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 IN OPPOSITION

David I. Gindler
Counsel of Record
Joseph M. Lipner
Andrei Iancu
Josh B. Gordon
Irell & Manella LLP
1800 Avenue of the Stars
Los Angeles, CA 90067
(310) 277-1010
dgindler@irell.com
Counsel for Respondent, Ariosa Diagnostics, Inc.

QUESTION PRESENTED

Whether the Federal Circuit correctly applied *Mayo Collaborative Services v. Prometheus Laboratories, Inc.,* 132 S. Ct. 1289 (2012) (*Mayo*), and *Alice Corporation Pty. Ltd. v. CLS Bank International,* 134 S. Ct. 2347 (2014) (*Alice*), to invalidate patent claims that broadly cover the detection of a natural phenomenon using conventional methodology.

CORPORATE DISCLOSURE STATEMENT

Ariosa Diagnostics, Inc. ("Ariosa") is a wholly-owned subsidiary of Roche Molecular Systems, Inc., which is a wholly-owned subsidiary of Roche Holdings, Inc. and an indirect subsidiary of Roche Holding Ltd. Novartis AG, a publicly held company, owns more than 10 percent of the voting shares of Roche Holding Ltd. Novartis AG has no representation on Roche Holding Ltd.'s board of directors and does not in any way control Roche Holding Ltd. or any of its subsidiaries.

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Page(s)

Cases

Statutes

STATEMENT OF THE CASE

This case involves U.S. Patent No. 6,258,540 (the "'540 Patent"), which announces the discovery of a naturally occurring phenomenon and claims the use of routine and conventional laboratory procedures to detect that natural phenomenon. In the words of the Federal Circuit, the patent claims a method that "begins and ends with a natural phenomenon." App. 10a.

In the future, there may be a case that tests the boundaries of the Court's recent decisions in *Mayo* and *Alice*, but this is not that case. The '540 Patent broadly claims the use of routine and conventional steps, described at a high level of generality, to detect a naturally occurring phenomenon. This is precisely what *Mayo* and *Alice*, which explained and applied nearly a century of established Section 101 jurisprudence, held not to be patentable.

By contending that the claims of the '540 Patent *should* be patentable, Petitioner Sequenom, Inc. ("Petitioner") is inviting the Court to revisit and rewrite decades of jurisprudence covering patent-eligible subject matter, particularly the Court's recent, unanimous decisions in *Mayo, Alice*, and *Association for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107 (2013) (*Myriad*). Unless the Court is inclined to overrule its long-settled holdings regarding the patent eligibility of claims directed to natural phenomena, including cases that the Court decided within the last few years, there is no reason to grant this petition.

I. The '540 Patent

The '540 Patent was issued to Drs. Yuk-Ming Dennis Lo and James Wainscoat ("applicants") and assigned to Isis Innovation Limited, which in turn exclusively licensed it to Petitioner. App. 26a. The patent's "Summary of the Invention" announces that "[i]t has now been discovered that foetal DNA is detectable in maternal serum or plasma samples." Pat. 1:50-51. The patent then describes the claimed invention as a method of "detecting the presence of a nucleic acid of foetal origin in the sample,"—*i.e.*, detecting the naturally occurring phenomenon of cell-free fetal DNA ("cffDNA") in maternal serum or plasma. *Id.*, 2:1-4.[1]

The claims of the '540 Patent are expressly directed to the detection of that natural phenomenon. For example, Claim 1 broadly covers detecting naturally-occurring "paternally inherited nucleic acid of fetal origin" in maternal serum or plasma. The claim reads in its entirety as follows:

> A method for detecting a paternally inherited nucleic acid of fetal origin performed on a maternal serum or plasma sample from a pregnant female, which method comprises

[1] "Blood is made up of cells and plasma (the fluid containing proteins and other molecules in which cells are suspended). Serum is plasma without the clotting proteins (platelets), i.e., blood minus the cells and the clotting factors." App. 27a n.1 (citations omitted).

> amplifying[2] a paternally inherited nucleic acid from the serum or plasma sample and
>
> detecting the presence of a paternally inherited nucleic acid of fetal origin in the sample.

Pat. 23:60-67. Aside from the amplification (i.e., copying) step, Claim 1 is entirely circular, beginning and ending with detecting a paternally inherited nucleic acid of fetal origin in the sample, without reciting any specific laboratory procedures to do so.

Claim 21, which Petitioner stresses in its petition, depends from Claim 1 and, as the District Court observed, merely adds "the limitations of fractionating the blood sample" into its cellular and non-cellular portions (i.e., serum and plasma)[3] "and providing a diagnosis based on the cffDNA." App. 47a n.5. Claim 21 reads in its entirety as follows:

> A method of performing a prenatal diagnosis, which method comprises the steps of:
>
> (i) providing a maternal blood sample;
>
> (ii) separating the sample into a cellular and a non-cellular fraction;

---

[2] At the Federal Circuit's direction, the District Court construed the term "amplifying" as "increasing the amount … by making copies of it." Case No. 14-1139, Dkt. No. 67 ("Fed. Cir. Appx.") at A1253.

[3] "Fractionating" a blood sample means separating the sample into plasma (the portion of blood without any cells) and serum (the portion of plasma without clotting factors).

> (iii) detecting the presence of a nucleic acid of foetal origin in the non-cellular fraction according to the method of claim 1;
>
> (iv) providing a diagnosis based on the presence and/or quantity and/or sequence of the foetal nucleic acid.

Pat. 26:4-14.[4]

Like several other companies, including respondent Ariosa, Petitioner markets a test directed to identifying the risk of fetal aneuploidy (an abnormal number of chromosomes) without invasive procedures such as amniocentesis. App. 3a. After obtaining an exclusive license to the '540 Patent, Petitioner took the position that the patent would "block all non-invasive cell-free DNA-based approaches." App. 56a-57a. It asserted that one of its competitors, Verinata Health, Inc. ("Verinata"), would infringe the '540 Patent by virtue of Verinata's "use of circulating cell-free fetal nucleic acids." Fed. Cir. Appx. at A1006. Petitioner also informed Natera, Inc. ("Natera") and Natera's licensee, DNA Diagnostics Center ("DDC")—both respondents here—that "[Petitioner] holds an exclusive license to patent rights relating to detecting fetal nucleic acids from maternal circulation, and as such, [Natera's] noninvasive paternity test requires a license." *Id.*, A1002-03 (¶ 6(b)).

