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

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QUESTION PRESENTED

In *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 132 S. Ct. 1289 (2012), this Court unanimously established a comprehensive framework for evaluating patent-eligibility under 35 U.S.C. § 101. In *Alice Corp. Pty. Ltd. v. CLS Bank International*, 134 S. Ct. 2347 (2014), this Court unanimously reaffirmed the *Mayo* framework. The Federal Circuit and the district court both concluded that the asserted claims are not patent-eligible under the *Mayo* framework. Rather than defend the asserted claims under that framework, petitioner asks this Court to adopt an *alternative* standard for patent-eligibility. *See* Pet. i. The predicate question is whether this Court should revisit and overrule *Mayo* and *Alice*.

RULE 29.6 STATEMENT

Pursuant to this Court's Rule 29.6, undersigned counsel states that Natera, Inc. has no parent corporation and that no public companies own more than ten percent (10%) of Natera's stock. The parent corporation of DNA Diagnostics Center, Inc. is DDC-DNA Holdings Inc. The ultimate parent corporation of DDC-DNA Holdings Inc. is GHO Capital Fund I LP. No public company owns more than ten percent (10%) of DNA Diagnostics Center, Inc.'s stock.

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BRIEF IN OPPOSITION

Respondents Natera, Inc. and DNA Diagnostics Center (DDC) respectfully submit that the petition for a writ of certiorari should be denied.*

STATEMENT

On summary judgment, the district court ruled that the asserted claims of U.S. Patent No. 6,258,540 are not eligible for patenting under 35 U.S.C. § 101. Pet. App. 25a–58a. The Federal Circuit unanimously affirmed. *Id.* at 1a–19a.

1. "In 1996, Drs. Dennis Lo and James Wainscoat discovered cell-free fetal DNA ('cffDNA') in maternal plasma and serum, the portion of maternal blood samples that other researchers had previously discarded as medical waste." Pet. App. 3a. "[T]he '540 patent claims certain methods of using cffDNA." *Ibid.* For example, "[t]he steps of the method of claim 1 of the '540 patent include amplifying the cffDNA contained in a sample of a plasma or serum from a pregnant female and detecting the paternally inherited cffDNA." *Id.* at 3a–4a; *see also id.* at 5a (reproducing claim 1 in its entirety). "The remaining claims explain how the method of detection occurs or how it can be used." *Id.* at 6a.

2. Petitioner Sequenom, Inc. and respondents Natera and Ariosa are competitors in the market for non-invasive fetal testing, and respondent DDC

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* Natera and DDC adopt the arguments made by respondent Ariosa Diagnostics, Inc. in its separate brief in opposition.

markets certain Natera diagnostic tests. Pet. App. 63a. In this litigation, Sequenom—as the exclusive licensee of the '540 patent—alleges that Natera, Ariosa, and DDC infringe several claims of that patent. *Id.* at 4a & n.1.

On summary judgment, respondents demonstrated that the asserted claims are not eligible for patenting under 35 U.S.C. § 101 as construed in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 132 S. Ct. 1289 (2012), and *Association for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107 (2013). The patent recites the general application of well-known techniques to analyze naturally occurring cffDNA in the human body. *Myriad* holds that human genes are unpatentable natural phenomena, and *Mayo* precludes reciting such phenomena with the instruction to "apply it" in a conventional manner; yet that is all the asserted claims of the patent-in-suit do. *See* Pet. App. 43a, 45a.

The district court agreed "that the claims of the '540 patent were directed to the natural phenomenon of paternally inherited cffDNA and did not add enough to the natural phenomenon to make the claims patent eligible under § 101." Pet. App. 7a–8a; *see id.* at 43a–54a. In particular, "the steps of amplifying and detecting were well-understood, routine, or conventional activity in 1997, when the application for the '540 patent was filed." *Id.* at 8a; *see id.* at 54a (viewed "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"). Indeed, "Sequenom acknowledge[d] that the claims of the '540 patent merely apply 'conventional techniques' to

the newly discovered natural phenomenon of cffDNA." *Id.* at 47a (citing petitioner's district court briefing and oral argument).

3. The Federal Circuit unanimously affirmed.

a. The court of appeals recognized 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." Pet. App. 9a. "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." *Ibid.* (quoting *Mayo*, 132 S. Ct. at 1297–98) (citations omitted).

With respect to step one of the *Mayo* framework, the Federal Circuit explained that "[i]t is undisputed that the existence of cffDNA in maternal blood is a natural phenomenon"; "[t]hus, the claims are directed to matter that is naturally occurring." Pet. App. 10a; *see also id.* at 11a ("the claims at issue, as informed by the specification, are generally directed to detecting the presence of a naturally occurring thing or a natural phenomenon, cffDNA in maternal plasma or serum").

And at step two, the Federal Circuit determined that "[t]he method at issue here amounts to a general instruction to doctors to apply routine, conventional techniques when seeking to detect cffDNA." Pet. App. 13a. "Because the method steps were well-understood, conventional and routine, the method of

detecting paternally inherited cffDNA is not new and useful." *Ibid.* The amplification step and the detecting step of claim 1 were well-known in the art of DNA analysis both individually and in combination at the time of the application. *Id.* at 13a–15a; *see also id.* at 15a (noting that the other asserted claims do not "differ substantially" in this respect).

