony to support that the current approach is working well and, indeed, is both beneficial for patients and not harmful to innovation. *See, e.g.*, The State of Patent Eligibility in America, Part II (testimony of Jeffrey Francer, Association for Accessible Medicines), at 4 ("[A]llowing patents on basic breast cancer diagnostic methods and tools would have far-reaching negative effects, including *preventing sick women from obtaining a second medical opinion*."); The State of Patent Eligibility in America, Part I (testimony of Charles Duan, R Street Institute), at 12-13 ("[T]he effects of patent exclusivity on genetic and diagnostic tests are especially severe—errors lead to improvident surgery or undiagnosed deadly disorders—and . . . the incentive value of patents for gene and diagnostic discoveries is particularly low."); *see also generally* The State of Patent Eligibility in America, Part II (testimony of Kate Ruane,

American Civil Liberties Union); The State of Patent Eligibility in America, Part II (testimony of David Jones, High Tech Investors Alliance).

Given this diversity of opinion, this Court has already recognized that the congressional process is the appropriate vehicle for addressing the very issue Athena's petition raises. *Mayo*, 566 U.S. at 92. And that process has in the past been used to reconcile differing views on other aspects of the Patent Act. *See, e.g.*, *Microsoft Corp. v. AT & T Corp.*, 550 U.S. 437, 457-59 (2007) (noting that *Deepsouth Packing Co. v. Laitram Corp.*, 406 U.S. 518 (1972), led Congress to enact 35 U.S.C. § 271(f)).

If § 101 is to be changed in some manner, the congressional process is the appropriate avenue to do so, not through Athena's request that this Court reinterpret the statute now in a way that is more favorable to Athena's generic medical diagnostic claims.

CONCLUSION

The petition should be denied.

Respectfully submitted,

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