No. 15-1182

IN THE
Supreme Court of the United States

SEQUENOM, INC.,
Petitioner,
v.

ARIOSA DIAGNOSTICS, INC., NATERA, INC., AND DNA DIAGNOSTICS CENTER, INC.,
Respondents.

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

BRIEF OF *AMICUS CURIAE* NEW YORK INTELLECTUAL PROPERTY LAW ASSOCIATION IN SUPPORT OF PETITIONER

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INTEREST OF *AMICUS CURIAE*[1]

The New York Intellectual Property Law Association ("NYIPLA") is a bar association of more than 1,300 attorneys who practice in the area of patent, copyright, trademark and other intellectual property ("IP") law.[2] It is one of the largest regional IP bar associations in the United States. Its members include in-house counsel for businesses and other organizations, and attorneys in private practice who represent both IP owners and their adversaries (many of whom are also IP owners). Its members represent inventors, entrepreneurs, businesses, universities, and industry and trade associations. Many of its members are involved in research, patenting, financing and other commercial activity across industries.

The NYIPLA's members and their clients regularly participate in patent litigation on behalf of both plaintiffs and defendants in federal court and in proceedings before the United States Patent and

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[1] Pursuant to Sup. Ct. R. 37.6, the NYIPLA and its counsel represent that they have authored the entirety of this brief, and that no person other than the *amicus curiae* or its counsel has made a monetary contribution to the preparation or submission of this brief.

[2] Pursuant to Sup. Ct. R. 37.2(a), both Petitioner and Respondents have consented to the filing of any *amicus curiae* brief in support of either or neither side's position on this petition for certiorari. Petitioner's consent letter was filed in a docket entry dated March 28, 2016. Respondents' consent letters were filed in docket entries dated March 28, 2016 (Ariosa Diagnostics), March 30, 2016 (DNA Diagnostics Center), and March 31, 2016 (Natera), respectively.

Trademark Office ("PTO"). They also actively engage in licensing matters representing both patent licensors and licensees. The NYIPLA thus brings an informed perspective to the issues presented.

The NYIPLA's members and their respective clients have a strong interest in the issues in this case because their day-to-day activities depend on the consistently-applied and longstanding broad scope of patent-eligible subject matter under the Patent Act. Moreover, because of the vital and increasing importance of biotech and medical innovation to the economy, the NYIPLA and its members have a particularly strong interest in ensuring that those principles continue to be consistently and flexibly applied in those important areas.[3]

[3] The arguments made in this brief were approved by an absolute majority of the NYIPLA's officers and members of its Board of Directors, but do not necessarily reflect the views of a majority of the members of the Association, or of the law or corporate firms with which those members are associated. After reasonable investigation, the NYIPLA believes that no officer or director or member of the Amicus Briefs Committee who voted in favor of filing this brief, nor any attorney associated with any such officer, director or committee member in any law or corporate firm, represents a party to this litigation. Some officers, directors, committee members or associated attorneys may represent entities, including other *amici curiae*, which have an interest in other matters that may be affected by the outcome of this litigation.

SUMMARY OF THE ARGUMENT

This petition for a writ of certiorari presents issues fundamental to patent eligibility that are of exceptional importance to patent owners, patent challengers, and to innovation across all industries. These issues are particularly critical to the life sciences and medical fields where innovations of profound public benefit are often based on applying known techniques to new discoveries in nature.

This case involves taking such a medical innovation out of the realm of patent eligibility even though the Federal Circuit "agree[d]" that the patent "'combined and utilized man-made tools of biotechnology in a new way that revolutionized prenatal care.'" App. 18a. The inventors of the patent discovered that cell-free fetal DNA (cffDNA) was circulating in pregnant women's plasma, and that by amplifying and detecting paternally inherited genetic sequences they could reliably identify fetal DNA in a sample otherwise dominated by maternal DNA. This made it possible for them to diagnose certain fetal genetic conditions by obtaining blood from the pregnant mother through a non-invasive finger prick rather than putting the mother and fetus through risky and invasive amniocentesis.