---

[4] The Petition describes Claim 21 as an independent claim. Pet. at 34. This is incorrect. Claim 21 expressly incorporates the limitations of Claim 1 and is thus written in dependent form. *See* 35 U.S.C. § 112(d).

Ariosa filed suit against Petitioner in the Northern District of California on December 19, 2011, seeking a declaration that its test does not infringe any claim of the '540 Patent. *Id.*, A0058 (Dkt. No. 1). Petitioner counterclaimed for infringement, *id.*, A0061 (Dkt. No. 33), and filed a motion for a preliminary injunction to enjoin Ariosa from offering its Harmony Prenatal Test, a non-invasive test for assessing the risk of fetal aneuploidy. *Id.* (Dkt. No. 34). As one of its affirmative defenses, Ariosa alleged that all asserted claims of the '540 Patent are invalid. *Id.*, A0063 (Dkt. No. 52).

In early 2012, Natera and Verinata also initiated declaratory judgment actions against Petitioner, seeking declarations that their products do not infringe the '540 Patent and that all claims of the '540 Patent are invalid. *Id.*, A0093 (Dkt. No. 1); A0115 (Dkt. No. 1). Petitioner counterclaimed against each of them for infringement. *Id.*, A0096 (Dkt. No. 40); A0116 (Dkt. No. 15). The District Court related the three cases and coordinated them for purposes of claim construction and scheduling.[5] *Id.*, A0062 (Dkt. No. 41).

On July 5, 2012, the District Court issued an Order denying Petitioner's preliminary injunction motion against Ariosa. *Id.*, A0071 (Dkt. No. 121). Petitioner appealed and the Federal Circuit vacated and remanded. *Aria Diagnostics, Inc. v. Sequenom, Inc.*, 726 F.3d 1296 (Fed. Cir. 2013). In its ruling, the Federal Circuit offered no opinion "as to whether there is or is not a substantial question regarding the

[5] Petitioner and Verinata subsequently entered into a settlement agreement.

subject matter eligibility of the asserted claims" of the '540 Patent, *id.* at 1304, and remanded "for the district court to examine subject matter eligibility" in light of the recently-decided *Myriad* case and the Federal Circuit's claim construction determinations. *Id.*

II. The District Court's Grant of Summary Judgment

After remand, on August 16, 2013, Ariosa filed a motion for summary judgment that each asserted claim of the '540 Patent fails to recite patent-eligible subject matter. *Id.*, A0080 (Dkt. No. 219). Petitioner opposed and cross-moved on the same issue. *Id.*, A0081 (Dkt. No. 223).

On October 30, 2013, the District Court granted Ariosa's summary judgment motion and denied Petitioner's cross-motion, ruling that the claims of the '540 Patent "are not drawn to patent-eligible subject matter and are invalid under 35 U.S.C. § 101." App. 57a. The District Court noted that Petitioner had conceded "that neither cffDNA nor the discovery of cffDNA in maternal plasma or serum is patentable, because the presence of cffDNA in maternal plasma or serum is a natural phenomenon." App. 43a. The District Court found it was undisputed that the additional claimed steps beyond that natural phenomenon—such as fractionation of blood into serum and plasma, amplification (i.e., copying) of DNA found in a serum or plasma sample, and detection of the DNA in the sample—were "well-understood, routine, and conventional activity at the time of the invention" and that "it was well-understood, routine, and conventional activity to combine these steps to detect DNA in serum or

plasma." App. 54a. The District Court concluded that, "looking at the claimed processes as a whole, the only inventive component of the processes in the '540 Patent is to apply those well-understood, routine processes to paternally inherited cffDNA, a natural phenomenon." App. 54a.

The District Court also considered whether the asserted claims posed "a risk of preempting a law of nature, natural phenomenon, or abstract idea." *Id*. First, relying on *Bilski v. Kappos*, 561 U.S. 593 (2010) and *Parker v. Flook*, 437 U.S. 584 (1978) (*Flook*), the District Court rejected Petitioner's argument that "whether the claims preempt all uses of the natural phenomenon is dispositive of the analysis." App. 54a n.9. Second, and in any event, the District Court concluded that the scope of the asserted claims did pose a substantial risk of preempting the natural phenomenon. App. 55a-57a. The District Court observed that "[Petitioner] itself has acknowledged the preemptive effect of its patent." App. 56a-57a (citing Petitioner's statement that "management believes that the in-licensed '540 patent … will block all non-invasive cell-free DNA-based approaches"); App. 57a (citing Petitioner's statement that "we believe [the '540 patent] is the underpinnings of this whole field, and potentially believe anybody whose [sic] developing, an approach that interrogates the circulating cell [free] DNA is infringing this key patent in the field").

III. The Federal Circuit's Decision Affirming Summary Judgment of Invalidity

Petitioner appealed. On June 12, 2015, the court of appeals unanimously affirmed. Pet. App. A.

The court of appeals recognized that in *Mayo* this Court "set forth a framework for distinguishing patents that claim laws of nature, natural phenomena, and abstract ideas from those that claim patent-eligible applications of those concepts." App. 9a. The court began its analysis by setting forth that framework:

> First, we determine whether the claims at issue are directed to a patent-ineligible concept. If the answer is yes, then we next consider the elements of each claim both individually and as an ordered combination to determine whether additional elements transform the nature of the claim into a patent-eligible application. The Supreme Court has described the second step of this analysis as a search for an inventive concept—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.

App. 9a (internal citations and quotations omitted).

Applying this framework, the court of appeals concluded that the claims of the '540 Patent (i) "are directed to naturally occurring phenomena," App. 12a, and (ii) do not contain an "inventive concept that transforms the natural phenomenon of cffDNA into a patentable invention." *Id.*

First, the court explained how the claimed method "begins and ends with a natural phenomenon" and is thus directed to that phenomenon, i.e., the presence of cffDNA in maternal plasma or serum. App. 10a-

11a. Second, having made that threshold determination, the court considered whether the claims of the '540 Patent contained an "inventive concept sufficient to 'transform' the claimed naturally occurring phenomena into a patent-eligible application." App. 12a. Applying this Court's decisions to the undisputed facts before it, the court below unanimously concluded that those claims did not contain any such inventive concept.

