No. 19-

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

PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

Across eight opinions concurring or dissenting in the denial of rehearing en banc, the Federal Circuit unanimously agreed that the claims to a medical diagnostic method in this case should be patent-eligible. But the court split 7-5 on whether this Court's precedent foreclosed such a result or whether it was the Federal Circuit's own misinterpretation of that precedent that has denied patent protection to diagnostic tests. Numerous judges asked this Court to provide guidance.

The question presented is:

Whether a new and specific method of diagnosing a medical condition is patent-eligible subject matter, where the method detects a molecule never previously linked to the condition using novel man-made molecules and a series of specific chemical steps never previously performed.

CORPORATE DISCLOSURE STATEMENT

Quest Diagnostics Incorporated is the parent corporation of petitioner Athena Diagnostics, Inc. The parent corporation of Oxford University Innovation Ltd. is the Chancellor, Masters, and Scholars of the University of Oxford. Max-Planck-Gesellschaft Zur Forderung der Wissenschaften E.V. has no parent corporation and no publicly held company owns 10% or more of its stock.

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JURISDICTION

The Federal Circuit entered judgment on February 6, 2019. The court denied Athena's timely petition for rehearing en banc on July 3, 2019. This Court has jurisdiction under 28 U.S.C. § 1254(1).

STATUTORY PROVISION INVOLVED

Section 101 of Title 35 of the U.S. Code provides: "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title."

INTRODUCTION

Across eight separate opinions in which the court divided 7-5 on denying en banc review, the Federal Circuit issued an unprecedented cry for help from this Court to clarify the patent eligibility of medical diagnostic tests. This Court should heed that cry and provide much-needed guidance on the proper application of the judicially-created exceptions to Section 101 of the Patent Act.

Since this Court's decision in *Mayo Collaborative Services* v. *Prometheus Laboratories, Inc.*, 566 U.S. 66 (2012), the Federal Circuit has invalidated every diagnostic claim to come before it as ineligible subject matter for patent protection. A divided panel of the Federal Circuit extended that precedent in this case to hold that a method of diagnosing a neurological disorder—using non-naturally occurring molecules and specific chemical reactions to detect a harmful molecule for which there was no prior test—is not the type of subject matter that can be patented. As several judges explained, the Federal Circuit's decision means that the vast majority of diagnostic tests performed in a laboratory are now effectively unpatentable.

The members of the en banc Federal Circuit agreed with Athena that sufficiently specific diagnostic methods with proven utility like the ones here *should* be patent-eligible. But a slight majority believed their hands were tied under this Court's precedent, while five judges believed the problem lay in the Federal Circuit's own misinterpretation of this Court's decisions. On both sides of that divide, there was broad consensus that this Court's review is desperately needed. Numerous government officials, practitioners, and scholars have echoed and amplified the message that the law of patent-eligible subject matter is in a state of turmoil and there is no more important question facing the patent system.

This Court should grant the petition to clarify the eligibility of diagnostic tests for patent protection. This case is an ideal vehicle to address that question because the claims consist of a series of specific chemical steps that begin with a man-made molecule and create at least two more man-made molecules in the process of detecting something never before associated with any

disease. If these claims do not even meet the threshold requirement of being the kind of subject matter eligible for patent protection, that is the end of patent eligibility for the overwhelming majority of medical diagnostic methods—leading to profound consequences for future investment in scientific research and public health.

STATEMENT

A. Judicially-Created Exceptions To Section 101

This case addresses the important question of what types of inventions may be claimed in a patent. Concluding that a claim's subject matter is *eligible* for patent protection does not mean that a patent will be granted. Subject-matter eligibility is merely a threshold question. Many other requirements—including that the claim be novel, 35 U.S.C. § 102, non-obvious, *id.* § 103, and described adequately to enable its use, *id.* § 112—must be met before a patent is granted.

Congress used broad language to describe the subject matter eligible for patent protection. Section 101 of the Patent Act provides that "[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title." 35 U.S.C. § 101. An "invention" means "invention or discovery," and "process" includes "a new use of a known process, machine, manufacture, composition of matter, or material." *Id.* § 100. Section 101 is "cast in broad terms to fulfill the constitutional and statutory goal of promoting 'the Progress of Science and the useful Arts' with all that means for the social and economic benefits." *Diamond* v. *Chakrabarty*, 447 U.S. 303, 315 (1980) (quoting U.S. Const. art. I, § 8.).

This Court has limited Section 101's plain text with implicit exceptions to patent eligibility for "laws of nature, natural phenomena, and abstract ideas," on the premise that such discoveries are "'manifestations of … nature, free to all men and reserved exclusively to none.'" *Diamond* v. *Diehr*, 450 U.S. 175, 185 (1981) (ellipsis in original). Accordingly, "'[a] new mineral discovered in the earth or a new plant found in the wild is not patentable subject matter,'" and "'Einstein could not patent his celebrated law that $E=mc^2$.'" *Id.*

At the same time, the Court has repeatedly cautioned that "too broad an interpretation of this exclusionary principle could eviscerate patent law," "[f]or all inventions at some level embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas." *Mayo*, 566 U.S. at 71. Thus, while a process may not "too broadly preempt the use of a natural law," it is also "'not unpatentable simply because it contains a law of nature.'" *Id.* at 71-72. Rather, "an *application* of a law of nature" even "to a known structure or process may well be deserving of patent protection." *Diehr*, 450 U.S. at 187-188.

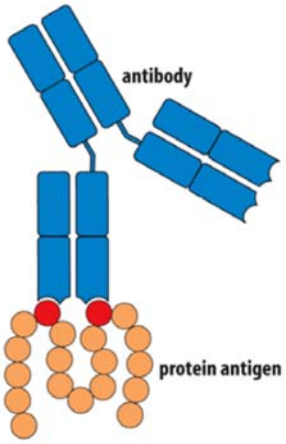
Several years ago, the Court established a two-step framework for determining the threshold question of whether a patent claims subject matter eligible for patent protection. At step one, a court inquires "whether the claims at issue are directed to [a] patent-ineligible concept[]." *Alice Corp.* v. *CLS Bank Int'l*, 573 U.S. 208, 217 (2014). If the claims are not directed to such a concept, the subject matter of the claims is eligible for patent protection. If they are, the court searches for an "'inventive concept'" that would confer patent eligibility—i.e., "an element or combination of elements that is 'sufficient to ensure that the patent in practice amounts

to significantly more than a patent upon the [ineligible concept] itself.'" *Id.* at 217-218 (alteration in original).

As discussed below, lower courts have struggled to apply this framework.