The Federal Circuit summarized its conclusion as follows:

> Thus, in this case, appending routine, conventional steps to a natural phenomenon, specified at a high level of generality, is not enough to supply an inventive concept. Where claims of a method patent are directed to an application that starts and ends with a naturally occurring phenomenon, the patent fails to disclose patent eligible subject matter if the methods themselves are conventional, routine and well understood applications in the art. The claims of the '540 patent at issue in this appeal are not directed to patent eligible subject matter and are, therefore, invalid.

Pet. App. 15a–16a.

Judge Linn joined the panel decision and added a concurrence observing that there is "no room to distinguish *Mayo* from this case." Pet. App. 22a.

b. The Federal Circuit denied rehearing en banc. Pet. App. 74a. Judge Lourie concurred in the denial on the ground that there is "no principled basis to distinguish this case from *Mayo*." *Id.* at 76a. Judge Dyk also concurred, noting that "*Mayo* is controlling precedent that governs the outcome here." *Id.* at

86a. Only Judge Newman dissented, opining that "[t]he facts of this case diverge significantly from the facts and rulings in [*Mayo*] and [*Myriad*]." *Id.* at 100a–01a.

ARGUMENT

This petition should be denied if the Court remains satisfied that the framework for evaluating patent-eligibility under 35 U.S.C. § 101 unanimously articulated in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 132 S. Ct. 1289 (2012), and unanimously reaffirmed in *Alice Corp. Pty. Ltd. v. CLS Bank International*, 134 S. Ct. 2347 (2014), is correct and should be retained. To grant the petition, the Court would have to be prepared to revisit and overrule *Mayo* and *Alice*.

To be clear, this petition is *not* about whether the *Mayo* standard was properly applied on these facts. That patent-specific question would not warrant certiorari in any event; and petitioner does not even attempt to defend the eligibility of the asserted claims under the two-part eligibility framework that this Court articulated and applied in *Mayo*. Rather, petitioner asks the Court to scrap the existing framework and start over with a completely different approach to patent-eligibility. *See* Pet. i.

Petitioner's proposed alternative—which would allow patent protection for methods comprising no more than a "straightforward application" of a new discovery (Pet. 23)—is the antithesis of *Mayo*. It has no grounding in or consonance with either Section 101 of the Patent Act or this Court's unbroken line of precedents construing that provision. Accordingly, petitioner and its allies do not seek mere adjustment

to, or "clarification" of (*id.* at 11), the current regime; they seek to overthrow it.

Petitioner's suggestion that *Mayo* should be overruled is extraordinary enough given that *Mayo* was unanimously decided less than five years ago; and all the more extraordinary since this Court expressly reaffirmed *Mayo*, again unanimously, just two Terms ago in *Alice*. Petitioner and its *amici* obviously disagree with those precedents, but they have not come close to making the case for revisiting or overruling them.

Petitioner and its *amici* provide no "special justification" sufficient to overcome *stare decisis*, a bedrock principle that applies with enhanced force to statutory interpretations. *Kimble v. Marvel Entm't, LLC*, 135 S. Ct. 2401 (2015); *Halliburton Co. v. Erica P. John Fund, Inc.*, 134 S. Ct. 2398 (2014). Now that the Court has authoritatively and comprehensively construed Section 101, Congress—not this Court—is the best forum for weighing the policy of the extant eligibility regime and any alternatives, including how best to "promote the Progress of Science and useful Arts." *See* U.S. Const. art. I, § 8, cl. 8. This Court has already discharged its function in interpreting the statute; the judicial role now entails consistent adherence to clear and administrable precedent, thereby promoting the rule of law.

For the most part, petitioner and its *amici* propound the same arguments that this Court rejected, expressly or impliedly, in *Mayo* and *Alice*. They contend, for example, that any specific application of a natural law should be patent-eligible; this Court emphatically rejected that position in requiring at least

some inventive contribution. They maintain that the *Mayo* standard contradicts *Diamond v. Diehr*, 450 U.S. 175 (1981); this Court has already explained, twice, that this argument misreads *Diehr*. And they insist that only claims that completely preempt all uses of a natural law are ineligible; this Court recognized that the principle of preemption is a relative one, such that *any* preemption is too much where (as here) the claims disclose *no invention*. In the few short years since *Mayo* and *Alice*, nothing has transpired to call these conclusions into question.

Petitioner's argument for overruling *Mayo* boils down to the proposition that the Court did not know what it was doing when it set forth the eligibility framework in that case. *See* Pet. 11. To the extent that charge does not answer itself, *Alice*'s reaffirmation of *Mayo*—over objections very similar to those now mounted—puts it to rest. As *Alice* recognized, *Mayo* articulated a robust framework for evaluating patent-eligibility under Section 101. 134 S. Ct. at 2355. The courts below faithfully applied that framework in holding the asserted claims ineligible. This Court should stay the course and deny the petition.

I. THE ASSERTED CLAIMS ARE INELIGIBLE UNDER THE *MAYO* FRAMEWORK

This is not a close case under *Mayo*. Indeed, the asserted claims here so closely resemble those in *Mayo* that this case is essentially *Mayo* redux.