In particular, the court noted that "*Mayo* made clear that transformation into a patent-eligible application requires 'more than simply stating the law of nature while adding the words 'apply it.'" *Id.* (quoting *Mayo*, 132 S. Ct. at 1294). It also noted that a "claim that recites an abstract idea, law of nature, or natural phenomenon must include 'additional features' to ensure that the claim is more than a drafting effort designed to monopolize" that non-patentable subject matter. *Id.* (quoting *Mayo*, 132 S. Ct. at 1297). For "process claims that encompass natural phenomenon," like those at issue here, the court further noted that "the process steps are the additional features that must be new and useful." *Id.*

The court of appeals found that the claims of the '540 Patent did not meet this standard because they merely instructed practitioners "to apply routine, conventional techniques when seeking to detect" the natural phenomenon of cffDNA. App 13a. The court thus concluded that, "[b]ecause the method steps were well-understood, conventional and routine, the method of detecting paternally inherited cffDNA is not new and useful. The only subject matter new and useful as of the date of the application was the discovery of the presence of cffDNA in maternal

plasma or serum." *Id.* The court unanimously held that is not sufficient to confer patentability, as "appending routine, conventional steps to a natural phenomenon, specified at a high level of generality, is not enough to supply an inventive concept." App. 15a. As a result, the court found that the "claims of the '540 Patent at issue in this appeal are not directed to patent eligible subject matter and are, therefore, invalid." App. 15a-16a.

In addition, the court of appeals rejected Petitioner's argument that a claim that does not preempt all uses of a natural phenomenon is "by definition, patent-eligible under Section 101." App. 16a. The court observed that "questions on preemption are inherent in and *resolved by* the § 101 analysis." App. 17a. (emphasis added). Accordingly, the court correctly recognized that, "[w]hile preemption may signal patent ineligible subject matter, the absence of complete preemption does not demonstrate patent eligibility." *Id.* The court concluded that "[Petitioner's] attempt to limit the breadth of the claims by showing alternative uses of cffDNA outside of the scope of the claims does not change the conclusion that the claims are directed to patent ineligible subject matter. Where a patent's claims are deemed only to disclose patent ineligible subject matter under the Mayo framework, as they are in this case, preemption concerns are fully addressed and made moot." *Id.*

All three members of the Federal Circuit panel concurred in the result. Although Judge Linn wrote separately to express his view that the '540 Patent was "deserving of patent protection," App. 23a, he

agreed that this Court's test, as set forth in *Mayo*, demanded the result the court reached. App. 20a.

On August 13, 2015, Petitioner filed a petition with the court of appeals to rehear the panel decision *en banc*. That petition did not contest that the existence of cffDNA in maternal serum and plasma is a natural phenomenon that, on its own, is not patent-eligible. Nor did it deny that the claimed method in the '540 Patent is directed to that natural phenomenon. Nor did it contest that the "amplification" and "detection" steps of the asserted claims were "well-understood, routine, and conventional" at the time the patent was filed. App 13a. Instead, Petitioner argued that this Court's Section 101 decisions, including *Mayo*, must be read as holding that "a combination of known steps that incorporates or is motivated by an unpatentable natural phenomenon is nonetheless patentable if that combination 'considered as a whole' was not routine before the patent disclosed it." Case No. 14-1139, Dkt. No. 101 at 10.

The court of appeals denied Petitioner's petition for rehearing on December 2, 2015. Pet. App. C. Although Judges Lourie and Dyk wrote separately, both concurred in the denial of the petition for rehearing under this Court's established precedent. *E.g.*, App. 82a (Lourie, J., concurring) ("I agree that the panel did not err in its conclusion that under Supreme Court precedent it had no option other than to affirm the district court."); App. 86a (Dyk, J., concurring) ("The panel thus held correctly that *Mayo* is controlling precedent that governs the outcome here."). Only Judge Newman dissented, arguing that the claimed "breakthrough" reflected in the discovery

of cffDNA in maternal serum and plasma was deserving of patent protection. App. 101a-102a.

In his concurrence, Judge Dyk specifically noted that any modifications he would recommend for the *Mayo* framework "would not change the result in this case." App. 98a. He explained that the asserted claims of the '540 Patent—including Claims 1 and 21—are so broadly phrased that they are "impermissible attempts to capture the entire natural phenomenon of cffDNA rather than any particular applications thereof developed and actually reduced to practice by the inventors." *Id.* He therefore concluded that it was a "future case" in which the claim is "narrowly drawn," rather than the current case, that would provide a suitable vehicle for this Court to revisit the *Mayo* framework. App. 98a-99a.

REASONS FOR DENYING THE PETITION

This case presents no novel or undecided issue that is appropriate for this Court's review. The court of appeals did nothing other than straightforwardly apply the test that this Court recently and unanimously described in *Mayo* and *Alice* for determining whether patent claims cover patentable subject matter under 35 U.S.C. § 101.

Nor is this a close case. *Mayo* requires an inquiry into whether patent claims "add *enough* to their statements of the [natural law or phenomenon] to allow the processes they describe to qualify as patent-eligible processes that *apply* natural laws." 132 S. Ct. at 1297.[6] In *Mayo*, the Court explained that "to transform an unpatentable law of nature into a

[6] Emphases are in the original unless otherwise noted.

patent-eligible *application* of such a law, one must do more than simply state the law of nature while adding the words 'apply it.'" *Id.* at 1294. The Court has explained that patent claims must contain an "inventive concept" separate from the natural phenomenon. *Alice*, 134 S. Ct. at 2355.

Here, the claims of the '540 Patent do no more than recite the natural phenomenon of paternally inherited cffDNA coupled with instructions to "make more of it" and then "detect it"—without even describing any method whatsoever to "detect" the cffDNA. The claims recite nothing about the method to detect cffDNA because the applicants relied on, and expected practitioners would apply, routine laboratory techniques to detect DNA. As the Federal Circuit observed, the applicants made this abundantly clear during prosecution of the application that became the '540 Patent: "[O]ne skilled in the art is readily able to apply the teachings of the present application to any one of the well-known techniques for detection of DNA with a view to analysis of foetal DNA in [m]aternal plasma or serum." App. 14a-15a. The court of appeals correctly held that those claims, which contain no inventive concept other than the discovery of the natural phenomenon, are not patentable.