B. The Groundbreaking Invention

1. "Antibodies" are proteins that play an important role in the immune system by detecting foreign "antigens" in our bodies, such as viruses and bacteria. An antibody's arms contain regions that bind to complementary portions of the antigen being detected, tagging the antigen for elimination by the immune system.



"Autoantibodies" are antibodies that bind to the body's own proteins rather than foreign substances. These autoantibodies can cause autoimmune diseases such as lupus and multiple sclerosis.

Myasthenia gravis ("MG") is a neurological disorder whose symptoms include muscle weakness, double vision, and slurred speech. C.A.J.A. 43; App. 2a. Before the work of the inventors in this case, it was known that approximately 80% of MG patients develop the disorder because they generate antibodies against their own acetylcholine receptors. C.A.J.A. 43; App. 2a-3a. But the cause of MG in about 20% of patients was unknown. *Id.* Scientists could not determine whether these patients had "the same or a distinct and separate MG condition," and there was "no basis for

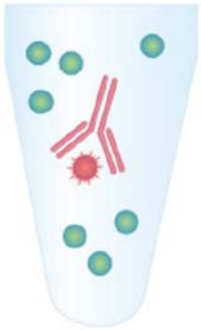
providing an immediate clinical diagnosis for such patients." C.A.J.A. 43-44. This meant that some MG patients would not receive treatments that could "vastly improve the length and quality of life." C.A.J.A. 43.

The inventors of U.S. Patent 7,627,820 made a critical discovery regarding an alternative cause of MG. C.A.J.A. 36, 43; *see* App. 2a-3a. After substantial research and investment, they proved that many of the MG patients whose cause was unknown generate autoantibodies to a protein called muscle-specific tyrosine kinase (MuSK). C.A.J.A. 43. They also identified the particular region of MuSK bound by the autoantibodies. C.A.J.A. 37, 44, 46-47. MuSK had not previously been associated with any disease.

2. This discovery was a huge breakthrough in the understanding of MG, but the inventors did not stop there. They also devised ways to apply their new insight in a practical manner to improve medical care. At issue here is their development of a method of diagnosing neurological disorders, including MG, through a series of chemical steps that detect MuSK autoantibodies. C.A.J.A. 44. The method "allow[s] for more accurate and speedy diagnosis" of MG in the 20% of patients who could not be expeditiously diagnosed before. *Id.*

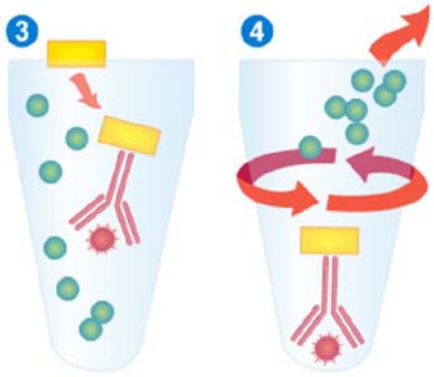
The inventors disclosed and claimed their invention in the '820 patent. Athena Diagnostic is the exclusive licensee of the patent. App. 2a. Claim 9, on which the Federal Circuit focused its analysis, claims a method of diagnosing MuSK-related neurological disorders. C.A.J.A. 48-49; App. 4a-5a. The method begins with a man-made molecule: MuSK, or a MuSK fragment, labeled with a radioactive isotope of iodine, known as ^{125}I. This "^{125}I-MuSK" does not exist in nature. It is an arti-

ficial form of MuSK created in the lab to be radioactive and therefore easily detectable.



In the first step of the claim, the radioactive ^{125}I-MuSK is brought into contact with bodily fluid, such as a blood sample. If the sample contains autoantibodies to MuSK, they will bind to the ^{125}I-MuSK to create a second compound that does not exist in nature: a "complex" of ^{125}I-MuSK and anti-MuSK autoantibody. The complex formed by the Y-shaped autoantibody and the radioactive ^{125}I-MuSK is depicted to the right in red.

Next, the complex of ^{125}I-MuSK and anti-MuSK autoantibody is separated from the surrounding fluid through a process known as "immunoprecipitation." In that process, a "secondary" antibody, often derived from an animal, is introduced. For example, one of the examples in the '820 patent discloses the use of an antibody derived from sheep. C.A.J.A. 47. The secondary antibody binds to the complex of ^{125}I-MuSK and anti-MuSK autoantibody, forming a third composition not found in nature. That composition can then be separated from the rest of the solution with a centrifuge.



The final step is to monitor for the radioactive label. If a signal is detected, it means the sample contained autoantibodies to MuSK, which indicates the presence of a MuSK-related disorder, such as MG. If no signal is detected, it means that MuSK autoantibodies were not present, and thus the ^{125}I-MuSK washed away without binding.

Claims 7 and 8 recite steps similar to claim 9, but vary the label attached to the MuSK. C.A.J.A. 48-49; App. 3a-6a. Claim 8 requires a "radioactive label." C.A.J.A. 49. Claim 7 requires a "suitable" (but not necessarily radioactive) label, C.A.J.A. 48-49, such as a fluorescent label, C.A.J.A. 44.[1]

The '820 patent describes the techniques of "iodination" (i.e., adding iodine to a compound) and "immunoprecipitation" as "standard techniques in the art, the details of which may be found in references." C.A.J.A. 44. But the record contains no evidence that ^{125}I-MuSK had been created before or that iodination or immunoprecipitation had ever been adapted to identify MuSK autoantibodies. C.A.J.A. 43, 46-47. In fact, before the '820 patent, there was no test of any kind for detecting autoantibodies to MuSK.

C. The Proceedings

Before 2015, Mayo Collaborative Services, LLC ("Mayo") would send orders for MuSK autoantibody tests to Athena, but in that year, Mayo decided to start offering two competing tests that infringe the '820 patent. App. 2a; C.A.J.A. 71. When Athena sued, Mayo moved to dismiss on the ground that the asserted

[1] Claim 6, the other asserted claim, uses the "ELISA" method, which is a different technique from the radioimmunoassays used by claims 7-9. C.A.J.A. 44, 48-49; App. 5a-6a.

claims were ineligible for patent protection under Section 101. App. 2a. After several reversals of course, the district court agreed with Mayo and granted its motion, holding that the asserted claims were invalid. App. 39a-52a.