As detailed in Judge Linn's concurring opinion, it is undisputed that the invention in this case is nothing short of "groundbreaking," a "'paradigm shift'" in prenatal care that "should be patent eligible." App. 23a. But the Federal Circuit invalidated the claimed process for prenatal diagnosis under the two-part test set forth in *Mayo Collaborative Services v. Prometheus Labs., Inc.*, 132

S. Ct. 1289 (2012). The panel held that the claims were "directed to detecting the presence of a naturally occurring thing or a natural phenomenon, cffDNA in maternal plasma or serum," under step 1 of *Mayo*. App. 11a. They then read step 2 of *Mayo* to require divorcing the other steps of the claims from the natural phenomenon to see if the steps were "new and useful" apart from their application to cffDNA. *Id.* 12a. They found the additional steps routine and conventional and that the patent therefore failed to disclose patent eligible subject matter (*id.* 15a) even though the claims, when considered as a whole, were novel and unforeseen since "*no one* was amplifying and detecting paternally-inherited cffDNA using the plasma or serum of pregnant mothers," and indeed, the maternal plasma was previously discarded. *Id.* 22a (Linn, J.) (emphasis in original).

Further, although there were uses for cffDNA other than those claimed in the patent and no concern of preempting future use of a natural phenomenon, the Federal Circuit held that the *Mayo* test "fully addressed and made moot" a preemption inquiry. *Id.* 17a. The Federal Circuit also declared that "the absence of complete preemption does not demonstrate patent eligibility" despite the fact that "[this Court] has made clear that the principle of preemption is the basis for the judicial exceptions to patentability," *i.e.*, laws of nature, natural phenomena and abstract ideas. *Id.*

The Federal Circuit's decision has turned this Court's precedent on its head, raising a cloud of uncertainty over the patent eligibility of inventions

that pose no preemption concerns. Judicial exceptions to patentability are being applied by courts (and the PTO) to deny patent eligibility to novel processes in the absence of preemption. The result under this Court's precedents should be the opposite. The Federal Circuit's failure to consider preemption in a patent eligibility analysis is a clear error of law and urgently requires this Court's intervention.

The Federal Circuit also interprets *Mayo's* test as an exclusive test, one that eliminates the need for any further inquiry, although this Court has made clear that the test in *Mayo* is supposed to assist courts in distinguishing patents that preempt natural laws, natural phenomena and abstract ideas from those that do not, rather than to eliminate or moot the inquiry. This case is uniquely suited for this Court to clarify that the *Mayo* test cannot be rigidly applied, ignoring the goal of the inquiry, since it demonstrates that the *Mayo* test may provide no information as to preemption in some cases and therefore cannot be employed as an exclusive, fully developed test for patent eligibility in all cases.

The Federal Circuit also erred in interpreting *Mayo* to require divorcing the natural phenomenon from the other steps of the claim. This Court's precedents have long recognized that claims must be considered as a whole and that a natural law or phenomenon should not be dissected away from the claim in assessing patent eligibility. There is no doubt that what Judge Lourie called a "crisis of patent law and medical innovation" (App. 78a) is upon us if *Mayo* is read to require such dissection.

But that is precisely how the Federal Circuit reads it.

Multiple opinions from Federal Circuit judges make clear that there is a pressing need for this Court to clarify the scope of *Mayo* now to avoid manifestly incorrect results that the Federal Circuit believes are required by its language even if unintended. For example, in concurring with the panel decision, Judge Linn bemoaned "***the consequence—perhaps unintended—of th[e] broad language [in Mayo]*** in excluding a meritorious invention from the patent protection it deserves and should have been entitled to retain." App. 21a (emphasis added).

