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 Writ Of Certiorari To The United States Court Of Appeals For The Federal Circuit

BRIEF OF *AMICUS CURIAE* BIOTECHNOLOGY INNOVATION ORGANIZATION IN SUPPORT OF PETITIONERS

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INTEREST OF *AMICI CURIAE*[1]

The Biotechnology Innovation Organization ("BIO") is the principal trade association representing the biotechnology industry in all fifty states and abroad. BIO has more than 1,000 members, ranging from small start-up companies and biotechnology centers to research universities and Fortune 500 companies. The majority of BIO's members are small companies that have yet to bring products to market or attain profitability. Approximately 90% of BIO's corporate members have annual revenues of under $25 million. These members rely heavily on venture capital and other private investment.

BIO's members are involved in the research and development of innovative healthcare, agricultural, industrial and environmental biotechnology products and services. They invest vast resources to develop breakthrough technologies that improve public health and welfare, including novel antibody therapeutics, seeds and plants with novel traits, industrial enzymes and advances in personalized medicine. Diagnostic methods are an essential part of biotechnology innovation. In the healthcare sector, for example, diagnostic methods can change the odds of serious, life-threatening conditions affecting millions of patients. Diagnostic methods provide precise tools for early screening and

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[1] Rule 37 statement: The parties were notified and consented to the filing of this brief more than 10 days before its filing. *See* Sup. Ct. R. 37.2(a). No party's counsel authored any of this brief; *amicus* alone funded its preparation and submission. *See* Sup. Ct. R. 37.6.

detection, identifying at-risk patients to prevent disease onset or progression, allowing physicians to tailor treatments to maximize outcomes, and minimize risks and side effects.

The question presented in the petition is of fundamental importance to BIO's members. Intellectual property is the lifeblood of the biotechnology industry. BIO's members rely on the patent system to structure their businesses and protect their inventions. Strong patents, and an efficient, predictable, and objective patent system, are critical to ensuring a steady stream of capital investment. This investment supports the massive development costs of new biotechnology products and services and enables biotechnology companies to continue to innovate and disseminate their technologies benefitting the U.S. economy and the public. BIO's members are concerned that seven years after the Court decided *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66 (2012) ("*Mayo*"), the Federal Circuit feels compelled to announce a "per se rule that all diagnostic claims are [patent] ineligible."[2] This striking pronouncement impacts the biotechnology

[2] Judge Moore, with Judges O'Malley, Wallach and Stoll joining. App. 111a; *see also* App. 99a ("a per se rule that diagnostic kits and techniques are ineligible"); App. 100a ("a per se rule that excludes all diagnostics from eligibility"). Judge Stoll, with Judge Wallach joining, expressed this as "a bright-line rule of ineligibility for all diagnostic claims" and "a wholesale bar on patent eligibility for diagnostic claims." App. 135a; App. 136a; *see also id.* ("this court's bright-line rule").

industry at its core: disincentivizing scientific and medical progress and technological innovation.

Amicus BIO submits this brief in the hope that it will assist the Court in the orderly evaluation of the law in this important area. BIO has no direct stake in the result of this appeal and takes no position on the ultimate validity of the patents at issue. This brief reflects the consensus view of BIO's members, but not necessarily the view of any individual member.

SUMMARY OF ARGUMENT

BIO urges the Court to grant the Petition to provide essential clarification and guidance as to the patent-eligibility of diagnostic methods.

This case turns on a judicially created exception to 35 U.S.C. § 101 and, in particular, on the application by the Federal Circuit of the two-part test the Court set forth in *Mayo*. The claims-in-issue employ at least two specific new products of human ingenuity in a series of specific new chemical steps, to diagnose a newly identified subclass of disorder. The Federal Circuit found these claims directed to a natural law and lacking an inventive concept. In so-holding, multiple panel members pronounced a "wholesale bar," a "bright-line," and a "per se rule that all diagnostic claims are ineligible." App. 111a; App. 135a; App. 136a. This cannot reflect the Court's intention. At the very least, the Court has suggested that new applications of knowledge about the natural world, including diagnostic applications,

can be patent-eligible. *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576, 596 (2013) ("*Myriad*") (endorsing Judge Bryson's "apt" statement that "[as] the first party with knowledge of the [BRCA1 and BRCA2] sequences, Myriad was in an excellent position to claim applications of that knowledge.").