A divided panel of the Federal Circuit affirmed, extending precedent that has held every diagnostic claim the court has addressed since this Court's decision in *Mayo* to be patent-ineligible. App. 1a-37a; *see, e.g.*, *Roche Molecular Sys., Inc.* v. *CEPHEID*, 905 F.3d 1363, 1374 (Fed. Cir. 2018); *Cleveland Clinic Found.* v. *True Health Diagnostics LLC*, 859 F.3d 1352, 1363 (Fed. Cir. 2017); *Genetic Techs. Ltd.* v. *Merial L.L.C.*, 818 F.3d 1369, 1380 (Fed. Cir. 2016); *Ariosa Diagnostics, Inc.* v. *Sequenom, Inc.*, 788 F.3d 1371, 1379-1380 (Fed. Cir. 2015); *In re BRCA1- & BRCA2-Based Hereditary Cancer Test Patent Litig.*, 774 F.3d 755, 765 (Fed. Cir. 2014).

At step one of the analysis, the panel majority found that Athena's claims were "directed to" a natural law, namely the correlation between MuSK autoantibodies and MG. App. 8a-14a. It made no difference, according to the majority, that: the inventors had claimed a specific set of chemical reactions to detect MuSK; no one had previously diagnosed MG by detecting MuSK autoantibodies; the process uses novel man-made molecules; or the claims left "open to the public other ways of interrogating the correlation between MuSK autoantibodies and MuSK-related disorders without practicing the claim's concrete steps." App. 13a-14a.

The majority also thought there was no "inventive concept" at step two of the analysis because the claims recite known labeling and assay techniques. In the ma-

jority's view, it was irrelevant that the techniques "had not been applied to detect MuSK autoantibodies prior to Athena's discovery." App. 15a-18a.

The majority expressed reservations, however, about its decision. It noted that "providing patent protection to novel and non-obvious diagnostic methods," like Athena's, would "promote the progress of science and useful arts" and that "'the public interest is poorly served'" by law that requires denying its patent eligibility. App. 14a-15a n.4. But the majority felt that "precedent leaves no room for a different outcome here." *Id.*

Judge Newman dissented, noting that Athena's claims are a patent-eligible "chemical-biomedical procedure." App. 23a-37a. She explained that the inventors "did not patent their scientific discovery," but rather "applied this discovery to create a new method of diagnosis, for a previously undiagnosable neurological condition." App. 24a.

D. The Denial Of Rehearing En Banc

Athena petitioned for rehearing en banc. The judges on the Federal Circuit broadly *agreed* that Athena's claims *should* be patent-eligible, but the court denied rehearing because a slight majority believed this Court's decision in *Mayo* required affirming the panel majority's decision. The court issued eight concurring and dissenting opinions to explain its disparate views of *Mayo* while repeatedly calling for this Court's guidance. App. 55a-142a.

Seven judges concurred because they believed *Mayo* required holding Athena's claims ineligible, even though they questioned that result. Judge Lourie (joined by Judges Reyna and Chen) reiterated prior

concerns with the state of the law, but concluded that the Federal Circuit "can accomplish little" in rehearing the case en banc, as it is "bound by the Supreme Court's decision in *Mayo*." App. 58a, 60a. Judge Hughes (joined by Chief Judge Prost and Judge Taranto) agreed "that the bottom line for diagnostics patents is problematic," but also believed "this is not a problem that [the Federal Circuit] can solve." App. 62a.

Judge Dyk (joined by Judge Hughes, and by Judge Chen in part) "share[d] the concerns expressed by [his] dissenting colleagues that the *Mayo* test for patent eligibility should leave room for sufficiently specific diagnostic patents." App. 68a. He explained that specific applications of natural laws with proven utility should not be barred. App. 69a-77a. *Mayo* was problematic because, in his view, it "left no room" for the court of appeals to find more "typical diagnostic claims patent eligible." App. 68a.

Judge Chen, in a fourth concurrence, explained that although Athena's claims "likely would have been found" patent-eligible under prior Supreme Court case law, *Mayo* established "a more far-reaching, aggressive version of the judicial exceptions to the statute," "largely incompatible with [the earlier precedent's] core rationale." App. 79a. He noted that new diagnostic methods represent "a practical application of the discovered law of nature" in "any meaningful sense" and should be patent-eligible in a "well-functioning patent system." App. 94a-95a.

The remaining five judges believed that *Mayo* does not require finding claims like Athena's patent-ineligible, and that it is only the Federal Circuit's *misinterpretation* of *Mayo* that led to the panel majority's decision. Judge Moore (joined by Judges O'Malley,

Wallach, and Stoll) explained that the Federal Circuit's "fervor for clarity and consistency has resulted in a per se rule that excludes all diagnostics from eligibility." App. 100a. Further, "[w]ithout the possibility of patent protection to recoup the high costs of research and development associated with" diagnostic claims, "the impact can only be that there will be fewer advances in diagnostic medicine." App. 103a. She concluded that "the statute clearly permits the eligibility of" Athena's claims and "no judicially-created exception should have such a vast embrace." App. 118a-119a.

Reiterating her panel dissent, Judge Newman (joined by Judge Wallach) stated that the Federal Circuit has "mistakenly enlarged" *Mayo*. App. 121a. She explained that *Mayo* did not equate diagnostic methods with ineligible natural laws, and that the statue, this Court's precedent, and policy concerns all support finding Athena's claims patent-eligible. App. 121-132a.

Judge Stoll (also joined by Judge Wallach) similarly lamented that the Federal Circuit has "established a bright-line rule of ineligibility for all diagnostic claims." App. 135a. That rule, she noted, is "based on an overreaching and flawed test for eligibility" and is "inconsistent with the precepts of *Mayo* and our patent system as a whole." App. 136a.

Judge O'Malley, in a fourth dissent, agreed that the Federal Circuit has read *Mayo* "too broadly." App. 138a. In her view, the "confusion and disagreements over patent eligibility have been engendered by" "ignor[ing] Congress's direction to the courts to apply" Section 101 "as written," instead requiring an "inventive concept." App. 138a-139a. She explained the historical development of patent law that she believed

is inconsistent with the "inventive concept" requirement. App. 138a-142a.

All eight opinions agreed that something needs to change, and many judges called for guidance from this Court.

REASONS FOR GRANTING THE PETITION

I. THE COURT SHOULD REVIEW THIS CASE TO CLARIFY ITS SECTION 101 PRECEDENT

A. The Federal Circuit Is Divided And Has Called For This Court's Guidance

1. The Federal Circuit is deeply divided on how to apply this Court's precedent. Every judge of the en banc court was troubled by the conclusion that Athena's claims are not patent-eligible, despite their use of specific chemical steps and man-made molecules in the first diagnostic test ever developed for a large number of patients with MG. The disagreement focused on whether this Court's decision in *Mayo Collaborative Services* v. *Prometheus Laboratories, Inc.*, 566 U.S. 66 (2012) mandates such an unfortunate result, or whether, as five judges argued, the Federal Circuit itself created the problem by misinterpreting this Court's precedent. Either way, the fractured decisions of the Federal Circuit are a clarion call for this Court to grant certiorari and provide much-needed guidance on the important question of the patent eligibility of medical diagnostic tests.