As both courts below correctly concluded, the asserted claims are not patent-eligible under Section 101 because they describe only the application of routine and conventional methods of genetic analysis

to the newly discovered natural phenomenon that cffDNA exists in maternal plasma. Pet. App. 13a ("The method at issue here amounts to a general instruction to doctors to apply routine, conventional techniques when seeking to detect cffDNA"); *id.* at 54a ("the only inventive component of the processes in the '540 patent is to apply those well-understood, routine processes to paternally inherited cffDNA").

The asserted claims are directed to the discovery of "naturally occurring non-cellular fetal DNA that circulates freely in the blood stream of a pregnant woman." Pet. App. 10a. That discovery itself is an unpatentable natural phenomenon. *See Myriad*, 133 S. Ct. at 2118. And the asserted claims include no "additional features that provide practical assurance that the process is more than a drafting effort designed to monopolize the [natural phenomenon] itself." *Mayo*, 132 S. Ct. at 1297. Instead, the claims recite only the application of "well-understood, routine, conventional activity already engaged in by the scientific community," which is "not sufficient to transform unpatentable natural [phenomena] into patentable applications." *Id.* at 1298.

The claimed methods are routine and conventional both step-by-step and in ordered combination (*i.e.*, as a whole). The district court found that "[t]he unrebutted evidence does not merely show that the individual steps of fractionation, amplification and detection were well-understood, routine, and conventional activity. The evidence shows that it was well-understood, routine, and conventional activity to combine these steps to detect DNA in serum or plasma." Pet. App. 54a. The Federal Circuit agreed, noting that the patent's specification acknowledges

that "[t]he preparation of serum or plasma from the maternal blood sample is carried out by standard techniques." *Id.* at 13a–14a (alteration in original) (internal quotation marks omitted).

As in *Mayo*, the claims here merely instruct practitioners to apply known analytical methods to a new discovery. *See Genetic Techs. Ltd. v. Merial L.L.C.*, 2016 WL 1393573, at *5 (Fed. Cir. Apr. 8, 2016) (observing that, in this case, "the claimed advance over the prior art was allegedly newly discovered information about human biology"). But "transformation into a patent-eligible application requires 'more than simply stating the [natural phenomenon] while adding the words 'apply it.'" *Alice*, 134 S. Ct. at 2357 (quoting *Mayo*, 132 S. Ct. at 1294) (alterations omitted).

Petitioner does not even attempt to show that the asserted claims are eligible under the *Mayo* framework. Instead, petitioner's entire submission (as well as that of several *amici*) assumes that *Mayo* must be wrong because it "condemn[s] this meritorious patent." Pet. 11. Petitioner insists that, "[h]ere, unlike *Mayo*, every intuition points towards patent-eligibility." *Ibid.* But courts must decide cases based on neutral *ex ante* legal standards, not *ex post* intuitions of interested parties.

As *Alice* reiterated, the *Mayo* framework gives patent applicants, examiners, challengers, and judges a principled and meaningful standard by which to evaluate eligibility, regardless of the technology involved or the nature of the particular "invention." And under the *Mayo* standard, the claims asserted

by petitioner are *not* patent-eligible. So long as *Mayo* stands, the decision below can only be affirmed.

II. THE COURT SHOULD NOT UPEND THE *MAYO* FRAMEWORK

Unable to defend the eligibility of the '540 patent under the *Mayo* framework, petitioner maintains that the *Mayo* framework was "not intended to serve as a fully developed legal rule," but "merely sketched the outer shell of the content for its test in an obvious case." Pet. 17 (internal quotation marks omitted). Yet petitioner cannot fit the asserted claims within that shell. Instead, it proposes a wholly different standard under which any "*new combination* of otherwise conventional techniques is patent-eligible even if it is straightforwardly motivated by a patentee's unique discovery of a natural law or phenomena." *Id.* at 12; *see also id.* at 23 (patent law should reward "every straightforward application" of a phenomenon).

Petitioner's proposed alternative is the antithesis of the *Mayo* framework. By its own terms, petitioner's approach would permit "apply it" claims that add nothing inventive to an ineligible concept. But "*Mayo* made clear that transformation into a patent-eligible application requires 'more than simply stating the abstract idea while adding the words 'apply it,'" or their functional equivalent. *Alice*, 134 S. Ct. at 2357 (quoting *Mayo*, 132 S. Ct. at 1294) (alterations omitted). Otherwise, an applicant could claim any principle of nature or science simply by reciting it in the context of a conventional method. Such a rule "would make the determination of patent eligibility 'depend simply on the draftsman's art.'" *Id.* at

2359 (quoting *Parker v. Flook*, 437 U.S. 584, 593 (1978)).

Although petitioner insists that a "new combination of steps" may be patent-eligible, the only thing "new" about the combination here is the discovery of cffDNA in maternal plasma; all other aspects of the asserted claims were well-known and conventional, both individually and in ordered combination. *See* Pet. App. 54a. In these circumstances, petitioner is effectively claiming a monopoly on the cffDNA discovery itself. *See* Pet. i & 26. Yet that is precisely what *Mayo* and *Myriad* prohibit.