The question for inventors in the biotechnology industry remains: How? What does it take for a diagnostic method claim to meet the eligibility threshold set forth in *Mayo*? In the seven years since the Court decided *Mayo*, the Federal Circuit has not once found a diagnostic claim patent-eligible. App. 97a-98a. At this point inventors, businesses, and patent practitioners are at a loss. If the particularized laboratory processes at issue in this case are not patent-eligible, then what more must an inventor do? Under the Federal Circuit's reasoning, a diagnostic claim is necessarily "directed to" the biological relationship it seeks to exploit. This method will, therefore, always satisfy step one of *Mayo*. In order to implement that biological relationship in a sufficiently "creative" and "unconventional" way under step two of *Mayo*, it seems that the inventor must also integrate a second invention, such as a new microscope or reagent. But this is not consistent with the Court's precedent. The inventor in *Diamond v. Diehr*, 450 U.S. 175 (1981) ("*Diehr*"), did not have to separately invent the Arrhenius equation and the rubber-curing steps before combining them into a patent-eligible process. And Myriad's cDNA did not have to meet an elevated standard of inventiveness to be patent-eligible—it was "unquestionably something new" despite being derived

from nature by conventional means. *Myriad*, 569 U.S. at 595.

The claims-in-issue here are at least as unconventional and creative as Diehr's method or Myriad's cDNA. They are more particularized and specific than the method in *Mayo*. And they are less preemptive than the process in *Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 573 U.S. 208 (2014) ("*Alice*"). And yet, according to the Federal Circuit, diagnostic inventors just cannot get it right. Guidance from the Court is urgently needed to clarify the applicability of the judicial exceptions to diagnostic laboratory processes. This case is a suitable and illustrative vehicle to provide this guidance because it concerns claims that range from general statements of principle to specific laboratory applications using particular reagents, intermediates and detection methods that may fall on either side of the patent-eligibility divide.

Too much is at stake for the Court to pass over this petition. If there is no path to patent-eligibility for diagnostic methods, inventors and businesses need to know this so they can plan and maintain their inventions in trade secrecy or redirect their efforts and investments into other endeavors.

ARGUMENT

I. This Case Is A Suitable Vehicle To Affirm The Patent-Eligibility Of Particularized Diagnostic Laboratory Processes

This case is a suitable vehicle for the Court to clarify the patent-eligibility of diagnostic methods. As Judge Stoll remarked: "the question of the eligibility of diagnostic inventions is exactly the type of exceptionally important issue that warrants" further review by the Court. App. 136a.

The Federal Circuit focused its analysis here on claim 9 of Petitioner's patent. App. 4a; App. 11a. Claim 9 recites a series of new chemical steps that employ two new human-made constructs: a specific protein ("MuSK") labelled with a specific radioactive iodine label ("^{125}I-MuSK"); and a specific protein-antibody complex ("^{125}I-MuSK-autoantibody"). Claim 9 employs these new constructs in a method for diagnosing a new subclass of neurotransmission disorders. The method involves: *first*, contacting ^{125}I-MuSK with bodily fluid which may contain autoantibodies to MuSK ("MuSK-autoantibodies"); *second*, immunoprecipitating any complex that subsequently forms between ^{125}I-MuSK and a MuSK-autoantibody; and *third*, detecting such complexes by detecting the label, which allows for the disorders to be diagnosed. App. 4a-5a. The record establishes that labelling and immunoprecipitation had previously been used to detect antibodies—although not the particular MuSK-autoantibodies in issue. App. 5a; App. 25a. The record also establishes that radioactive labels had previously been used

(including the specific label ^{125}I), but no label (including ^{125}I) had previously been applied to MuSK. App. 18a; App. 122a. Also, "[t]he reaction between" these autoantibodies and MuSK "was not previously known"; "the specified claim steps had not previously been performed, separately or in combination"—and, further, prior to the invention, this subclass of disorders was "undiagnosable". App. 24a; App. 25a; App. 26a; App. 120a; App. 123a.