All twelve active judges of the Federal Circuit agreed that the current patent-eligibility standard as applied by the Federal Circuit is problematic, particularly in the context of diagnostic claims. Numerous judges thus solicited this Court's review of this case to clarify the patent eligibility standard.

Judge Hughes (joined by Chief Judge Prost and Judge Taranto) explained that "[t]he multiple concurring and dissenting opinions regarding the denial of en banc rehearing in this case are illustrative of how fraught the issue of § 101 eligibility, especially as applied to medical diagnostics patents, is." App. 62a. They "welcome[d] further explication of eligibility standards in the area of diagnostics patents. Such standards could permit patenting of essential life saving inventions based on natural laws while providing a reasonable and measured way to differentiate between overly broad patents claiming natural laws and truly worthy specific applications." App. 63a.

Judge Dyk stated that "it would be desirable for the Supreme Court to refine the *Mayo* framework to allow for sufficiently specific diagnostic patent claims with proven utility." App. 71a. He further explained, "Because at least some of the claims here recite specific applications of the newly discovered law of nature with proven utility, this case could provide the Supreme Court with the opportunity to refine the *Mayo* framework as to diagnostic patents." App. 77a.

Judge Chen agreed that the Federal Circuit "would benefit from the Supreme Court's guidance." App. 79a. He noted that "*Mayo*'s framework is in tension on its face with" earlier precedent, "considerably harder to apply consistently," and "more aggressive in its reach." App. 87a-88a. The Federal Circuit is "not in a position to resolve" those issues, but the Supreme Court can." App. 89a.

Judge Lourie (joined by Judges Reyna and Chen) explained that his "concerns over current precedent" could not be resolved "as long as the Court's precedent stands." App. 58a, 61a. He observed, "If I could write

on a clean slate, I would write as an exception to patent eligibility, as respects natural laws, only claims directed to the natural law itself, e.g., $E=mc^2$, F=ma, Boyle's Law, Maxwell's Equations, etc. I would not exclude uses or detection of natural laws." App. 59a.

The dissenting judges joined the majority's call for further clarification in the law. Judge Newman (joined by Judge Wallach) stated that "Federal Circuit precedent is ripe for reconsideration." App. 133a. Judge Stoll (joined by Judge Wallach) similarly argued that "the question of the eligibility of diagnostic inventions is exactly the type of exceptionally important issue that warrants" further review. App. 136a. And Judge Moore (joined by Judges O'Malley, Wallach, and Stoll) bluntly told future litigants: "No need to waste resources with additional en banc requests. Your only hope lies with the Supreme Court or Congress. I hope that they recognize the importance of these technologies, the benefits to society, and the market incentives for American business." App. 119a.

2. This is not the first case in which the Federal Circuit has expressed confusion and division on patent eligibility or called for this Court's intervention. Last year, Judge Plager observed that the "incoherent body of doctrine" surrounding Section 101 "renders it near impossible to know with any certainty whether [an] invention is or is not patent eligible," and that "the state of the law is such as to give little confidence" in the court's decisions. *Interval Licensing LLC* v. *AOL, Inc.*, 896 F.3d 1335, 1348 (Fed. Cir. 2018) (Plager, J., concurring-in-part and dissenting-in-part).

Judge Linn has similarly observed that Section 101 jurisprudence "is indeterminate and often leads to arbitrary results." *Smart Sys. Innovations, LLC* v. *Chica-*

go Transit Auth., 873 F.3d 1364, 1377 (Fed. Cir. 2017) (Linn, J., dissenting-in-part and concurring-in-part); *see also Ariosa Diagnostic, Inc.* v. *Sequenom, Inc.*, 788 F.3d 1371, 1381 (Fed. Cir. 2015) (Linn, J., concurring) (concurring in a decision invalidating patent claims even though he "s[aw] no reason, in policy or statute, why th[e] breakthrough invention [at issue] should be deemed patent ineligible").

Judges Lourie and Newman have also remarked that "the law needs clarification by higher authority." *Berkheimer* v. *HP Inc.*, 890 F.3d 1369, 1374 (Fed. Cir. 2018) (Lourie and Newman, JJ., concurring in the denial of rehearing en banc).

3. The collective and consistent cry for help from the Federal Circuit, culminating in this case, is extraordinary and emphasizes just how critical this Court's guidance is. Patent-eligibility is a threshold question of enormous importance to innovation and the economy, and yet the Federal Circuit has badly misinterpreted the judicially-created exceptions to the statute to bar patent protection to inventions that meet all the statutory criteria for patenting, including the requirements that claims be novel and nonobvious. The judges tasked with hearing all patent appeals in the United States have now told this Court in no uncertain terms that they are confused and need clarification on how to apply those judicial exceptions. The Court should heed that call.

B. The Federal Circuit Decision Highlights Multiple Points Of Confusion In Applying This Court's Precedent

The Federal Circuit's decision reflects the lower courts' fundamental misunderstanding about this

Court's precedent. In particular, five points of confusion have emerged as courts and litigants have struggled to apply—or have misapplied—the judicially-created exceptions to Section 101.

First, courts have struggled with the tension between the Federal Circuit's striking down a diagnostic method claim that uses novel man-made molecules and this Court's holding that a "molecule that is not naturally occurring" is "not a 'product of nature' and is patent eligible under § 101." *Association for Molecular Pathology* v. *Myriad Genetics, Inc.*, 569 U.S. 576, 594-595 (2013) ("*Myriad*"); App. 69a-72a (Dyk, J.) (noting the "tension" with *Myriad*). The complementary DNA (cDNA) that this Court held patent-eligible in *Myriad* was simple to create using routine techniques, and its sequence was "'dictated by nature.'" *Myriad*, 569 U.S. at 595. Still, as an artificial molecule created by a lab technician, it was eligible for patent protection. *Id.* The same was true of the genetically engineered bacterium held to be patent-eligible in *Diamond* v. *Chakrabarty*, 447 U.S. 303, 309-310 (1980).

Yet the Federal Circuit held that Athena's diagnostic claim that begins with a novel man-made composition, and requires the creation of at least two more novel man-made compositions during performance of the method, somehow loses its eligibility for patent protection merely by reciting specific uses for those compositions. It is counterintuitive, to say the least, that a claim would become *less* patentable when it is made *more* specific through the addition of multiple steps.