The Court should decline petitioner's invitation to rewrite *Mayo*. The bedrock principle of *stare decisis* counsels against changing course, particularly so soon after the Court unanimously articulated the eligibility framework in *Mayo* and unanimously reaffirmed it in *Alice*. And petitioner identifies no change in law or circumstance that would justify such an abrupt and extraordinary reversal.

1. "*Stare decisis* ... is a foundation stone of the rule of law." *Kimble*, 135 S. Ct. at 2409 (internal quotation marks omitted). For Section 101 of the Patent Act, this Court's precedents "have defined the reach of the statute as a matter of statutory *stare decisis* going back 150 years." *Bilski v. Kappos*, 561 U.S. 593, 602 (2010). Adhering to these precedents "promotes the evenhanded, predictable, and consistent development of legal principles, fosters reliance on judicial decisions, and contributes to the actual and perceived integrity of the judicial process." *Payne v. Tennessee*, 501 U.S. 808, 827 (1991).

The judicial values of predictability, stability, and integrity make it usually "more important that the applicable rule of law be settled than that it be settled right." *Burnet v. Coronado Oil & Gas Co.*, 285 U.S. 393, 406 (1932) (Brandeis, J., dissenting). That principle carries "enhanced force when a decision … interprets a statute," for "unlike in a constitutional case, critics of [the] ruling can take their objections across the street, and Congress can correct any mistake it sees." *Kimble*, 135 S. Ct. at 2409. The principle applies equally where the decision rests "on the policies and purposes animating the law." *Ibid.* (citing *Bilski*). This Court's "interpretive decisions, in whatever way reasoned, effectively become part of the statutory scheme, subject (like the rest) to congressional change." *Ibid.*

In light of these fundamental judicial values, this Court requires a "'special justification'" for overturning settled precedent, "not just an argument that the precedent was wrongly decided." *Halliburton*, 134 S. Ct. at 2407 (citation omitted). The "'primary reason'" for overruling statutory precedent is that "'either the growth of judicial doctrine or further action taken by Congress'" has removed the basis for a prior decision. *Kimble*, 135 S. Ct. at 2410 (quoting *Patterson v. McLean Credit Union*, 491 U.S. 164, 173 (1989)). Another "'traditional justification'" is that the prior decision "has proved unworkable." *Id.* at 2411 (citation omitted); *see*, *e.g.*, *Swift & Co. v. Wickham*, 382 U.S. 111, 116 (1965).

2. No action taken by the Legislative, Judicial, or Executive Branches suggests that *Mayo* should be revisited or overruled, or that the current approach to patent-eligibility is unworkable.

a. The congressional response to recent decisions on subject-matter eligibility has reinforced the Court's approach. A year after this Court held in *Bilski* that business method patents are not categorically ineligible, Congress passed the Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011). Section 18 of the AIA established "a separately-designated transitional program under which the USPTO conducts post-grant review proceedings concerning the validity of covered business method patents." *Versata Dev. Grp., Inc. v. SAP Am., Inc.*, 793 F.3d 1306, 1310 (Fed. Cir. 2015), *petition for cert. filed*, No. 15-1145 (U.S. Mar. 11, 2016). This provision reflects both Congress's continuing concern with such patents and its endorsement of this Court's approach to eligibility.

Congress has not further addressed patent-eligibility following the *Mayo-Myriad-Alice* trilogy, even though patent reform is perennially on the legislative agenda and commentators have proposed a variety of statutory responses. *See*, *e.g.*, Ryan Davis, *Kappos Calls for Abolition of Section 101 of Patent Act*, Law360 (Apr. 12, 2016). "Congress legislates actively with respect to patents" (*Kimble*, 135 S. Ct. at 2414), and has acted swiftly to reverse this Court on such matters where it saw fit. *See*, *e.g.*, *Halliburton Oil Well Cementing Co. v. Walker*, 329 U.S. 1 (1946), *superseded by statute as stated in Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 27–28 (1997); *Deepsouth Packing Co. v. Laitram Corp.*, 406 U.S. 518 (1972), *superseded by statute as stated in Limelight Networks, Inc. v. Akamai Techs., Inc.*, 134 S. Ct. 2111, 2118 n.4 (2014).

Congress clearly does not share the view of petitioner and some of its *amici* that a radical new approach to Section 101 is called for. *See Halliburton*, 134 S. Ct. at 2411 ("*stare decisis* has special force in respect to statutory interpretation because Congress remains free to alter what we have done") (internal quotation marks omitted). This is significant because the "choice of what patent policy should be lies first and foremost with Congress." *Kimble*, 135 S. Ct. at 2414; *see also* U.S. Const. art. I, § 8, cl. 8.

b. Subsequent judicial decisions have confirmed and applied the *Mayo* framework as the ultimate synthesis and statement of the law on patent subject-matter eligibility. Most obviously, this Court unanimously reaffirmed *Mayo* in *Alice*. The lower courts, too, continue to add meat to the bones of the *Mayo* framework.