Petitioner, which argues that routine laboratory procedures applied to a newly-discovered natural phenomenon should be patentable, asks the Court to revisit and rewrite over a century of precedent—including the Court's three unanimous decisions on this very subject in the past four years. In particular, Petitioner asks the Court to declare that any patent claim reciting a newly discovered natural

phenomenon is patent-eligible *because the discovery itself* renders any additional steps—even when those steps are conventional and thus lack an inventive concept—part of a "new combination of otherwise conventional techniques." Pet. at 12. According to Petitioner, "discovering practical natural phenomena must be allowed to contribute to taking the 'inventive step' that *Mayo* requires." *Id.* at 26.

Petitioner's argument conflicts with the rules explained and applied in *Mayo* in 2012 and *Alice* in 2014, and would replace the Court's requirement of an inventive concept *in addition to* the natural phenomenon with a fundamentally different inquiry. Petitioner's reformulation of the patent-eligibility standard would essentially collapse the Court's two-part test into a one-part test satisfied by virtually any method claim reciting a newly discovered natural phenomenon—because, in Petitioner's view, it would never be routine to apply "otherwise conventional techniques" to a previously unknown natural phenomenon. And that is the entire point of Petitioner's reformulated patent-eligibility inquiry—to secure patent protection for a previously unknown natural phenomenon even when combined with "well-understood, routine, conventional activity already engaged in by the scientific community." *See Mayo*, 132 S. Ct. at 1298.

That is precisely what this Court rejected in *Mayo* and *Alice*. Absent a desire to cast aside those decisions—and the decades of precedent on which they are based—further review by this Court is not warranted.

I. This Case Involves a Straightforward Application of the Court's Decisions

A. The Court has Recently Articulated the Governing Standard

This Court has unanimously decided three cases in the past four years defining with clarity the standard for patent-eligibility under 35 U.S.C. § 101. In these cases, the Court decided the very question that Petitioner presents.

First, in *Mayo* (decided in 2012), the Court reviewed precedent dating to the 19th century and explained that its prior decisions have "made clear" that "to transform an unpatentable law of nature into a patent-eligible *application* of such a law, one must do more than simply state the law of nature while adding the words 'apply it.'" 132 S. Ct. at 1294. Indeed, the Court's decisions "insist that a process that focuses upon the use of a natural law *also* contain *other* elements or a combination of elements, sometimes referred to as an 'inventive concept,' sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the natural law itself." *Id*. at 1294 (emphasis added); *see also id*. at 1297 (holding that a process reciting a law of nature is not patentable "unless that process has additional features…").

Therefore, when patent claims are directed to laws of nature, *Mayo* requires an inquiry into what else is included in the claims and whether the claims "add *enough* to their statements of the [natural law or phenomenon] to allow the processes they describe to qualify as patent-eligible processes that *apply* natural laws." *Id*. at 1297. The Court concluded that it is *not* enough to combine a natural phenomenon with

additional steps that "consist of well-understood, routine, conventional activity already engaged in by the scientific community; and those steps, when viewed as a whole, add nothing significant beyond the sum of their parts taken separately." *Id*. at 1298. Those conventional steps do not supply the "inventive concept" required for processes that focus on the use of a natural law or phenomenon. *Id*. at 1294, 1298. As a result, "simply appending conventional steps, specified at a high level of generality, to laws of nature, natural phenomena, and abstract ideas cannot make those laws, phenomena, and ideas patentable." *Id*. at 1300.

Second, in *Myriad* (decided in 2013), the Court invalidated a patent directed to newly-discovered genes (BRCA1 and BRCA2) that were isolated from their surrounding genetic material. 133 S. Ct. at 2120. The Court noted that "Myriad did not create or alter any of the genetic information encoded in the BRCA1 and BRCA2 genes. The location and order of the nucleotides existed in nature before Myriad found them. Nor did Myriad create or alter the genetic structure of DNA." *Id.* at 2116. The Court reasoned that Myriad "found an important and useful gene," but "that discovery, by itself," is not patent eligible. *Id*. at 2117

In language that addresses the very issue presented in this case, the Court noted that "[h]ad Myriad created an innovative method of manipulating genes while searching for the BRCA1 and BRCA2 genes, it could possibly have sought a method patent." *Id*. at 2119. But Myriad did not, as the processes it used "to isolate DNA were well understood by geneticists at the time of Myriad's

patents[,] ... widely used, and fairly uniform insofar as any scientist engaged in the search for a gene would likely have utilized a similar approach ...." *Id.* at 2119-20. That is, Myriad's claims recited no "inventive concept" that added enough to the natural phenomenon of the newly discovered genes to warrant patent protection.

Finally, in *Alice* (decided in 2014), another unanimous Court reiterated the two-part test set forth in *Mayo*. After reviewing its long-standing Section 101 jurisprudence, the Court stated that in *Mayo* "we set forth a framework for distinguishing patents that claim laws of nature, natural phenomena, and abstract ideas from those that claim patent-eligible applications of those concepts." 134 S. Ct. at 2355. The Court specifically broke the *Mayo* framework into two distinct steps: "First, we determine whether the claims at issue are directed to one of those patent-ineligible concepts." *Id.* Second, if the claims are so directed, "we then ask, '[w]hat else is there in the claims before us?' To answer that question, we consider the elements of each claim both individually and 'as an ordered combination' to determine whether the additional elements 'transform the nature of the claim' into a patent-eligible application." *Id.*

The Court then summarized its prior decisions as describing "step two of this analysis as a search for an 'inventive concept'—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.* Applying this framework, the Court concluded that the claims at issue "amounted to

'nothing significantly more' than an instruction to apply the abstract idea of an intermediated settlement using some unspecified, generic computer," which, under this Court's precedent, "is not '*enough*' to transform an abstract idea into a patent-eligible invention." *Id*. at 2360 (quoting *Mayo*, 132 S. Ct. at 1297).

These three, recent cases require an inventive concept in addition to the natural phenomenon to satisfy Section 101. They hold that it is not sufficient to append routine, conventional techniques to the natural phenomenon—which is exactly what the claims of the '540 Patent recite.