Similarly, in concurring with the denial of *en banc* review, Judge Lourie, joined by Judge Moore, stated that the panel "had no option" under *Mayo* but to "divorce" the natural phenomenon from the other steps in the claims although the claims, when considered as a whole, recite "innovative and practical" uses for cffDNA, and there was no preemption concern. *Id.* 81a-82a. Judge Dyk also said that the Federal Circuit was "bound by the language of *Mayo*" and that "any further guidance must come from the Supreme Court." *Id*. 84a. In the only dissent from the denial of rehearing *en banc*, Judge Newman noted that all her colleagues seemed to agree "that this case is wrongly decided" but that they viewed this "incorrect decision [to be] required by Supreme Court precedent." *Id*. 100a.

There is no question that this Court's intervention is crucial to return predictability to a patent eligibility determination.

ARGUMENT

I. The Role of Preemption in a Patent Eligibility Analysis Is an Issue of Exceptional Importance

This Court should grant the petition for a writ of certiorari to clarify that the *Mayo* two-part test does not moot a preemption analysis and that inventions posing no preemption concerns remain patent eligible under *Mayo*.

A. Preemption Concerns Are Fundamental to a Patent Eligibility Analysis

This Court has long recognized that preemption concerns are central to a patent eligibility analysis. Section 101 sets out four broad statutory categories of inventions or discoveries that are eligible for protection. These statutory categories are subject to an "implicit exception: Laws of nature, natural phenomena, and abstract ideas are not patentable." *Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 134 S. Ct. 2347, 2354 (2014) (quoting *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107, 2116 (2013)). As this Court has explained, the "concern that drives this exclusionary principle [is] one of pre-emption." *Alice*, 134 S. Ct. at 2354. Laws of nature (like gravity), natural phenomena (like the DNA sitting in our chromosomes), and abstract ideas (like mathematical algorithms) are the "building blocks of human ingenuity." *Id.* "'[M]onopolization of those tools through the grant of a patent might tend to impede innovation more than it would tend to promote it,' thereby thwarting the

primary object of the patent laws." *Id.* (quoting *Mayo*, 132 S. Ct. at 1293). This Court has "'repeatedly emphasized this . . . concern that patent law not inhibit further discovery by improperly tying up the future use of' these building blocks of human ingenuity." *Id.* (quoting *Mayo*, 132 S. Ct. at 1301). As a result, this Court's Section 101 precedents "warn [] against upholding patents that claim processes that too broadly preempt the use of a natural law." *Mayo*, 132 S. Ct. at 1294.

At the same time, this Court has long recognized that "too broad an interpretation of this exclusionary principle could eviscerate patent law." *Id*. at 1293. This is because "all inventions at some level embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas." *Id*. It is therefore necessary to "distinguish between patents that claim the 'buildin[g] block[s]' of human ingenuity and those that integrate the building blocks into something more." *Alice*, 134 S. Ct. at 2354 (quoting *Mayo*, 132 S. Ct. at 1303). The former would "risk disproportionately tying up the use of the underlying natural laws, inhibiting their use in the making of further discoveries." *Mayo*, 132 S. Ct. at 1294. "The latter pose no comparable risk of pre-emption, and therefore remain eligible for the monopoly granted under [the] patent laws." *Alice*, 134 S. Ct. at 2355.

B. *Mayo* Did Not Provide an Exclusive Test for Patent Eligibility and Did Not Moot Preemption

In *Mayo*, this Court set forth a two-part test, "for distinguishing patents that claim laws of nature,

natural phenomena, and abstract ideas from those that claim patent-eligible applications of those concepts." *Alice*, 134 S. Ct. at 2355 (citing *Mayo*, 132 S. Ct. at 1297). The *Mayo* test asks (1) whether a patent's claims are directed to one of the patent-ineligible concepts, and if so, (2) whether the elements of those claims—both individually and as an "ordered combination"—"transform the nature of the claim[s]" into a patent-eligible application. *Mayo*, 132 S. Ct. at 1297-98.