Since *Mayo*, the Federal Circuit has issued published opinions in nearly 500 patent cases. Only a small fraction (about 30) have involved subject-matter eligibility. While many of the decisions to date have involved *ineligibility* determinations, that largely reflects the reality that such determinations end the case and are immediately appealable. While many such determinations have been affirmed, not all have been. *See*, *e.g.*, *Enfish, LLC v. Microsoft Corp.*, 2016 WL 2756255 (Fed. Cir. May 12, 2016) (reversing determination that database invention was ineligible). *Eligibility* determinations, in contrast, are not immediately appealable and the litigation may continue for months or years before ending in settlement or an appealable judgment. In fact, only one eligibility determination has reached the Federal Circuit since *Alice*. *DDR Holdings, LLC v. Ho-*

tels.com, L.P., 773 F.3d 1245 (Fed. Cir. 2014) (affirming determination that web page display invention was eligible).

Other than this case, the Federal Circuit has issued only three published decisions regarding the eligibility of life-sciences patents since *Mayo*. *See Genetic Techs.*, 2016 WL 1393573; *In re BRCA1- & BRCA2-Based Hereditary Cancer Test Patent Litig.*, 774 F.3d 755 (Fed. Cir. 2014); *In re Roslin Inst. (Edinburgh)*, 750 F.3d 1333 (Fed. Cir. 2014). The relative paucity of decisions in this area demonstrates that petitioner's predictions of gloom and doom for the life-sciences industry (*see* Pet. 10–12) are both hyperbolic and premature.

Petitioner and its *amici* level inconsistent criticisms against the Federal Circuit and its application of the *Mayo* framework. On one hand, they complain that the post-*Mayo* decisions "threaten[] to destroy the predictability and certainty the patent system needs" (*e.g.*, Pet. 31; Brief of Microsoft Corp. at 5–12)—a charge that has absolutely no empirical basis. On the other, they complain that patents are consistently being ruled ineligible (*e.g.*, Pet. 35; Brief of 19 Law Professors at 10)—which also is empirically untrue, and in any event should hardly surprise given that the claims asserted in *Mayo* and *Myriad* and *Alice* were all ruled ineligible by this Court, and virtually all the patents that have reached the Federal Circuit since then were prosecuted and allowed even before *Bilski* under outdated eligibility guidelines. The reality is that the Federal Circuit is faithfully applying the Court's recent directives.

While petitioner contends that ineligibility determinations require a "principled line" (Pet. 35), the line drawn by this Court in *Mayo* and *Alice is* principled: Petitioner's real complaint is that its patent falls on the wrong side of that line. The answer is not to redraw the line, but to prosecute and allow better (*i.e.*, inventive) patents.

c. The Patent and Trademark Office has also embraced the *Mayo* eligibility framework.

After *Mayo*, the PTO promulgated extensive guidance on eligibility for applicants and the examination corps. *See* U.S.P.T.O., 2014 Interim Guidance on Patent Subject Matter Eligibility (2014) ("Post-*Mayo* Guidelines"); U.S.P.T.O., July 2015 Update: Subject Matter Eligibility (2015) ("Post-*Alice* Guidelines"). Even more recently, the PTO issued additional guidance. Memorandum, U.S.P.T.O., Formulating a Subject Matter Eligibility Rejection and Evaluating the Applicant's Response to a Subject Matter Eligibility Rejection (May 4, 2016).

The PTO's guidelines aim to ensure that patent examiners consistently apply the *Mayo* framework in a clear and understandable way across the full range of technological arts. In particular, the guidelines "help examiners and applicants understand when a proper *prima facie* case [for rejecting claims] has been made, so there is no doubt as to whether examiners have met their burden." Post-*Alice* Guidelines at 6. The guidelines also provide exemplary analyses to "illustrate the proper application of the eligibility analysis to a variety of claims in multiple technologies, and to guide examiners in evaluating eligibility in a consistent manner across the corps." *Id.* at 8.

This demonstrates the value of the *Mayo* framework, and how the PTO has adopted it as a guiding compass for determining patent eligibility.

The PTO's guidance belies petitioner's lament that *Mayo* threatens to "gut[] protections for a host of meritorious inventions, especially in the life-sciences." Pet. 13. For instance, the PTO's most recent Guidelines set forth examples that illustrate application of the *Mayo* framework to seven hypothetical "diagnostic and treatment claims." *See* U.S.P.T.O., Subject Matter Eligibility Examples: Life Sciences 9–16 (2016). The PTO's exemplary analysis finds that six of the seven hypothetical claims would be eligible under the *Mayo* framework either because the claims are "not directed to any judicial exception" or "they recite specific and unconventional reagents and/or treatments that amount to significantly more than the exception." *Id.* at 9. Only hypothetical Claim 2—which is apparently modeled on the claims in this case—is unpatentable. *Id.* at 9, 11–12.

3. In the absence of any changed circumstances (and there are none), this Court should not upset public reliance on the authoritative and comprehensive eligibility framework that the Court has painstakingly articulated. *See Myriad*, 133 S. Ct. at 2119 n.7. Among the "prudential and pragmatic considerations designed to test the consistency of overruling a prior decision with the ideal of the rule of law" is "whether the rule is subject to a kind of reliance that would lend a special hardship to the consequences of overruling and add inequity to the cost of repudiation." *Planned Parenthood of Se. Pa. v. Casey*, 505 U.S. 833, 854 (1992). And here, changing course would unfairly affect those who bought or sold patent

rights in reliance on their perceived value under this Court's authoritative construction of governing law.