B. The Court of Appeals Correctly Applied this Standard

Here, the Federal Circuit followed the two-part framework discussed in *Mayo* and *Alice* and concluded that the '540 Patent "begins and ends with a natural phenomenon" and thus is directed to that phenomenon, i.e., the presence of cffDNA in maternal plasma or serum. App. 10a-11a.

The court then considered whether the claims of the '540 Patent contained an "inventive concept that transforms the natural phenomenon of cffDNA into a patentable invention." App. 12a. The court concluded that there was no such "inventive concept" because the claims merely instructed practitioners "to apply routine, conventional techniques when seeking to detect" that natural phenomenon. App. 13a; *see also* App. 15a (finding the claims not patentable because they do nothing more than "append[] routine, conventional steps to a natural phenomenon, specified at a high level of generality").

That is the inquiry mandated by *Mayo* and *Alice*, and the court of appeals correctly determined that the claims of the '540 Patent do not meet the standard. Claim 1—which Petitioner treated as representative of all claims both in the District Court and on appeal—well illustrates this point. Indeed, setting aside the amplification (i.e., copying) step—which even Petitioner concedes was routine and well understood at the time of the invention—the language of Claim 1 of the '540 Patent is circular and devoid of content:

> A method for detecting a paternally inherited nucleic acid of fetal origin performed on a maternal serum or plasma sample from a pregnant female, which method comprises … detecting the presence of a paternally inherited nucleic acid of fetal origin in the sample.

The claim thus recites a method for detecting naturally-occurring paternally inherited nucleic acid whose only step (aside from making more copies of the nucleic acid) is detecting the naturally-occurring paternally inherited nucleic acid.

This is little more than a claim to the natural phenomenon itself—and thus it is hardly surprising that the court of appeals found this claim "fails to disclose patent eligible subject matter." App. 15a. The claim recites absolutely nothing about the method of detecting cffDNA—aside from making more copies of it—instead relying on the skilled artisan's knowledge of well-known techniques of detecting DNA. Accordingly, Claim 1 fails to recite anything "sufficient to ensure that the patent in practice

amounts to significantly more than a patent upon the natural law itself." *Mayo*, 132 S. Ct. at 1294.

Claim 21 is similarly ineligible (although Petitioner never separately defended that claim in the courts below). That dependent claim, which expressly incorporates the generic "detecting" method of Claim 1, adds only the conventional steps of fractionating the blood sample and "providing a diagnosis." *See* App. 46a n.5 ("[F]ractionating blood and providing a diagnosis based on fetal DNA were well-understood, routine, conventional activity engaged in by those in the field at the time of the invention."). While Claim 21 adds the notion of using the method for a diagnosis, Petitioner does not actually argue that this would render a non-patentable method patentable. *Mayo* itself rejected this notion. 132 S. Ct. at 1297 (use of method in treatment does not render claim patentable).

Although Petitioner never defended any other dependent claim of the '540 Patent in the District Court or on appeal to the Federal Circuit—relying instead on Claim 1 as representative for Section 101 purposes—none of the dependent claims fares any better under the Court's patent eligibility framework. Indeed, as the Federal Circuit concluded, those dependent claims are focused on the use of the natural phenomenon of cffDNA "in combination with well-understood, routine, and conventional activity" and therefore are not patentable. App. 15a.

For example, as the Federal Circuit determined, "claim 2 identifies the polymerase chain reaction [("PCR")] as the amplification technique to be used in the detection method of claim 1," but PCR "was well-understood, routine, and conventional" at the time of

the invention, "as specified by the patent itself." *Id.* Similarly, Claim 4 adds that DNA is "detected by means of a sequence specific probe." Pat. 24:65-67. As the District Court determined, however, that technique was also commonplace at the time of the invention. App. 46a n.5.

In addition, Petitioner argues that certain dependent claims recite patent-eligible subject matter because they "refine" the steps of fractionation, amplification, and detection of cffDNA "down to the level of *individual tests*," such as to detect Down Syndrome or gender. Pet. at 34; *see also id.* at 4. This is a mischaracterization that the District Court and the Federal Circuit have previously rejected. Indeed, these dependent claims do not recite "individual tests" at all, but instead "merely limit the natural phenomenon of paternally inherited cffDNA to specific types of that natural phenomenon, such as requiring that the cffDNA is from a Y chromosome or requiring that the cffDNA is at least a certain percentage of the total DNA." App. 46a-47a n.5. But, a "specific type of a natural phenomenon is still a natural phenomenon," App. 47a n.5, and detecting a specific chromosome adds "no inventive concept to the limitations of claim 1." App. 15a.

Finally, Claim 22, which depends from Claim 21, identifies a specific type of fractionation of blood, which was also well understood, routine, and conventional. App. 47a n.5. Therefore, none of the dependent claims recites any "inventive concept" and none warrants granting this petition.

Petitioner's various requests for an exemption from *Mayo* are equally unpersuasive. For example, Petitioner asserts that *Mayo* should not apply

because the '540 Patent reflects a scientific "breakthrough" and a "revolutionary" discovery. *E.g.*, Pet. at 11-12. But this argument conflates discovery with patentability in a way the Court has firmly rejected. "Groundbreaking, innovative, or even brilliant discovery does not by itself satisfy the § 101 inquiry." *Myriad*, 133 S. Ct. at 2117. Petitioner's argument that it is entitled to a patent because the applicants made a "breakthrough" discovery of a useful natural phenomenon contradicts the most basic principles of the Court's Section 101 jurisprudence.

Petitioner also suggests that *Mayo* "was not intended to serve as a fully-developed legal rule that could be easily or mechanistically applied to all future cases." Pet. at 17. However, this Court's subsequent decisions provide the proper insight into *Mayo's* applicability. And this Court has twice reiterated and applied *Mayo* to invalidate patent claims that did not contain the requisite inventive concept in addition to the patent-ineligible natural phenomenon (*Myriad*) or abstract idea (*Alice*)—precisely the aspect of the controlling standard that Petitioner seeks to eradicate.