Second, courts have struggled to apply the principles articulated in the context of the unusual facts of *Mayo* to more typical patent claims. The claim in *Mayo*

was an oddity. The only two actions required by the claim—(i) administering a thiopurine drug and then (ii) determining metabolite levels (i.e., levels of chemicals that form as the body breaks down the drug)—were steps that were *already performed* in that exact manner before the patent. 566 U.S. at 73-74, 78-79. The only thing the claim added was the recitation of a correlation the inventors had discovered between the metabolite levels and the need to increase or decrease the amount of drug administered. *Id.* at 74-75. The claims thus did not require any tangible *action* beyond what was "already engaged in by the scientific community." *Id.* at 79-80. This meant that doctors who continued performing the exact same steps they had performed before the claims existed—administering a thiopurine drug and measuring metabolite levels—might suddenly be considered infringers merely because the claims had, in effect, published an abstract research finding.

Because the claim in *Mayo* was so unusual, this Court's opinion has created uncertainty regarding how to analyze claims that integrate a newly discovered natural law into a new process. Nowhere is that clearer than in this case's 7-5 split on how to interpret *Mayo*. The majority believed it could not distinguish *Mayo*, but the dissenters argued that while there is "some broad language in *Mayo*," "the Supreme Court did not intend *Mayo* to be the 'sweeping' decision [our] colleagues have concluded it is," and "[i]t is the role of this court to both faithfully follow *Mayo* and to determine its reach when facts and circumstances differ." App. 101a-102a (Moore, J.). This split underscores the urgent need for guidance on how the principles articulated in *Mayo* apply to less unusual claims.

Third, and relatedly, courts have struggled with the level of abstraction at which to determine whether the steps of a claim "transform an unpatentable law of nature into a patent eligible application of such a law." *Mayo*, 566 U.S. at 72. This Court emphasized that a patentee "must do more than simply state the law of nature while adding the words 'apply it.'" *Id.* The Court also stated that "simply appending conventional steps, *specified at a high level of generality*" is not enough to make a law of nature patent-eligible. *Id.* at 82 (emphasis added). This suggests that courts "should consider the level of specificity in the claims to determine whether the claim is even directed to the natural law." App. 111a (Moore, J.). But the Federal Circuit has "since ignored" this principle, treating a "claim that includes a law of nature as directed to that law, even if the claim as a whole recites a specific way of applying that law of nature to a new and useful end." App. 113a-114a (Moore, J.). The Federal Circuit has also taken an overbroad view of whether the steps of a claim apart from a natural law "consist of well-understood, routine, conventional activity already engaged in by the scientific community." *Mayo*, 566 U.S. at 79-80.

The panel majority in this case made the same errors when it analyzed the claims at a high level. It treated the claims as being directed to a natural law and disregarded most of the specific claim elements because the patent stated, as a general matter, that iodination and immunoprecipitation are "standard techniques." App. 5a. As other judges recognized, however, there was nothing standard about the way that techniques, known only from other contexts, were applied here. *E.g.*, App. 101a, 117a-119a (Moore, J.), 125a-126a (Newman, J.). No one had created radioactive ^{125}I-MuSK before, let alone used labeled MuSK and a sec-

ondary antibody to isolate MuSK autoantibodies as a means of diagnosing MG in the 20% of patients for whom no diagnostic test was previously available. That divide in the Federal Circuit reflects a fundamental disagreement about the level of generality at which elements that are conventional in the abstract but not in their claimed application should be viewed.

Fourth, the Federal Circuit's approach gives little consideration to the "preemptive" scope of a claim, contrary to this Court's guidance. In articulating the animating principle behind the judicially-created exceptions to Section 101, the Court has "described the concern that drives this exclusionary principle as one of pre-emption." *Alice*, 573 U.S. at 216; *see also id.* at 223-224 ("the pre-emption concern … undergirds our § 101 jurisprudence"). The idea is that claims to a natural law risk preempting the use of that natural law by others. *See Mayo*, 566 U.S. at 85-87 (noting preemption concern with claims "set forth in highly general language" rather than "confin[ing] their reach to particular applications of [natural] laws"); *Diamond* v. *Diehr*, 450 U.S. 175, 187 (1981).

The Federal Circuit, however, has transformed the preemption analysis into a one-way ratchet. The panel majority agreed that the claims here did not prevent others from using any natural law because the claims "leave[] open to the public other ways of interrogating the correlation between MuSK autoantibodies and MuSK-related disorders without practicing the claim's concrete steps." App. 13a. But echoing prior decisions, the panel broadly declared: "Preemption is sufficient to render a claim ineligible under § 101, but it is not necessary." *Id.*

This one-sided approach to preemption defies this Court's guidance and misses the critical distinction between "claims that sweep too broadly" and claims that, as here, are "sufficiently tied to a specific and useful application of a natural law." App. 73a, 75a (Dyk, J.); *see also* App. 116a (Moore, J.) ("The concreteness and specificity of the claims in *Athena* moves them from reciting a law of nature to a particular application of a law of nature.").

Fifth, courts have struggled with what it means to review a claim "as a whole." As Judge Chen explained, for more than 30 years following *Diehr*, it was understood that this Court had rejected the practice of dividing claims into new and old elements and searching for an inventive concept by disregarding any natural law recited in the claims. App. 80a-89a (Chen, J.). *Mayo* upended this practice by adopting a "framework … that strongly tracked the reasoning of … the *Diehr* dissent." App. 83a. "As such, *Mayo* is in considerable tension with *Diehr*'s instruction" and "considerably harder to apply consistently than the *Diehr* framework." App. 85a, 87a. The Federal Circuit is "not in a position to resolve" that tension, Judge Chen noted, "but the Supreme Court can." App. 89a.

C. Government Officials, Practitioners, And Commentators Agree That This Court's Guidance Is Needed

Given the lower courts' widespread confusion about the judicially-created exceptions to patent eligibility, government officials, practitioners, and commentators have all echoed and amplified the need for guidance from this Court.

Paul Michel, the retired Chief Judge of the Federal Circuit, recently testified that Section 101 "case law ha[s] produced unending chaos." *The State of Patent Eligibility in America, Part I: Hearing Before the Subcomm. on Intellectual Property of the S. Comm. on the Judiciary*, 116th Cong. 2 (2019), https://bit.ly/2WEZugp. He explained that "[b]ecause court decisions are so unpredictable," patents have become "unreliable" and "no longer sufficiently incentivize the large investments in research and development in new technologies our nation needs." *Id.* "Massive uncertainty," he further noted, "pervades all determinations, whether by 8,300 patent examiners, 1,000 federal trial judges, or 18 Federal Circuit judges." *Id.* at 6.