Indeed, innumerable patent-related transactions—including licensing agreements, transfers, joint ventures, acquisitions, divestitures, mergers, security interests, research and development investments, and more—have been negotiated or consummated since *Mayo*, each accounting for the impact of the eligibility framework established by this Court. The Court should not pull out the rug just as the market is internalizing *Mayo*'s impact. *See* Sean Sheridan, *How Mayo, Myriad, and Alice May Impact Patent Valuations*, Law360 (Mar. 4, 2015) ("greater clarity on the issue of patentable subject matter should lead to greater confidence in the long-term financial projections required for making critical transaction decisions in the life sciences sector").

In short, nothing has changed in the last few years except that *Mayo*'s place in the law has become more firmly entrenched, not least by its ringing endorsement in *Alice*. The ball is now in Congress's court. This Court's respect for *stare decisis* will "promote the rule-of-law values to which courts must attend while leaving matters of public policy to Congress." *Kimble*, 135 S. Ct. at 2414.

III. PETITIONER'S PROPOSED ALTERNATIVE TO THE *MAYO* FRAMEWORK CONTRADICTS SECTION 101

As noted above, petitioner urges this Court to adopt an alternative to *Mayo* under which "every straightforward application" of an ineligible concept would be entitled to patent protection. Pet. 23. Several of petitioner's *amici* similarly train their fire on the "inventive contribution" aspect of the *Mayo*

framework. *See*, *e.g.*, Brief of Profs. Lefstin & Menell at 15–16 ("the test of patent-eligibility focuses not on whether the inventor claims an *inventive* application of a scientific principle, but whether the inventor claims a *practical* application of a scientific principle"); Brief of Novartis at 15 (the inventive-step requirement "could eviscerate patent law"); Brief of BioIndustry Association at 23 ("[t]he 'significantly more' requirement enunciated in *Mayo*, *Myriad*, and *Alice* has no direct equivalent in the interpretation of patent laws of other industrialized countries"). This Court has never accepted such a construction of Section 101, and it should not start now.

Under the approach urged by petitioner, the claims asserted in *Mayo* would have been patentable. Those claims recited a method of administering thiopurine drugs based on the prevalence of certain metabolites in a patient's blood. The patentees discovered "the precise correlations between metabolite levels and likely harm or ineffectiveness" of the drugs. *Mayo*, 132 S. Ct. at 1295. The asserted claims recited a process for administering the drugs based on precise metabolite levels. *Ibid.* But the process was not patentable because it "amount[ed] to nothing significantly more than an instruction to doctors to apply the applicable laws when treating their patients." *Id.* at 1298. Yet under petitioner's alternative standard, *Mayo*'s method would be patentable as a "straightforward application" of a natural law.

Petitioner's alternative standard would likewise have flipped the result in *Alice*. In that case, the asserted claims recited a "computerized scheme for mitigating 'settlement risk.'" 134 S. Ct. at 2352. As

the Court recognized, "the concept of intermediated settlement is 'a fundamental economic practice long prevalent in our system of commerce.'" *Id.* at 2356 (quoting *Bilski*, 561 U.S. at 611). The asserted claims recited that concept in a "wholly generic computer implementation," which "is not generally the sort of 'additional feature' that provides any 'practical assurance that the process is more than a drafting effort designed to monopolize the abstract idea itself'." *Id.* at 2358 (quoting *Mayo*, 132 S. Ct. at 1297) (alterations omitted). Yet under petitioner's alternative standard, *Alice*'s straightforward computer application would suffice.

In support of its proposed alternative, petitioner makes much of *Myriad*'s unremarkable observation that the first party with knowledge of a phenomenon is "in an excellent position to claim applications of that knowledge." 133 S. Ct. at 2120 (internal quotation marks omitted). According to petitioner, under the *Mayo* framework, first discoverers are "in no better position to claim applications of their knowledge, because, before claiming anything at all, they would have to invent a second, entirely new technique to incorporate into their methods for applying their discovery." Pet. 20–21. Petitioner's facile fix is to eliminate the need for an invention altogether.

Of course, the discoverer of a natural phenomenon *is* in an excellent position to invent new applications. After all, nobody else even knows about the discovery yet, so the discoverer has a head-start. And that is exactly what inventors like Morse, Bell, and Edison did in securing their respective patents. The Court has never, however, authorized the patent monopoly in the complete absence of invention, as

the rejection of Morse's eighth claim establishes. *See O'Reilly v. Morse*, 56 U.S. (15 How.) 62, 101–02 (1854).

1. Petitioner offers two doctrinal justifications for overthrowing *Mayo*: an anti-dissection principle it derives from *Diehr* (Pet. 18–19), and a complete-preemption requirement it pulls out of thin air (*Id.* at 21–24). Both of these arguments have been previously rejected by this Court, and they fare no better as recycled here.

a. Petitioner and its *amici* repeat the trope that the *Mayo* framework improperly allows courts to "dissect" claims into old and new elements. *See Diehr*, 450 U.S. at 189. But this Court has repeatedly rejected the view that *Diehr* permits patents for well-known and conventional (in a word, old) applications of ineligible concepts. *See Mayo*, 132 S. Ct. at 1299 (*Diehr* "nowhere suggested that all these steps, or at least the combination of those steps, were in context obvious, already in use, or purely conventional"); *Alice*, 134 S. Ct. at 2355 n.3; *see also Flook*, 437 U.S. at 594; *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 132 (1948).