In *Myriad*, the Court applied the "well-established standard" outlined in *Mayo* in concluding that the discovery of the BRCA1 and BRCA2 genes itself did not confer patentability. 133 S. Ct. at 2116. In so ruling, the Court noted that the case presented no method claims that recited novel processes of isolating the newly-discovered genes that would provide an inventive concept apart from the patent-ineligible discovery itself. *Id.* at 2119-20. In *Alice*, the Court held that *Mayo* "set forth a framework for

distinguishing patents that claim laws of nature, natural phenomena, and abstract ideas from those that claim patent-eligible applications of those concepts." 134 S. Ct. at 2355. The Court then followed that framework to invalidate a claim reciting only the abstract idea of an intermediated settlement that failed to add anything beyond a conventional "generic computer" to support patentability. *Id*. at 2360.

These are well-articulated rules established by the Court, not mere suggestions subject to future debate. Here, the court of appeals faithfully applied these rules to patent claims that do not come close to meeting the requirements that the Court has articulated. That decision provides no reason for this Court's review.

II. Petitioner Invites the Court to Dismantle and Rewrite Current Law, Which the Court Should Decline to Do

Petitioner's main contention is that the Federal Circuit's "rote version of *Mayo*" improperly "invalidates any method patent combining a natural discovery with 'conventional' techniques—even if those techniques are admittedly 'new' in combination," i.e., new when combined with a previously unknown phenomenon. Pet. at 13. As Petitioner explains, "discovering practical natural phenomena must be allowed to contribute to taking the "inventive step" that *Mayo* requires." Pet. at 26. But what Petitioner derides as a "rote" application of *Mayo* was actually faithful adherence to this Court's established law. And there is no support for Petitioner's proposed overhaul of this Court's Section 101 jurisprudence, which would contradict decades of Supreme Court precedent.

Petitioner fails to recognize that the patentability of the claims in *Mayo* did not turn on whether the natural phenomenon recited in the claims was newly discovered. Rather, *Mayo* held that a process that focuses upon the use of a natural phenomenon must contain an "inventive concept" *separate and apart* from the natural phenomenon—and that "well-understood, routine, conventional activity already engaged in by the scientific community" cannot supply that inventive concept. *Mayo,* 132 S. Ct. at 1294, 1298. Nowhere did *Mayo* suggest, let alone hold, that this rule does not apply to a newly discovered natural phenomenon. Indeed, it would make no sense to apply a different rule, with a different outcome, to a newly discovered natural phenomenon, as doing so would permit the patenting of a method that does not amount "to significantly more than a patent upon the natural law itself." *Id*. at 1294. Yet that is precisely what Petitioner seeks to accomplish with the '540 Patent.

Mayo built on decades of precedent that rejects the very rule Petitioner urges the Court to adopt. For example, in *Funk Bros. Seed Co. v. Kalo Inoculant Co*., 333 U.S. 127 (1948), the Court made clear that one "who discovers a hitherto unknown phenomenon of nature has no claim to a monopoly of it which the law recognizes. If there is to be invention from such a discovery, it must come from the application of the law of nature to a new and useful end." *Id*. at 130 (citing cases). At issue in *Funk Brothers* were claims directed to a useful mix of bacteria strains that, when combined, did not inhibit the beneficial properties of any of the individual strains. *Id*. at 130-31. Although the discovery that the bacteria could be mixed without harmful effects may have been laudable, the

Court held that it was "no more than the discovery of some of the handiwork of nature and hence is not patentable." *Id.* at 131.

Moreover, in language directly applicable here, this Court concluded that "once nature's secret of the non-inhibitive quality of certain strains of [the bacteria] were discovered, the state of the art made the production of a mixed inoculant a simple step. Even though it may have been the product of skill, it certainly was not the product of invention." *Id.* at 132. Indeed, the Court concluded that there "is no way in which we could call it such *unless we borrowed invention from the discovery of the natural principle itself*." *Id.* (emphasis added). Here, Petitioner asks the Court to call its method of detecting cffDNA "invention" solely because it incorporates the discovery of the presence of cffDNA in maternal plasma and serum. *Funk Brothers* rejected precisely this argument 68 years ago.

Petitioner's proposed approach also conflicts with the 1978 decision in *Flook*. There, the Court considered a patent application that covered a method of updating "alarm limits," which reflected numerical measurements of certain operating conditions. The only novel feature of the claimed method was a mathematical formula for updating the alarm limits; all other elements reflected "conventional methods of changing alarm limits" (referred to as "post-solution activity"). 437 U.S. at 586, 590. Relying on previous precedent holding "that the discovery of a novel and useful mathematical formula may not be patented," *id.* at 585, the Court concluded that the application did not cover patent-eligible subject matter. *Id.* at 590. The Court

reasoned that the "notion that post-solution activity, no matter how conventional or obvious in itself, can transform an unpatentable principle into a patentable process exalts form over substance." *Id.* The Court reiterated that the discovery of "a phenomenon of nature or mathematical formula ... cannot support a patent unless there is some *other* inventive concept in its application." *Id.* at 594 (emphasis added). Here, Petitioner's proposed standard for patent eligibility, which does not require any "inventive concept" in the application of a natural phenomenon, runs contrary to this long-standing rule.

In support of its argument, Petitioner relies almost entirely on *Diamond v. Diehr*, 450 U.S. 175 (1981), where the Court remarked that "[i]t is inappropriate to dissect the claims into old and new elements and then to ignore the presence of the old elements in the analysis." *Id.* at 188. Petitioner relies on this passage to argue that the court of appeals improperly "dissected" the discovery of cffDNA from the conventional laboratory techniques used to detect it when analyzing whether the claims of the '540 Patent recite an inventive concept. Pet. at 19.

Petitioner misreads *Diehr*. In that case, the patent claimed a "process of constantly measuring the actual temperature inside" a mold used to cure rubber and then feeding these temperature measurements "into a computer which repeatedly recalculates the cure time by use of" the unpatentable Arrhenius equation and "signals a device to open the press." 450 U.S. at 178-79. The Court noted that "the continuous measuring of the temperature inside the mold cavity, the feeding of this information to a

digital computer which constantly recalculates the cure time, and the signaling by the computer to open the press, *are all new in the art*." *Id*. at 179 (emphasis added). Indeed, *Mayo* noted that the claimed method steps in *Diehr* (i.e., the steps other than the use of the Arrhenius equation) were found not to be "obvious, already in use, or purely conventional." 132 S. Ct. at 1299.