Although this Court has rejected the notion of an exclusive test for patent eligibility, *see Bilski v. Kappos*, 561 U.S. 593 (2010), the Federal Circuit views *Mayo* as the definitive test for patent eligibility to be rigidly applied to all future cases to the exclusion of any other inquiry. In this case—in invalidating a patent that did not claim a patent-ineligible concept itself but rather a practical application of a discovery that "'revolutionized prenatal care'" (App. 18a)—the Federal Circuit stated that "[w]here a patent's claims are deemed only to disclose patent ineligible subject matter under the *Mayo* framework . . . ***preemption concerns are fully addressed and made moot***." *Id*. 17a (emphasis added). The panel decision set forth this unprecedented rule (which the PTO has also adopted) despite acknowledging that "[this Court] has made clear that the principle of preemption is the basis for the judicial exceptions to patentability." *Id*. (citing *Alice*, 134 S. Ct. at 2354).

Nowhere does *Mayo* or *Alice* suggest that the *Mayo* test makes a preemption inquiry unnecessary. To the contrary, *Mayo* and *Alice* discuss preemption

ad nauseam since it is the "basis for the judicial exceptions to patentability" (App. 17a), and the "driv[ing]" concern behind these exceptions. *Alice*, 134 S. Ct. at 2354. This Court also made clear that upholding the patent in *Mayo* "would risk disproportionately tying up the use of the underlying natural laws, inhibiting their use in the making of further discoveries." 132 S. Ct. at 1294. Similarly, in *Alice*, this Court stressed that its patent eligibility conclusion was in "accord[] with the pre-emption concern that undergirds [this Court's] §101 jurisprudence." 134 S. Ct. at 2358. The Federal Circuit's conclusion that the *Mayo* test fully addresses preemption and supplants the need for a preemption inquiry is contrary to this Court's precedents and is clear legal error.

The Federal Circuit's wooden application of *Mayo* (much like the machine-or-transformation test, Freeman-Walter-Abele and technological arts tests that had been applied in the past) ignores the goal of the inquiry—to determine if the claim avoids preempting the patent-ineligible concept in question. This Court rejected this type of rigid analysis of its machine-or-transformation test in *Bilski* and such an approach also is incorrect here. 561 U.S. at 604. Just as in *Bilski*, here the Federal Circuit has elevated the test in *Mayo* from a "useful and important clue" and "investigative tool" to the "exclusive test" or "sole test for deciding whether an invention is" patent eligible. *Bilski*, 561 U.S. at 604. In doing so, the Federal Circuit missed the forest for the trees, untethering the *Mayo* test from preemption despite the fact that the purpose of the test is to assist courts in distinguishing patents that

claim laws of nature, natural phenomena and abstract ideas from those that do not improperly monopolize such concepts. *Alice*, 134 S. Ct. at 2355.

Indeed, here, remarkably, the Federal Circuit denied patent eligibility in the absence of any concern that a law of nature or natural phenomenon was being improperly monopolized. There is no dispute that the patent at issue does not claim cffDNA itself but rather uses it in a new diagnostic method. The panel opinion—before concluding that *Mayo* "moot[ed]" preemption—acknowledged that there were practical uses of cffDNA aside from those claimed in the patent. App. 17a; *see also id*. 81a-82a (Lourie, J.) ("The panel . . . noted that there were other uses for cffDNA and other methods of prenatal diagnostic testing using cffDNA that do not involve the steps recited in the various claims."); *id.* 102a (Newman, J.) ("Nor does patenting of this new diagnostic method preempt further study of this science, nor the development of additional applications."). As Judge Lourie explained, this "fact should sufficiently address the concern of improperly tying up future use of natural phenomena and laws." *Id*. 82a.

The absence of a preemption concern here, unlike in *Mayo* and *Alice*, should have conclusively confirmed patent eligibility. The panel, however, declared that "[w]hile preemption may signal patent ineligible subject matter, the absence of complete preemption does not demonstrate patent eligibility." App. 17a. Such a theory has no support in this Court's precedents. It is erroneous as a matter of law. This Court's intervention is critically important

to clarify that while preemption may signal patent ineligible subject matter, the absence of preemption is a reliable and conclusive indicator of patent eligibility.