Diehr did not claim either the Arrhenius equation, which had "long been used to calculate the cure time in rubber-molding processes" (450 U.S. at 177 n.2), or a straightforward application of that equation using known processes. Rather, Diehr developed a completely new system and process to constantly measure the temperature inside a mold and then automatically feed those measurements to a computer to recalculate the cure time. *Id.* at 178. Diehr thus created a brand new "physical and chemi-

cal process for molding precision synthetic rubber." *Id.* at 184.

In upholding Diehr's patent, this Court explained that the mere fact that the process used the Arrhenius equation did not render it unpatentable. But neither did the fact that the equation was applied necessarily make it patentable. Rather, the analysis turned on "the way the additional steps of the process integrated the equation into the process as a whole." *Mayo*, 132 S. Ct. at 1298 (discussing *Diehr*). "In other words, the claims in *Diehr* were patent eligible because they improved an existing technological process, not because they were implemented on a computer" using the Arrhenius equation. *Alice*, 134 S. Ct. at 2358.

In addition to advancing a misreading of *Diehr* that has already been rejected twice by this Court, petitioner and several *amici* argue that claims must be analyzed "as a whole" under *Diehr*. *See*, *e.g.*, Pet. 18–19; Brief of 19 Law Professors at 3; Brief of Federal Circuit Bar Association at 8. But the law is clear on that point already. *See Mayo*, 132 S. Ct. at 1298; *Alice*, 134 S. Ct. at 2355 n.3; *see also* Post-*Alice* Guidelines at 1–2. And the courts below properly analyzed the asserted claims as a whole. *See* Pet. App. 13a; *id.* at 53a–54a.

Under *Diehr*, a patentable process may be comprised entirely of old elements arranged in a new, inventive way, but it may not simply apply old methods to a new discovery. The '540 patent does only the latter. *See* Pet. App. 13a, 54a.

b. The asserted claims broadly preempt use of basic and routine techniques of genetic analysis on

fetal DNA (cffDNA) circulating naturally in maternal blood. Whether they preempt *every* possible use of cffDNA is irrelevant under *Mayo*.

Petitioner argues that the "way to identify patents that claim an impermissible natural law or abstract idea is to determine whether they preempt *all* uses of the law or idea, or rather only particular applications." Pet. 14. This is a corollary of petitioner's proposed rule that any straightforward application (that is, anything less than an unvarnished claim to the ineligible concept and nothing more) suffices, and it is equally misguided. Complete preemption is not, and has never been, required to find that a patent claims ineligible subject-matter.

The rationale for Section 101's subject-matter "exclusionary principle" is "one of pre-emption." *Alice*, 134 S. Ct. at 2354. This Court has "repeatedly emphasized … a concern that patent law not inhibit further discovery by improperly tying up the future use of laws of nature." *Mayo*, 132 S. Ct. at 1301. Laws of nature "are 'the basic tools of scientific and technological work.'" *Ibid.* (quoting *Gottschalk v. Benson*, 409 U.S. 63, 67 (1972)). The eligibility rules address the "danger that the grant of patents that tie up [these basic tools] will inhibit future innovation premised upon them, a danger that becomes acute when a patented process amounts to no more than an instruction to 'apply the natural law.'" *Ibid.*

While preemption is an animating consideration for the Court's patent-eligibility jurisprudence, it has never been considered an independently necessary (or sufficient) basis for ineligibility. *See Mayo*, 132 S. Ct. at 1302 (the "basic underlying concern that

these patents tie up too much future use of laws of nature simply *reinforces* our conclusion that the processes described in the patents are not patent eligible") (emphasis added). That is because courts are "not institutionally well suited" to weigh "how much future innovation is foreclosed relative to the contribution of the inventor." *Id.* at 1303. Instead, the two-part *Mayo* framework embodies "a bright-line prohibition against patenting laws of nature, mathematical formulas and the like, which serves as a somewhat more easily administered proxy for the underlying 'building-block' concern." *Ibid.*

Claims need not preempt all uses of natural law to be ineligible. *See*, *e.g.*, *Flook*, 437 U.S. at 586 (finding ineligible claims that "cover a broad range of potential uses" but "do not, however, cover every conceivable application of the formula"). Indeed, if complete preemption were required, "purely conventional or obvious" post-solution activity or limiting use of the natural law to a particular area would be sufficient for patent-eligibility because these limitations serve to confine the claims to some extent. *But see Mayo*, 132 S. Ct. at 1298. Instead, patentability rules "cannot be circumvented by attempting to limit the use of the [ineligible concept] to a particular technological environment" or adding "insignificant postsolution activity." *Diehr*, 450 U.S. at 191.