Claim 9 starkly contrasts with claim 1 from which it depends. Claim 1 (not in issue) recites a method for diagnosing the same disorders, comprising only "the step of detecting in a bodily fluid" MuSK autoantibodies. Claim 1, therefore, lacks the specific detail of claim 9—the additional elements that integrate any natural law or phenomenon into a specific practical application. Claim 1 is also strikingly similar to other broad, generalized diagnostic claims that have been held patent-ineligible under *Mayo*, for example claim 1 of Myriad's U.S. Patent No. 5,709,999: "[a] method for detecting [one of several enumerated germline alterations] in a BRCA1 gene . . . in a human which comprises *analyzing* a sequence of a BRCA1 gene or BRCA1 RNA from a human sample or *analyzing* a sequence of BRCA1 cDNA made from mRNA from said human sample. . . ." *Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office*, 689 F.3d 1303, 1309 (Fed. Cir. 2012), *aff'd in relevant part, Myriad*, 569 U.S. 576. Claims such as these face criticism that they add little to an abstract idea or natural law and require, at best, only the highly-generalized steps of "detecting" or "analyzing" such idea or law. But claim 9 is at the other

end of the spectrum—it recites a specific application using particular laboratory steps, reagents, intermediates, and detection methods. There is no question that claim 9, whatever its merits or demerits, is a far cry from merely stating a law of nature and adding the instruction to "apply it." *Mayo*, 566 U.S. at 72.

The Federal Circuit acknowledged the particularity of the claims-in-issue here but could not find a way to hold them patent-eligible under its reading of the Court's jurisprudence. The common thread of all eight opinions denying *en banc* review is discomfort with the result and uncertainty as to whether the Court's precedents, centering on the application of *Mayo*, intend an outcome that leaves no clear path forward even for meritorious, narrowly-claimed diagnostic inventions.

A majority of the *en banc* panel agreed that diagnostic methods *should* be patent-eligible—Judge Chen opining, for example, that "[i]n any meaningful sense" these claims represent a "practical application of the discovered law of nature, that is, [they are] applied science in every sense of that term. And [they] should be patentable subject matter in a well-functioning patent system." App. 94a-95a. Other members of the panel concurred that "the *Mayo* test for patent eligibility should leave room for sufficiently specific diagnostic patents," and "§ 101 and *Mayo*, when read together and in their entireties, compel the holding that the claims [in issue here] are eligible." App. 68a; App. 109a-110a.

And yet, as Judge Moore noted in her dissenting opinion: in the seven years since *Mayo*, the Federal

Circuit has "held every single diagnostic claim in every case before us ineligible," and "[t]he district courts are following our lead." App. 97a-98a. This case is, therefore, symptomatic of a problem that deserves the Court's attention. The claims here—claim 9 included—are the most specific and particularized diagnostic claims to reach the Court. This, BIO respectfully submits, presents the Court with the opportunity to at least establish "bookends" for the proper claiming of diagnostic methods under 35 U.S.C. § 101.

II. Guidance Is Needed To Clarify The Meaning Of An Inventive Concept

"[T]he disagreement" in this case "centers on . . . the inventive concept requirement" in step two of the Court's two-step test in *Mayo*. App. 141a (O'Malley J.). The majority found that the claims-in-issue "are directed to a natural law," and while they "involve . . . certain concrete steps," they "lack an inventive concept" because they "only apply conventional" or "standard technique[s]" to detect or observe that natural law. App. 2a; App. 9a; App. 11a; App. 12a; App. 13a; App. 14a; App. 22a; *see also* App. 14a; App. 16a. These techniques, identified in the majority opinion, are "iodination, immunoprecipitation, and the overall radioimmunoassay." App. 16a; App. 20a.

These findings are worryingly broad-brush. They also exacerbate uncertainty in the biotechnology industry about what exactly constitutes an "inventive concept." No diagnostic claim with an inventive concept

has survived 35 U.S.C. § 101 analysis at the Federal Circuit since *Mayo*. Therefore, neither the Federal Circuit nor the patent user community has any certainty as to what such a claim may look like. If the particularized laboratory processes of Petitioner's claims here do not qualify, this begs the question: What more could the inventors have done? Does the Court's jurisprudence require "even more" than that provided in claim 9—for example, the integration of a new, independently patentable device such a microscope with which a natural law is to be detected? This cannot be what the Court envisages, nor would it be a realistic requirement, not least because such devices are a very different field of endeavor than diagnostic methods.