Current and former directors of the U.S. Patent and Trademark Office agree. PTO Director Andrei Iancu declared that the interpretation of Section 101 is "the most important substantive patent law issue in the United States today. And it's not even close." Davis, *Courts Can Resolve Patent Eligibility Problems, Iancu Says*, Law360 (Apr. 11, 2019), https://bit.ly/2mdkE4J. He further noted that "[r]ecent case law has created significant confusion" that "must be addressed now." Nurton, *Iancu Calls on Federal Circuit to Fix Section 101 Problem*, IP Watchdog (May 2, 2019), https://bit.ly/2lQECSg. Former PTO Director David Kappos testified that "patent eligibility law truly is a mess" with courts and the PTO "spinning their wheels on decisions that are irreconcilable, incoherent, and against our national interest." *State of Patent Eligibility, Part I*, at 1-2, https://bit.ly/2K3JjTW. His predecessor, Q. Todd Dickinson, testified that "the current rules are unnecessarily ambiguous and uncertain, and this uncertainty ends up serving no one." *State of Patent Eligibility, Part I*, at 7, https://bit.ly/2mUmFn3.

The Federal Circuit's wavering hand has only made the PTO's struggle implementing this Court's Section 101 case law more difficult. As the PTO explained, "[t]he growing body of precedent [from the Federal Circuit] has become increasingly more difficult for examiners to apply in a predictable manner, and concerns have been raised that different examiners within and between technology centers may reach inconsistent results." 84 Fed. Reg. 50, 52 (Jan. 7, 2019).

Practitioners have also pointed out that the current Section 101 standard "ha[s] created significant uncertainty about what is eligible for patenting." *State of Patent Eligibility, Part II*, at 2 (testimony of Barbara Fiacco, President-Elect of the American Intellectual Property Law Ass'n), https://bit.ly/2ZeVrFb. That uncertainty has, in turn, "reduced investment in new technologies, produced inconsistency and uncertainty about patent rights and their enforceability, cast a cloud over licensing and other intellectual property transactions, and driven industry to foreign jurisdictions." *Id.*

The American Bar Association has expressed the same concerns that "the current jurisprudence on patent eligibility … is confusing, creates uncertainty as to the availability and enforceability of patent assets, arguably risks the incentive to innovate provided by patents in technologies …, and potentially places the U.S. in a less advantageous position on patent protection than our leading competitor nations." Letter Re: Request for Comments Related to Patent Subject Matter Eligibility from Donna Suchy, Chair, ABA Section of Intell. Prop. L. to Michelle Lee, Director, PTO, at 2 (Jan. 18, 2017), https://bit.ly/2mbtoIr.

Scholars and commentators have likewise observed that "[t]he law of patentable subject matter is a mess," and that the Federal Circuit's "inconsistent and uncertain" application of Section 101 seems to be getting only "less, not more, certain over time." *State of Patent Eligibility, Part I*, at 1-2 (testimony of Prof. Mark Lemley, Stanford Law School), https://bit.ly/2n8tH7x. This "uncertainty," they have warned, "has imposed a substantial cost on society" by making it "extreme[ly] difficult[] … for innovators and investors … to discern the validity of their existing patents and the availability of meaningful protection for future innovations." Holman, *Patent Eligibility Post-*Myriad*: A Reinvigorated Judicial Wildcard of Uncertain Effect*, 82 Geo. Wash. L. Rev. 1796, 1830 (2014).

This Court should grant review to provide the guidance that the Federal Circuit, the PTO, practitioners, and scholars all agree is urgently needed.

II. THE FEDERAL CIRCUIT'S HOLDING THREATENS TO DISRUPT IMPORTANT MEDICAL INNOVATION

The "question of the eligibility of diagnostic inventions" for patent protection is "the type of exceptionally important issue that warrants full consideration" by this Court. App. 136a (Stoll, J.). Indeed, medical-diagnostic methods like Athena's are "the kind of subject matter the patent system is designed for: to encourage the risky, expensive, unpredictable technical research and development that people would not otherwise pursue." App. 94a (Chen, J.). The Federal Circuit's erroneous bar on patenting the vast majority of diagnostic tests threatens innovation in this important industry.

Since *Mayo*, the Federal Circuit "ha[s] held every single diagnostic claim in every case before [it] ineligible" for patent protection. App. 97a (Moore, J.). The Federal Circuit's decision in this case has now effectively shut that door for good for the vast majority of diagnostic claims, establishing a "per se rule" that bars "diagnostic kits and techniques," App. 99a (Moore, J.)—insofar as they are deemed to "consist of routine steps to observe the operation of a natural law," App. 61a (Lourie, J.)—no matter how novel or useful they are. *See also* App. 68a (Dyk, J.) ("*Mayo* left no room for us to find typical diagnostic claims patent eligible[.]"); App. 135a (Stoll, J.) ("[W]e have established a bright-line rule of ineligibility for all diagnostic claims."). Simply put, "there are no more options at [the Federal Circuit] for diagnostic patents." App. 118a (Moore, J.).

This rule will have devastating consequences. In the month after *Mayo* was decided, the PTO rejected 32% of the patent applications for medical diagnostics, up from 7% before. Chien & Wu, *Decoding Patentable Subject Matter*, 2018 Patently-O Pat. L.J. 1, 15 (Oct. 21, 2018), https://bit.ly/2oBO1i5. By the time *Alice* was decided, that rejection rate had climbed to more than 50%, and at one point hit a high of 64%. *Id.* With the decision below, that rate will climb significantly higher—if inventors even bother to apply for patents for diagnostic methods at all.

Everyone loses as a result. "Diagnostics are an essential category of medical technologies, critical to treating illnesses and saving lives." App. 102a (Moore, J.). Diagnostics perform a variety of functions essential to public health: they enable doctors to screen for medical risk factors and take measures to prevent the onset of disease, detect and diagnose disease at an early stage, determine disease severity and the likelihood of

recovery, select and monitor appropriate treatment, and identify adverse consequences of treatments. Lewin Group, *Laboratory Medicine: A National Status Report* 2 (2008) ("*Laboratory Medicine*"), https://bit.ly/2oBPdSB.

Diagnostics also reduce healthcare costs by allowing substitution of cost-effective, early-stage interventions for more expensive and less effective late-stage therapies. For these reasons, although diagnostics account for only about 2.3% of national healthcare spending, *Laboratory Medicine* 2, they influence approximately 70% of health care decisions, Badrick, Editorial, *Evidence-Based Laboratory Medicine*, 34 Clin. Biochem. Rev. 43, 43 (2013), https://bit.ly/2oE3caG.