The Federal Circuit's errors also stem from the misapprehension of *Mayo* as the exclusive test for patent eligibility, eliminating the need for any further inquiry. It is crucial for this Court to clarify that *Mayo* is not a definitive, fully developed test for patent eligibility. This Court has repeatedly cautioned against over generalizations and exclusive tests. In addition, Justice Breyer, who authored *Mayo*, acknowledged that *Mayo* was "an obvious case" and therefore could only "sketch an outer shell" of a test that would be developed in future cases since it was hard to "figure out how much . . . to go beyond . . . an obvious case." Arg. Tr. 10-11, 28, *Alice*, 134 S. Ct. 2347 (No. 13-298) (Breyer, J.). Indeed, this Court described the patent claims in *Mayo* as nothing more than "a drafting effort designed to monopolize the law of nature itself." *Mayo*, 132 S. Ct. at 1297. This Court's guidance is needed to clarify that the test sketched in *Mayo* is a useful tool rather than the exclusive test for patent eligibility to be applied rigidly in all circumstances.

II. Whether Claims Must Be Considered as a Whole in a Patent Eligibility Analysis Is Also an Issue of Exceptional Importance

This Court should also grant the petition for a writ of certiorari to clarify that claims must be considered as a whole in a patent eligibility analysis. This Court has warned that "too broad an interpretation of th[e] exclusionary principle could

eviscerate patent law." *Mayo*, 132 S. Ct. at 1293. Without this Court's intervention, the Federal Circuit's too broad interpretation of *Mayo*, which requires dissecting claims into their individual elements without considering the claimed invention as a whole, will do just that, denying patent eligibility to novel and unforeseen processes.

This Court has long held that "claims must be considered as a whole" in a patent eligibility analysis. *Diamond v. Diehr*, 450 U.S. 175, 188 (1981). Indeed, it is "inappropriate to dissect the claims into old and new elements." *Id.* This Court emphasized that "[t]his is particularly true in a process claim because a new combination of steps in a process may be patentable even though all the constituents of the combination were well known and in common use before the combination was made." *Id*. *Mayo* did not change this well-settled rule in any way. In *Mayo*, this Court reiterated that the steps of a claimed method must be considered as an "ordered combination." 132 S. Ct. at 1298 (citing *Diehr*, 450 U.S. at 188); *see also Alice*, 134 S. Ct. at 2355 n.3 ("Because the approach we made explicit in *Mayo* considers all claim elements, both individually and in combination, it is consistent with the general rule that patent claims 'must be considered as a whole.'" (quoting *Diehr*, 450 U.S. at 188)).

Although *Mayo* did not change the "general rule that patent claims 'must be considered as a whole'" (*id*.), the Federal Circuit does not read or apply *Mayo* in this way (and the PTO and district courts have necessarily followed suit) turning this Court's general and well-established rule on its head

and casting a cloud over inventions that would otherwise unquestionably have been considered patent eligible under this Court's precedents. As explained by Judge Lourie, joined by Judge Moore, the Federal Circuit believes that to faithfully apply *Mayo*, it is "unfortunately ***obliged to divorce the [process] steps from the asserted natural phenomenon*** to arrive at a conclusion that they add nothing innovative to the process." App. 81a (emphasis added).

Consideration of the claims as a whole mandates a different result since the claims recite "innovative and practical *uses*" for cffDNA and "it is undisputed that before th[e] invention, the amplification and detection *of cffDNA from maternal blood*, and use of these methods for prenatal diagnoses, were *not* routine and conventional." *Id.* (emphasis in original). The panel "agree[d]" that the patent "combined and utilized man-made tools of biotechnology in a new way that revolutionized prenatal care." *Id.* 18a (internal quotation marks omitted). But the Federal Circuit interprets *Mayo* to require "tak[ing] inventions of this nature out of the realm of patent-eligibility." *Id.* 82a (Lourie, J.). The panel found Sequenom's claims to be patent ineligible after dissociating cffDNA from all the other steps in the claims, *i.e.*, the steps used to detect it and amplify it in maternal plasma or serum that previously was discarded as waste material, and determining that such steps were known and not innovative on their own. *Id.* 12a-16a.