An equally important problem with the inventive concept requirement, in the context of diagnostic claims, was succinctly articulated by Judge Dyk four years ago:

> The *Mayo/Alice* framework works well when the abstract idea or law of nature in question is well known and longstanding, as was the situation in *Mayo* itself. . . . But, as I see it, there is a problem with *Mayo* insofar as it concludes that inventive concept cannot come from discovering something new in nature—*e.g.*, identification of a previously unknown natural relationship or property. In my view, *Mayo* did not fully take into account the fact that an inventive concept can come not just from creative, unconventional application of a natural law, but also from the creativity and novelty of the discovery of the law itself. This

> is especially true in the life sciences, where development of useful new diagnostic and therapeutic methods is driven by investigation of complex biological systems.

Ariosa Diagnostics, Inc. v. Sequenom, Inc., 809 F.3d 1282, 1288-89 (Fed. Cir. 2015) (Dyk, J., concurring). This is such a case. The invention here identifies—for the first time—the existence of a new subclass of disorders, identifies their cause, and provides a new multi-step laboratory method for their "accurate and speedy diagnosis." App. 24a-26a; App. 41a.

It is also unclear how the Federal Circuit's application of *Mayo*—which suggests that a newly-discovered natural law can never be considered when evaluating the inventiveness of a diagnostic method—can be reconciled with *Myriad*. There, the Court suggested that while isolated DNA is patent-ineligible, new applications of knowledge about isolated DNA *could* be eligible. *Myriad*, 569 U.S. at 596 ("as the first party with knowledge of the BRCA1 and BRCA2 sequences, Myriad was in an excellent position to claim applications of that knowledge"). The Court appeared to recognize in *Myriad* that the discovery of a previously unknown natural phenomenon can sometimes provide, or at least contribute to, the requisite inventive concept.

Lower courts, following the Federal Circuit's lead, understand that the search for an inventive concept requires a form of claim dissection. But this dissection becomes highly problematic when the claim involves a natural law or natural phenomenon. In practice, a

diagnostic patentee's main contribution to the art over preexisting technology will almost always lie, at least in part, in the discovery of a previously unknown natural law or phenomenon. If that contribution is defined away as the patent-ineligible element of the claim, it is easy for courts to conclude that the remainder of the claimed method lacks the necessary inventive concept.

But the Court's jurisprudence does not support the proposition that claim elements—even those that are deemed directed at a judicial exception—can effectively be excised and removed from consideration altogether. The Court identified the fallacy of this when it explained that an otherwise statutory process such as Diehr's method for curing rubber does not become patent-ineligible just because it incorporates an improvement requiring a computer-implemented mathematical formula. *Diehr*, 450 U.S. at 187 ("a claim drawn to subject matter otherwise statutory does not become nonstatutory simply because it uses a mathematical formula, computer program, or digital computer."). If it is true—as *Diehr* teaches—that one cannot "flip" a claimed process out of patent-eligibility by including a mathematical formula (or law of nature, or natural phenomenon), then it cannot be correct to analyze the patent-eligibility of a claim in any way other than through scrupulous attention to all of the elements of the claim, the old and the new elements—even those involving a law of nature or a mathematical formula. Only if a claim is considered as a whole will a decision-maker be able perform a *Mayo* step-two analysis that, consistent with the Court's precedent,

searches for an inventive application *of* a law of nature. To do otherwise would be to search for an inventive application *apart* from a law of nature, which cannot be what the Court intended.

Judge Newman highlights this concern in this case when she observed that "[t]he majority does not distinguish between . . . whether the claimed method as a whole is eligible, and . . . whether the separate steps use conventional procedures." App. 32a. This is a fundamental flaw in the majority opinion. But unfortunately, lower courts seem to understand *Mayo* to require precisely that: *first*, the exclusion of patent-ineligible subject matter from the claim; and *second*, an inquiry into whether the claimed method would be patentable or "inventive" without that excluded subject matter. This approach is highly problematic because it means that a newly-discovered natural phenomenon can never support patent-eligibility. This also suggests that patentees must have to integrate an additional, independently patentable element into their claims that may be useful for diagnosis, such as a new laboratory reagent or a new analytical apparatus. If this is correct, patent law systematically rewards the invention of such tools, and denies reward to those who use these tools to invent real-world diagnostic, prognostic or other socially beneficial biotechnology processes. If this is an objective of the Court's patent-eligibility jurisprudence, inventors and businesses need to know.