For all of their benefits, diagnostics also have the very characteristics that make patent protection critical. A new diagnostic is "very expensive" and time-consuming to develop, but is usually "relatively cheap to reproduce." Krattiger, *Promoting Access to Medical Innovation*, World Intell. Prop. Org. Mag., Sept. 2013, at 5, 7, https://bit.ly/2n6a6VG. If diagnostics are broadly ineligible for patent protection—or even if there is substantial doubt about their eligibility—innovators will be unable to justify or recoup the high costs of research and development. "[T]he impact can only be that there will be fewer advances in diagnostic medicine." Matlock-Colangelo, Note, *Broadly Unpatentable: How Broad Method Claims Have Limited Patentability of Diagnostic Inventions*, 119 Colum. L. Rev. 797, 807 (2019); *see also* App. 103a (Moore, J.); App. 136a (Stoll, J.).

Research universities and pharmaceutical companies attest to that impact. The "[a]bility to get protectable intellectual property (usually in the form of a pa-

tent) is the first, and most influential factor in [their] assessment" whether to develop an invention into a commercial product, like a diagnostic test. *State of Patent Eligibility, Part III*, at 3 (testimony of Peter O'Neill, Executive Director of Cleveland Clinic Innovations), https://bit.ly/2naP08u. "If an invention can't get intellectual property protection, usually that is a fatal flaw and the invention is abandoned at that point." *Id.*; *see also State of Patent Eligibility, Part II*, at 4 (testimony of Natalie Derzko on behalf of the Pharmaceutical Research and Manufacturers of America) ("[T]he evolution of patent subject matter eligibility law in the United States has likely had a chilling effect on critical areas of research needed to address some of our most costly and challenging diseases[.]"), https://bit.ly/2n7hujE; *State of Patent Eligibility, Part II*, at 1 (testimony of Rick Brandon, Associate General Counsel of the University of Michigan, on behalf of Association of American Universities and the Association of University Technology Managers) ("If we do not allow for U.S. patenting of medical diagnostics, we'll miss out on better patient outcomes, cost savings through screening methods that predict disease or the most appropriate course of treatment, as well as other foundations for precision medicine."), https://bit.ly/2Io56SK.

The Federal Circuit's refusal will have a particularly negative impact in the emerging field of personalized medicine. Not all patients respond positively to medicine that helps others. Personalized medicine seeks to tailor treatment based on characteristics that make a patient susceptible to certain drugs, or less likely to suffer adverse effects from those drugs. *See* Vogenberg et al., *Personalized Medicine Part I: Evolution and Development into Theranostics*, 35 P&T 560, 560 (2010), https://bit.ly/2oC1uGF. The result is improved

health care outcomes and lower overall treatment costs compared to the traditional trial-and-error approach. But doctors cannot tailor treatment without diagnostics. The Federal Circuit's patent eligibility law therefore undermines the very foundation of personalized medicine. *Cf. The Age of Personalized Medicine*, Personalized Medicine Coalition, https://bit.ly/2kH3I5X (visited Oct. 1, 2019).

III. This Case Provides An Ideal Vehicle To Clarify The Patent Eligibility Of Diagnostic Methods

Athena's claims are not "methods of entering into contracts, or horse whispering, or speed dating or other methods" that have animated this Court's concerns regarding Section 101. App. 94a (Chen, J.); *see* Oral Arg. Tr. 7, 16, *Bilski* v. *Kappos*, No. 08-964 (U.S. Nov. 9, 2009). They instead recite a new and specific method of diagnosing MG through a series of concrete laboratory steps, so that patients can be accurately and expeditiously diagnosed. If these claims are patent-ineligible, that is truly the end for most medical diagnostic methods. This case is therefore an ideal vehicle to clarify the patent eligibility of medical diagnostic tests.

This case also provides a particularly good opportunity to address the doctrinal points that have confused the lower courts. *See supra* Part I.B. Several features of the case provide the Court flexibility to clarify the law and restore the patent eligibility of medical diagnostic tests in the manner it considers most appropriate, whether that means addressing only particular points on which the Federal Circuit has misapplied this Court's precedent or more broadly revisiting the framework articulated by this Court.

1. The first respect in which Athena's claims provide an opportunity to clarify the law is through their use of novel man-made molecules. The labeled MuSK with which the diagnostic method starts is itself a new molecule created by human ingenuity. A second new composition is formed when that ^{125}I-MuSK binds with MuSK autoantibodies. The addition of yet another antibody creates a third composition that, as disclosed in the patent, will usually consist of material derived from both humans and animals. C.A.J.A. 47.

The use of these man-made compounds makes this an easy case. This Court held in *Chakrabarty* that a new bacterium created in the lab is patent-eligible subject matter. 447 U.S. at 310. The Court similarly held in *Myriad* that while isolated DNA cannot be patented, laboratory-created cDNA in which the non-coding portions of the DNA have been removed is eligible for patent protection. 569 U.S. at 592-594. Under these decisions, the man-made molecules used in Athena's diagnostic method would themselves be eligible subject matter for patent protection.

There is no reason in law or logic that a claim that goes even *further* and limits itself to specific *uses* of novel man-made compounds should lose its eligibility for patent protection. Indeed, the Federal Circuit agreed shortly after *Mayo* was decided when it reviewed a method claim in the *Myriad* case (claim 20) that applied standard techniques for screening potential cancer therapeutics using a man-made cell into which an altered gene had been spliced. *Association for Molecular Pathology* v. *USPTO*, 689 F.3d 1303, 1310, 1335-1337 (Fed. Cir. 2012). The court explained:

> [P]erforming operations, even known types of steps, on, or to create, novel, i.e., transformed

> subject matter is the stuff of which most process or method invention consists. All chemical processes, for example, consist of hydrolyzing, hydrogenating, reacting, etc. … It is rare that a new reaction or method is invented; much process activity is to make new compounds or products using established processes. Thus, once one has determined that a claimed composition of matter is patent-eligible subject matter, applying various known types of procedures to it is not merely applying conventional steps to a law of nature. The transformed, man-made nature of the underlying subject matter in claim 20 makes the claim patent-eligible. The fact that the claim also includes the steps of determining the cells' growth rates and comparing growth rates does not change the fact that the claim is based on a man-made, non-naturally occurring transformed cell—patent-eligible subject matter.

Id. at 1336. This ruling remained intact when this Court granted certiorari to review other claims in *Myriad* while specifically declining to review the method claim that the Federal Circuit had upheld. *See* 689 F.3d 1303 (2012); Miscellaneous Order (U.S. Nov. 30, 2012) (petition "granted limited to Question 1").