This Court's guidance is essential to clarify that claims must be considered as a whole in a

patent eligibility analysis and that *Mayo* does not require divorcing the natural principle from the rest of the claim. As this Court previously explained, divorcing the natural principle from the other claim elements would, "if carried to its extreme, make all inventions unpatentable because all inventions can be reduced to underlying principles of nature which, once known, make their implementation obvious." *Diehr*, 450 U.S. at 189 n.12.

There is no reason why a novel way of using cffDNA, which was previously not used and discarded, is not patent eligible under this Court's precedents. Indeed, *Mayo* reiterates the well-established maxim that a "new way of using an existing drug" is patent eligible, 132 S. Ct. at 1302. Similarly, this Court stated that a party that discovers a natural phenomenon is "in an excellent position to claim applications of that knowledge." *Myriad*, 133 S. Ct. at 2120 (internal quotation marks omitted).

Multiple Federal Circuit judges recognized that the *Mayo* test, as they read it, produces an incorrect result and is also in tension with this Court's decision in *Myriad*. Judge Linn stated that "Sequenom effectuated a practical result and benefit not previously attained so its patent would traditionally have been valid." App. 24a (internal quotation marks omitted). Judge Lourie noted that Sequenom's claims "should not be patent-ineligible on the ground that they set forth natural laws or are abstractions" (*id*. 78a) and described the rule in *Mayo*, which he read as requiring process steps to be sufficiently innovative apart from the natural laws,

as "unsound." *Id*. 82a. Judge Dyk "worr[ied] that method claims that apply newly discovered natural laws and phenomena in somewhat conventional ways are screened out by the *Mayo* test." *Id*. 90a. He also noted that *Myriad* "appeared to recognize that an inventive concept can sometimes come from discovery of an unknown natural phenomenon." *Id*. 91a. But he saw no recourse without this Court's intervention due the Federal Circuit's "obligation to respect the sweeping precedent of *Mayo*." *Id*. 90a n.3.

III. This Case Is an Ideal Vehicle for the Court to Resolve These Critical Issues

The issues presented in this petition for a writ for certiorari are critically important to patent owners, patent challengers, and to innovation across all industries since "at some level, all inventions . . . embody, use, reflect, rest upon or apply laws of nature, natural phenomena, or abstract ideas." *Alice*, 134 S. Ct. at 2354 (internal quotation marks omitted). The proper role of preemption in a patent eligibility analysis and whether claims must be considered as a whole in that analysis are matters that impact innumerable patents and directly impact U.S. competitiveness and innovation.

These issues are squarely presented in this case and have been fully developed through extensive briefing of the parties and numerous *amici* as well as multiple judicial opinions at the panel and rehearing stage explaining the need for this Court's guidance.

A. The Record in this Case Allows the Issues to be Framed Precisely

The robust record in this case allows the issues to be presented precisely. It is undisputed that there is no preemption on the facts of this case and that the patent does not monopolize all uses of cffDNA. The precise question before the Court is then whether an otherwise meritorious invention can be denied patent eligibility in the absence of preemption. The panel also "agree[d]" that the patent "utilized man-made tools of biotechnology in a new way that revolutionized prenatal care." App. 18a (internal quotation marks omitted). The fact that the claimed method is to a new way of using an existing material also makes this case uniquely suited for the Court to clarify that *Mayo* requires consideration of the claims as a whole and that a new way of using a natural phenomenon is patent eligible just as a "new way of using an existing drug" is. *Mayo*, 132 S. Ct. at 1302.