III. The Federal Circuit Subjects Diagnostic Methods To A Heightened Inventive Concept Analysis

Various members of the panel below opined that the Federal Circuit has "mistakenly enlarged" *Mayo* as it applies to diagnostic method claims, "extend[ing]" it "too far." App. 101a; App. 121a. But the Court's jurisprudence is clear that where a process is "new and useful, it is just as patentable as is a piece of machinery." *Diehr*, 450 U.S. at 183; *see also Tilghman v. Proctor*, 102 U.S. 707, 722 (1881) ("That a patent can be granted for a process, there can be no doubt.").

Congress drafted section 101 of the Patent Act expansively, and the Court has long held that "Congress intended statutory subject matter to include anything under the sun that is made by man." *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980). However, the Court has also long held that "[l]aws of nature, natural phenomena, and abstract ideas" are judicial exceptions to this general rule. *Id.*; *Alice*, 573 U.S. at 216; *Mayo*, 566 U.S. at 71.

Preemption is a legitimate concern that underlies these exceptions. But at the same time, the Court has admonished courts to "tread carefully" so as to not let this carve out, "swallow all of," and "eviscerate patent law." *Alice*, 573 U.S. at 217; *Mayo*, 566 U.S. at 71. Not least, because "[a]t some level, all inventions embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas." *Mayo*, 566 U.S. at 71; *Alice*, 573 U.S. at 217; *see also id.* at 223-24.

The challenge is, therefore, to "distinguish between patents that claim" judicial exceptions—the so-called "building blocks of human ingenuity"; "the basic tools of scientific and technological work" that must be kept available for all—and patents that instead "integrate the[se] building blocks into something more," something "transform[ative]." *Alice*, 573 U.S. at 217 (internal quotation marks, brackets, and citations omitted); *see also Mayo*, 566 U.S. at 71-72, 89; *Diehr*, 450 U.S. at 187. The Court's precedent is clear that applications "of such concepts to a new and useful end . . . remain eligible for patent protection." *Alice*, 573 U.S. at 217 (citing *Gottschalk v. Benson*, 409 U.S. 63, 67 (1972)); *see also Funk Brothers Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948) ("If there is to be invention from a discovery of a law of nature, it must come from the application of the law of nature to a new and useful end.") (internal bracket omitted). In part, this is because where a judicial exception is integrated "into something more," there is "no comparable risk of pre-emption," and therefore no basis to deny eligibility. *Alice*, 573 U.S. at 217 (internal quotation marks, brackets, and citations omitted); *see also Mayo*, 566 U.S. at 71; *see also Diehr*, 450 U.S. at 187 (where a patent seeks only to foreclose others from use of an ineligible concept "in conjunction with all of the other steps in their claimed process," there is no undue preemption).

The Court has also said that "an 'inventive concept' under § 101 must be 'a product of human ingenuity.'" *CLS Bank Int'l v. Alice Corp. Pty. Ltd.*, 717 F.3d 1269, 1283 (Fed. Cir. 2013) (quoting *Chakrabarty*, 447

U.S. at 309). So, for example, when a "lab technician unquestionably creates something new," that new matter may be patent-eligible even when nature dictates the new matter's essential property. *Myriad*, 569 U.S. at 595 (finding a cDNA sequence patent-eligible even though this sequence retains naturally occurring material). Here, ^{125}I-MuSK and the ^{125}I-MuSK-autoantibody complex are not naturally occurring, they are specific new constructs, made in a laboratory. They are products of human ingenuity—transformative products that require skill, knowledge and effort. Without these specific human-made constructs it would not be possible to practice the claimed invention. But the claims-in-issue here are process claims, rather than product claims, and the Federal Circuit suggests that this is a fatal difference.

The fundamental flaw in the Federal Circuit's approach is similar to the "flip" analysis identified above—it cannot be correct that product claims to, for example, ^{125}I-MuSK or the ^{125}I-MuSK-autoantibody complex, are patent-eligible; but the specific use of these constructs in a process then renders the claim ineligible. Just as one cannot "flip" a claimed process into or out of patent-eligibility by omitting or including a natural law; the Court cannot have intended that one can "flip" a novel product into or out of patent-eligibility by claiming it alone rather than integrating it in a claim that also recites a natural law (or natural phenomenon or abstract idea).