By the time the Federal Circuit considered this case, however, it had painted itself into a corner. Based on its own subsequent decisions and a misinterpretation of *Mayo*, it held that "the use of a man-made molecule is not decisive." App. 13a. "For example," the panel explained, "*Mayo* involved claims requiring administering a man-made molecule (a drug "providing" 6-thioguanine) to a patient." *Id.*

This ruling overlooked a critical distinction between *Mayo* and this case. In *Mayo*, the man-made molecule was not new. "[D]octors used thiopurine drugs to treat patients suffering from autoimmune disorders long before" the patent at issue. 566 U.S. at 78. The doctors using thiopurine drugs were thus "a preexisting audience." *Id.* at 78. In contrast, the man-made molecules in this case *are* new. There is no evidence anyone had previously created radioactive ^{125}I-MuSK, an ^{125}I-MuSK/MuSK autoantibody complex, or the cross-species combination of that complex with a secondary antibody. This case provides an ideal opportunity for this Court to resolve this confusion and hold that diagnostic methods that use novel man-made molecules in new and useful ways constitute subject matter eligible for patent protection, provided they satisfy all of the other requirements the Patent Act imposes.

2. The second opportunity Athena's claims provide to clarify the law comes from their recitation of specific chemical steps to achieve a new and useful result. This distinguishes the claims from the unusual claims in *Mayo*, it means that the claims are directed to a specific diagnostic tool rather than a natural law, and it limits the claims' preemptive reach—any of which provides a ground for clarifying the law and restoring the patent eligibility of more typical diagnostic claims.

a. The patent claims here are a world apart from the claim invalided in *Mayo*. As discussed, the unusual *Mayo* claims merely recited information without requiring a single, real-world action not "already engaged in by the scientific community." 566 U.S. at 79-80. The claims were thus directed to the natural law itself. Here, the inventors made an undisputedly groundbreaking discovery that 20% of MG patients develop the disorder because they generate autoantibodies to

MuSK. C.A.J.A. 43-44. But that is not what they claimed. Rather, "as the first party with knowledge of" their discovery, they were "in an excellent position to claim *applications* of that knowledge." *Myriad*, 569 U.S. at 596 (emphasis added; brackets and quotation marks omitted). The inventors did exactly that, adapting techniques that had never previously been used to detect MuSK autoantibodies and using a series of specific chemical steps that had never been performed in that manner. The result was a highly effective new laboratory test for diagnosing patients for whom no test had previously been available.

b. The specificity of Athena's claims means that the claims are not "directed to" a natural law. Rather, they are directed to a particular chemical process for detecting a previously unused biomarker and diagnosing illness. The Federal Circuit ignored this distinction on the ground that the "'end result'" of the claim is "'an observation or detection'" of a natural law. App. 12a. But defining the focus of the claims by the result to be achieved, rather than the means used to achieve that result, is a mistake because that would mean that all diagnostic claims are directed to a natural law. At the very least, moreover, the use of specific chemical steps transforms the claims into more than a mere attempt to patent the natural law itself, which is the concern that motivates the judicially-created exceptions to Section 101.

The Federal Circuit compounded this error by examining the steps of the claims at a high level of generality. Dismissing claim elements as conventional techniques *in the abstract*, the court lost sight of the fact that there was nothing conventional about applying those techniques in the manner done here. No one had used labeled MuSK and immunoprecipitation to detect

MuSK autoantibodies, and the inventors had to overcome various obstacles to enable reliable detection of a molecule that had never before been used in a diagnostic test. It was only by ignoring the specificity of the claims, and defining the steps at a high level of generality, that the Federal Circuit could recast a series of chemical steps *never before performed in combination* as "conventional" activity entitled to no weight.

c. The specific combination of steps in Athena's claims also resolves concerns regarding preemption of future research. In *Mayo*, anyone who wanted to make use of, or merely study, the correlation disclosed in the claim had to infringe the claim by administering a thiopurine drug and measuring metabolite levels. 566 U.S. at 79. The opposite it true here. The Federal Circuit held that Athena's claims "leave[] open to the public other ways of interrogating the correlation between MuSK autoantibodies and MuSK-related disorders without practicing the claim's concrete steps." App. 13a. But the court ignored this fact because it viewed preemption as a one-sided test in which "[p]remption is sufficient to render a claim ineligible under § 101, but it is not necessary." *Id.* This relegation of preemption to the sidelines cannot be squared with this Court's description of "preemption" as "the concern that drives" the judicially-created exceptions to Section 101. *Alice*, 573 U.S. at 216.[2]

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[2] This Court has been skeptical of patent claims that broadly tie up use of an abstract idea even if limited to a particular field of technology. *Alice*, 573 U.S. at 216-217. But that type of artificial narrowing to try to monopolize all uses of a natural law in a particular industry is not the situation here. Athena's asserted claims are limited by the specific chemical steps they recite, and do not cover other detection techniques. Their preemptive scope is therefore inherently limited and does not depend on artifice.

Multiple judges have urged this Court to rely on the specificity of the chemical steps in Athena's claims to restore patent protection for similar diagnostic claims. Judge Dyk argued that "the *Mayo* test for patent eligibility should leave room for sufficiently specific diagnostic patents" and that "this case may involve claims that could be patent eligible under this suggested approach." App. 68a, 76a. Judge Moore agreed that Athena's "steps are not set out at the 'high level of generality' that concerned the Court in *Mayo*." App. 116a. Rather, "the concreteness and specificity of the claims in *Athena* moves them from reciting a law of nature to a particular application of a law of nature." *Id.* Judge Stoll likewise noted that "[c]ertain diagnostic claims, such as the ones at issue in this case, are so narrowly tailored that preemption is not a reasonable concern." App. 137a.

All of these distinctions failed to move a slight majority of the Federal Circuit, but it is incumbent on this Court to clarify the law, and correcting even one of these points would lead to a different result.

3. Finally, it bears consideration that the rules the Federal Circuit has relied on to invalidate medical diagnostic claims find no support in the statute. The capacious language of Section 101 provides that "[w]hoever invents or discovers *any* new and useful *process*, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title." 35 U.S.C. § 101 (emphases added). The language chosen by Congress easily encompasses Athena's claims. This case thus turns entirely on judicially-created exceptions, unsupported by the statutory text.

This Court, as the creator of those non-textual exceptions, bears a special responsibility to ensure that they are properly interpreted and applied. The Court has admonished courts to "tread carefully" lest the exceptions "swallow all of patent law." *Alice*, 573 U.S. at 217. But the Federal Circuit has not heeded that admonition, allowing those exceptions to expand ever outward and swallow the field of medical diagnostics. The legal issues are too fundamental, and the stakes too high, to allow that misapplication of the law to stand. The Court should grant the petition and reverse.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted.

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