Nothing in *Diehr* supports Petitioner's contention that the discovery of a natural phenomenon can be the "new" part of an ordered combination supplying the required inventive concept for patent eligibility. Indeed, *Diehr* did not even involve the discovery of a natural law, but rather the use of a well-known mathematical equation in an innovative process for curing rubber—and, as the decision reflects, the innovation was not the use of the mathematical equation. *Diehr* is entirely consistent with the Court's long-standing requirement, reiterated in *Mayo*, that "a process that focuses upon the use of a natural law *also* contain *other* elements or a combination of elements sometimes referred to as an 'inventive concept,' sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the natural law itself." *Mayo*, 132 S. Ct. at 1294 (emphasis added).

Petitioner's interpretation of *Diehr* contradicts decades of the Court's precedent. For example, in *Flook*, the Court held that the "novelty of the [unpatentable phenomenon] is not a determining factor at all. Whether the [unpatentable phenomenon] was in fact known or unknown at the time of the claimed invention … it is treated as though it were a familiar part of the prior art." 437

U.S. at 591-92. And, "once that [phenomenon] is assumed to be within the prior art," the question becomes whether the "application, considered as a whole, contains [a] patentable invention." *Id.* at 594.

In other words, irrespective of a newly discovered phenomenon, patent-eligible claims *still* must contain an inventive concept sufficient to transform unpatentable subject matter "into patentable applications" of that subject matter. *Mayo*, 132 S. Ct. at 1298. For this reason the claims of the '540 Patent are nothing like the patentable invention in *Diehr*. They "start and end with a naturally occurring phenomenon" and the method steps between those end points are "conventional, routine, and well understood applications in the art." App. 15a.

III. Petitioner's Preemption Arguments Also Seek to Revisit and Revise Established Supreme Court Law

Repeating an argument rejected by the District Court and the Federal Circuit, Petitioner contends that the claims of the '540 Patent are patent-eligible because they allegedly do not preempt all uses of cffDNA. Pet. at 21. The absence of complete preemption, however, does not save a claim that fails to include an inventive concept separate from a natural law or phenomenon. Rather, while concerns about preemption are an important consideration—i.e., courts are warned against "upholding patents that claim processes that too broadly preempt the use of a natural law"—this Court's decisions "insist" that the claimed processes contain an "inventive concept" apart from the recited natural law. *Mayo*, 132 S. Ct. at 1294.

Mayo demonstrates why Petitioner is wrong. *Mayo* addressed concerns about preemption—for example, that the claims at issue "threaten to inhibit the development of more refined treatment recommendations"—only after determining that the claims did not contain an inventive concept. *Id.* at 1302. If Petitioner were correct, the analysis would have been entirely different. The Court would have considered whether the claims preempted all other uses of the natural law and, if not, allowed the claims. But the Court took a different approach: It determined that the claims added "nothing of significance to the natural laws themselves" and *only then* referenced preemption to reinforce its conclusion of invalidity. *Id.* The Court observed that "upholding the patents would risk disproportionately tying up the use of the underlying natural laws, inhibiting their use in the making of further discoveries." *Id.* at 1294. It is the "risk" of "disproportionately tying up the use of" a natural phenomenon through the lack of inventive concept—not the actual complete preemption of a natural phenomenon—to which the patentable subject matter inquiry is addressed.

Moreover, on multiple occasions, this Court has invalidated patents notwithstanding the lack of complete preemption. For example, in *Flook*, the claims did not "wholly preempt" the mathematical formula. 437 U.S. at 589-90. Indeed, the Court stated that "Respondent *correctly* points out that [the preemption prohibition] does not apply to his claims. He *does not* seek to 'wholly preempt the mathematical formula,' since there are uses of his formula outside the petrochemical and oil-refining industries that remain in the public domain." *Id.* (emphasis added). Instead, respondent/patentee

argued that "the presence of specific 'post-solution' activity" made his process patentable. *Id.* at 590. It was this latter argument—that the claims had been meaningfully limited—that the Court rejected. *Id.* ("The notion that post-solution activity, no matter how conventional or obvious in itself, can transform an unpatentable principle into a patentable process exalts form over substance."). The Court in *Flook*, therefore, invalidated the claims for lack of inventive concept without engaging in a determinative preemption analysis. *Id.* at 594 (holding that the patentee's application of the natural law contained "no claim of patentable invention" because its components were "well known").

Similarly, in *Bilski*, the Court found that independent claim 1 was a non-patentable abstract idea that would preempt risk hedging in all fields. 561 U.S. at 611-12. But the Court's approach to the dependent claims illustrates that the absence of complete preemption does not mean that a claim recites patentable subject matter. The dependent claims in *Bilski* did not wholly preempt the abstract idea because they were specifically directed to commodities and energy markets. *Id.* at 612. Nonetheless, the Court found those claims invalid because they added "less to the underlying abstract principle than the invention in *Flook* did" and "*Flook* established that limiting an abstract idea to one field of use or adding token postsolution components [does] not make the concept patentable." *Id.*

Accordingly, the court of appeals here correctly concluded that "while preemption may signal patent ineligible subject matter, the absence of complete preemption does not demonstrate patent eligibility."

App. 17a. To apply the "ratchet the other way," as Petitioner suggests, would be to ignore established law.

Sequenom places much emphasis on three articles cited to the District Court that it claims show alternative methods of using cffDNA that are outside the scope of the '540 Patent. Pet. at 21-22. The District Court properly concluded that "Sequenom has failed to show that any alternative methods [of using cffDNA] existed at the time of the invention or at the time of issuance of the patent." App. 57a. This conclusion reflects the unremarkable proposition that, like all other validity issues (such as anticipation, obviousness, written description, enablement, and indefiniteness), the determination of whether patent claims recite patent-eligible subject matter must be made as of the relevant priority date, not based on later developments in the field. The articles cited by Sequenom were published in 2002, 2003, and 2012—all of which fall after the date of the earliest application to which the '540 Patent claims priority (March 4, 1997), as well as the actual issuance date of the patent (July 10, 2001). Pat. at 1.