B. The Federal Circuit's Application of *Mayo* Has Caused a Crisis of Patent Law and Medical Innovation

The issues are manifestly important and well elaborated as reflected by the participation of more than ten *amici* at the rehearing stage. The panel described the invention as "a significant contribution to the medical field" but one that is not patent eligible. App. 19a. A rigid application of *Mayo*, *i.e.*, one that denies patent eligibility in the absence of preemption concerns and fails to consider the claims as a whole, impedes precisely such valuable and significant applications of new discoveries. Multiple

Federal Circuit judges, despite concluding that they were bound to apply *Mayo* as they did, expressed concern about the consequences. As Judge Dyk stated, "a too restrictive test for patent eligibility under 35 U.S.C. § 101 with respect to laws of nature (reflected in some of the language in *Mayo*) may discourage development and disclosure of new diagnostic and therapeutic methods in the life sciences, which are often driven by discovery of new natural laws and phenomena." App. 84a. Judge Lourie, joined by Judge Moore, stated "[i]t is also said that a crisis of patent law and medical innovation may be upon us, and there seems to be some truth in that concern." *Id.* 78a. Judge Lourie also explained that "[a]ll physical steps of human ingenuity utilize natural laws or involve natural phenomena" but such steps "cannot be patent-ineligible solely on that basis because, under that reasoning, nothing in the physical universe would be patent-eligible." *Id.* 77a.

C. Judicial Opinions Make Clear that Only this Court's Guidance Can Avoid Anomalous and Unintended Results Under *Mayo*

Importantly, the Federal Circuit recognized the need for this Court's guidance in order to avoid anomalous and potentially unintended results. Multiple opinions at the panel and rehearing stage made clear that the Federal Circuit believed that it had no recourse due to *Mayo*'s broad language, and that "any further guidance must come from the Supreme Court, not [the Federal Circuit]." App. 84a (Dyk, J.). Judge Linn, who described Sequenom's

invention as "truly meritorious" and "deserving of patent protection" (*id*. 23a), explained that he joined the panel opinion "only because [he was] bound by the sweeping language of the test set out in *Mayo*." *Id*. 20a. He stressed that "[b]ut for the sweeping language in the Supreme Court's *Mayo* opinion, [he saw] no reason, in policy or statute, why this breakthrough invention should be deemed patent ineligible." *Id*. 24a.

Similarly, Judge Lourie, joined by Judge Moore, explained that he "f[ou]nd no principled basis to distinguish" (*id*. 76a) *Mayo*'s broad language although Sequenom's patent claimed "innovative and practical *uses* for" cffDNA and did not foreclose "other methods of prenatal diagnostic testing using cffDNA." *Id*. 81a (emphasis in original). Judge Lourie stated that while "it is unsound to have a rule that takes inventions of this nature out of the realm of patent-eligibility," he believed that the court "had no option" under this Court's precedent. *Id*. 82a. Judge Dyk also stated that "some further illumination as to the scope of *Mayo* would be beneficial" and must come from this Court given "the language of *Mayo*." *Id*. 84a.

D. Uncertainty Before the PTO Is Further Reason Why this Court's Intervention Is Needed

The NYIPLA's members also have observed first-hand in advising and representing their clients in patent matters before the PTO the increased difficulty in predicting whether inventions will be found patentable despite the absence of preemption concerns and whether the PTO will consider the

claims as a whole. Following the Federal Circuit's lead, the PTO's guidance simply restates the two-part test from *Mayo* as an exclusive test. These issues will continue to arise before the PTO and the courts. This is yet a further reason that it is critically important for this Court to clarify that the *Mayo* two-part test is only a helpful starting point, a "sketch [of] an outer shell," rather than an exclusive and fully developed framework for patent eligibility.

* * *

In sum, this case provides the Court an ideal vehicle for clarifying that *Mayo* is not an exclusive or rigid test, that claims must be considered as a whole, and that preemption is never moot in a patent eligibility analysis, thereby removing the cloud hanging over patents in the diagnostics and personalized medicine fields and spurring innovation and competitiveness across industries.

CONCLUSION

This Court should grant the petition for a writ of certiorari on the Question Presented.

Respectfully submitted,

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