The Federal Circuit also failed to give proper consideration here to the issue of preemption. Even the

majority "agree[d] that claim 9 leaves 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; *see also* App. 116a (Moore, J.); App. 127a (Newman J.). If there is no preemption as to at least claim 9, then there should be no bar to eligibility. Judge Moore, joined by Judges O'Malley, Wallach and Stoll concurred that the claims here "do not 'broadly preempt the use of a natural law,' and do not prevent any scientist from using the natural law in association with other common processes." App. 116a (citing *Mayo*, 566 U.S. at 72). Judge Stoll concurred 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.

Indeed, the "majority" of the panel below "repeatedly acknowledged that the claims in *Athena*, unlike the claims in *Mayo*, contain specific, concrete steps applying the law of nature." App. 116a (Moore, J.). As Judge Moore correctly noted: "[t]he 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"—"[t]he claims are directed to a new and useful process of specific, concrete steps for diagnosing MG using a particular immunoassay that had never been previously used to diagnose MG." App. 116a; App. 117a. Judge Newman went further, finding that the claims-in-issue recite a patent-eligible "chemical-biomedical procedure"—reasoning 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; App. 34a.

But the majority failed to acknowledge the specificity and detail of the claims. Finding that claim 9 (and the remaining claims-in-issue) applied only "conventional," "standard techniques . . . applied in a standard way," the majority did not analyze the claims as an integrated whole. App. 16a. Worse, they failed to heed the Court's warning that overgeneralizing claims, "if carried to [an] extreme, make[s] all inventions unpatentable because all inventions can be reduced to underlying principles of nature." *Diehr*, 450 U.S. at 189 n.12. The Federal Circuit here took a broad-brush approach, and held these diagnostic method claims to a heightened standard. The panel overlooked specific claim limitations that integrate a newly discovered biological relationship into a specific, practical, patent-eligible application.

IV. The Federal Circuit's Decision Undermines The Biotechnology Industry

Various members of the panel below rightly acknowledged the impact of their decision on the biotechnology industry, specifically the "chilling effect" a loss of patent-eligibility will have—fatally "inhibiting innovation" and investment. App. 107a (Moore, J.); App. 35a-36a (Newman, J.). As Judge Moore acknowledged: "[w]e are hard-pressed to identify facets of modern medicine that do not employ or rely on diagnostics."

App. 104a. "Diagnosis is the foundation of medicine." App. 102a. Diagnostic methods "guide approximately 66% of clinical decisions," and are "critical to treating illnesses and saving lives." App. 102a (internal citation omitted); *see also* App. 131a ("diagnostic tests form[] the basis of 60-70% of all medical treatment decisions.") (citation omitted). Various members of the *en banc* panel also acknowledged that the development of diagnostic methods "is expensive and time consuming," and can "cost up to $100 million and take nearly 10 years." App. 102a; App. 132a ("the cost of commercializing a diagnostic test is between $50-$100 million."). This is precisely why BIO is compelled to appear as *amicus curiae*.

Dependable patent protection is "required" for financial viability. App. 103a. Judge Moore, with Judges O'Malley, Wallach and Stoll joining, recognized that "[f]rom a business perspective," the absence of patent protection means that investing in biotechnology, and specifically in diagnostic methods "simply isn't worth the risk." App. 103a (internal citation omitted). Absent such protection, there is "little incentive" to invest, with the potentially catastrophic result that there "will be fewer advances in diagnostic medicine." App. 103a; App. 107a. As Judge Moore explained, citing the testimony of an industry member: section 101 "is the gateway to the patent system"—it therefore acts as "a guide to as to which fields of technology can support sustained investment, and which [] likely cannot." App. 108a; 35 U.S.C. § 101. "To put it simply, this is bad. It is bad for the health of the American people and for

the health of the American economy." App. 109a; *see also* App. 107a (an "uncertain patent climate" threatens "public health"). And "[t]he loser is the afflicted public, for diagnostic methods that are not developed benefit no one." App. 36a-37a (Newman, J.). At a time when "we face increasingly robust medical challenges," the stakes could not be higher. App. 106a.

This case turns on a judicially created exception. It presents the Court with a timely opportunity to explicate the law it set forth in *Mayo* and affirm that diagnostic method claims—like any other "process, machine, manufacture, or composition of matter" claim—are patent-eligible under 35 U.S.C. § 101. For all the reasons set forth above, this case provides the ideal vehicle for the Court to re-visit its jurisprudence and resolve the confusion in the Federal Circuit and in the courts below.

CONCLUSION

The Petition for Writ of Certiorari should be granted.

Respectfully submitted,

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