Under *Mayo*, it is the language of the claims that determines whether they are drawn to patent-eligible subject matter. 132 S. Ct. at 1294-98. Accordingly, the District Court correctly analyzed whether the claims of the '540 Patent were patent eligible as a matter of law when they issued. This analysis was consistent with the notion that patents should not "tie up too much future use of laws of nature," *e.g.*, *id.* at 1302, because the effect of the patent on such "future use" must be judged from the beginning of the patentee's monopoly. That is when patent eligibility

is analyzed, not years after patent issuance. To hold otherwise would make the patent-eligibility analysis dependent on the timing of the challenge and the ever-shifting factual landscape concerning developments in the relevant field.

IV. Petitioner's Policy Arguments Are Meritless and Have No Bearing on the Outcome of this Case

In addition to the flawed legal arguments addressed above, Petitioner contends that the straightforward application of *Mayo* to the asserted claims of the '540 Patent threatens to "eviscerate" and "swallow[] all of patent law." Pet. at 25-26. Petitioner claims that *Mayo* would invalidate other patents on existing inventions such as a method for making potash from 1790 and the modern invention of PCR. *E.g., id.* at 25-26, 28-29. Petitioner also warns of a parade of horribles that would foreclose valuable inventions in the biotechnology field. *Id.* at 30-31. Petitioner's "sky-is-falling!" rhetoric, however, is pure hyperbole.

The Court confronted the same dire parade-of-horribles prediction from parties and *amici* in previous cases, but has recognized that it is no reason to depart from established law. Instead, such complaints simply represent the views of those stakeholders who desire patent protection in areas that the Court has ruled are non-patentable. Thus, for example, in *Mayo* the Court considered arguments, like those made here, that the denial of patent coverage would "interfere significantly with the ability of medical researchers to make valuable discoveries." 132 S. Ct. at 1304. The Court recognized that other stakeholders held a contrary policy view.

Id. at 1304-05. The Court did not "find this kind of difference of opinion surprising. Patent protection is, after all, a two-edged sword." *Id.* at 1305. The Court explained that, "[o]n the one hand, the promise of exclusive rights provides monetary incentives that lead to creation, invention and discovery. On the other hand, that very exclusivity can impede the flow of information that might permit, indeed spur, invention." *Id.* The Court cautioned that "we must hesitate before departing from established general legal rules lest a new protective rule that seems to suit the needs of one field produce unforeseen results in another. And we must recognize the role of Congress in crafting more finely tailored rules where necessary." *Id.* Accordingly, in language directly applicable here, the Court concluded that "[w]e need not determine whether, from a policy perspective, increased protection for discoveries of diagnostic laws of nature is desirable." *Id.*

Nor does the Court need to revise any of its prior rulings to make it possible for interested parties to obtain patents directed to natural phenomena. Rather, contrary to Petitioner's suggestion that *Mayo* threatens innovation in the life-science and healthcare industries, the Court's standard does not preclude truly meritorious inventions. To the contrary, this Court has repeatedly stressed that inventors have a broad canvass with which to work, so long as they make an inventive application of natural phenomena. Countless inventions have done so, and countless more will do so. Indeed, as the Court noted in *Myriad*, many inventors who make important discoveries *are* in an "excellent position to claim applications of that knowledge." 133 S. Ct. at 2120.

Here, the applicants were similarly in an excellent position, but in the case of the '540 Patent they did *not* apply their knowledge in a way that this Court's long-standing precedent recognizes as patent-eligible. Instead, they sought to claim a broad method for detecting a natural phenomenon, applying routine, conventional steps to detect the presence of that same phenomenon. *See* Part III.B, *supra*. That fact is not the fault of *Mayo* or of any other decision of this Court. Instead, it is solely the product of decisions made by the applicants themselves. Indeed, like the inventors in *Myriad*, *had* Drs. Lo and Wainscoat "created an innovative method" of manipulating or otherwise applying the cffDNA they identified, they may have been able to pursue a patentable method. 133 S. Ct. at 2120. They did not do so for the '540 Patent.

Petitioner suggests that the Federal Circuit's decision would eliminate well-established categories of patentable inventions, such as patent claims directed to new ways of using an existing drug. Pet. at 19-20. But such claims would not even invoke the first step of the *Mayo* test for patent eligibility because they do not even recite (let alone focus on) a natural law or phenomenon. Rather, they are directed to the use of a *drug*—something that is manmade rather than discovered in nature. The same is true for patents covering new vaccines or other novel drug therapies developed in a laboratory through human ingenuity; none of them seek to claim the discovery of something found in nature. The Court confirmed the patentability of these inventions in *Myriad*. 133 S. Ct. at 2119 (confirming patentability of cDNA molecules made from exons of the BRCA1 and BRCA2 genes because "the lab

technician unquestionably creates something new when cDNA is made. cDNA retains the naturally occurring exons of DNA, but it is distinct from the DNA from which it was derived").

Similarly, Petitioner contends that *Mayo* would undo the patentability of past inventions, such as Mr. Hopkins's 1790 method of making potash and the modern day invention of PCR. Pet. at 25a-26a, 28a-29a. This is insupportable hyperbole and, even if the facts of those patents were before the Court, Petitioner is wrong. On its face, the 1790 patent addresses an "[i]mprovement, not known or used before" in the "making of Pot ash and Pearl ash by a new Apparatus" and process. U.S. Pat. X1, https://goo.gl/fIFfsg. The same is true of the PCR invention. See U.S. Pat. No. 4,683,195. As a result, those inventions "add *enough* to their statements of the [natural law or phenomenon] to allow the processes they describe to qualify as patent-eligible processes that *apply* natural laws." *Mayo*, 132 S. Ct. at 1297. As the District Court and the Federal Circuit correctly held, the same cannot be said for the '540 Patent. There is no reason to rewrite this Court's jurisprudence to change that result.

CONCLUSION

For the foregoing reasons, the Court should deny the petition for certiorari.

Respectfully submitted,

David I. Gindler
Counsel of Record
Joseph M. Lipner
Andrei Iancu
Josh B. Gordon

Irell & Manella LLP
1800 Avenue of the Stars
Los Angeles, CA 90067
(310) 277-1010
dgindler@irell.com
Counsel for Respondent, Ariosa Diagnostics, Inc.

May 20, 2016