The fundamental lesson of *Mayo* is that the patentee cannot monopolize laws of nature by using them in a conventional process, whether or not they might have other uses. Such non-inventive applications add nothing to the public good beyond the discovery of the law of nature; and the law of nature itself is in the public domain. *See Bilski*, 561 U.S. at

602 (ineligible concepts are "'part of the storehouse of knowledge of all men … free to all men and reserved exclusively to none'") (quoting *Funk Bros.*, 333 U.S. at 130). Patent rents cannot be collected on such information. *See Mayo*, 132 S. Ct. at 1302 (citing W. Landes & R. Posner, *The Economic Structure of Intellectual Property Law* 305–06 (2003)).

Yet that is precisely what Sequenom means to do. By laying claim to basic methods of analyzing cffDNA, the asserted claims purport to bar others from routine genetic analysis. *See* Pet. App. 56a–57a ("the effect of issuing the '540 patent was to wholly preempt all known methods of detecting cffDNA at that time"). Indeed, the claims are so broad as to cover future, presently unknown methods of "detecting" or "performing nucleic acid analysis" on cffDNA. *See* '540 Patent, cols. 23:66, 26:34 (C.A. App. A0050, A0051). And Sequenom has taken that very position with respect to Natera. *See* C.A. App. A1002 ¶ 6(b). As in *Mayo*, preemption analysis "simply reinforces" that the asserted claims are ineligible.

2. Petitioner and its *amici* also present a grab-bag of policy challenges to *Mayo*. All have been repeatedly raised and rejected by this Court.

a. Some *amici* contend that this Court's established standard for patent-eligibility—particularly in relation to diagnostic methods—violates international norms. *See generally* Brief of BioIndustry Association; Brief of Institute of Professional Representatives Before the European Patent Office; Brief of Profs. Minssen & Schwartz *et al*. *Mayo* rejected that very point. *See* 132 S. Ct. at 1305 (noting that methods of medical treatment are not patentable in most

of Western Europe); *see also* Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), art. 27.3(a) ("Members may also exclude from patentability … diagnostic, therapeutic and surgical methods for the treatment of humans or animals").

b. Some *amici* say that Section 101 should be made subservient to Sections 102, 103, and 112. *See* Brief of Dr. Chakrabarty at 13–19; *see generally* Brief of Eli Lilly & Co. *et al*. That, too, was rejected in *Mayo* over the recommendation of the U.S. government, among others. *See* 132 S. Ct. at 1304 ("to shift the patent-eligibility inquiry entirely to these later sections risks creating significantly greater legal uncertainty, while assuming that those sections can do work that they are not equipped to do").

c. Petitioner and some *amici* assert that the *Mayo* framework would invalidate a slew of "world-altering inventions" from yesteryear. *See* Pet. 27–29; Brief of Profs. Lefstin & Menell at 15–20. But this Court's recent decisions have carefully considered prior precedents. *See*, *e.g.*, *Mayo*, 132 S. Ct. at 1298–99; *Alice*, 134 S. Ct. at 2357–58. And petitioner's overblown parade of horribles should not obscure that its alternative approach would turn this Court's recent decisions on their heads. *See supra* 19–20.

d. Some *amici* contend that there should be a special carve-out to the *Mayo* framework for diagnostic methods. *See* Brief of JYANT Technologies, Inc. at 5–9; *see generally* Brief of Murgitroyd & Co.; Brief of Population Diagnostics, Inc. *et al.*; Brief of Coalition for 21st Century Medicine. Once again, this Court rejected that argument in *Mayo*. *See* 132

S. Ct. at 1305 ("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"). The Court wisely deferred to "the role of Congress in crafting more finely tailored rules where necessary." *Ibid.*

e. Finally, petitioner suggests that the sheer *number* of briefs filed indicates that this Court should grant review. Pet. 30. To be sure, eligibility affects many stakeholders in the patent system and past cases have drawn many briefs—on *all* sides of the issue. *See*, *e.g.*, *Alice*, 134 S. Ct. 2347 (52 *amici* briefs); *Mayo*, 132 S. Ct. 1289 (29 *amici* briefs). This Court remarked that it "do[es] not find this kind of difference of opinion surprising." 132 S. Ct. at 1305. On the contrary, the Court viewed these competing arguments as better resolved by the political branches. *Ibid.*; *see also Myriad*, 133 S. Ct. at 2119 n.7.

As this last point illustrates, not only have petitioner's and *amici*'s arguments all been rejected previously, but they are directed to the wrong organ of government. Congress is the appropriate institution to assess the charge that this Court's interpretation of Section 101 "suppresses technological progress." *See Kimble*, 135 S. Ct. at 2414. And if it finds that to be true, "Congress has the prerogative to determine the exact right response—choosing the policy fix, among many conceivable ones, that will optimally serve the public interest." *Ibid.*

3. Petitioner and its *amici* tell only one side of the patent policy story. Patent protection is a "two-edged sword" under which the "promise of exclusive rights provides monetary incentive that lead to crea-

tion, invention, and discovery," whilst "that very exclusivity can impede the flow of information that might permit, indeed spur, invention." *Mayo*, 132 S. Ct. at 1305. Overbroad patent protection in diagnostic research results in "a vast thicket of exclusive rights over the use of critical scientific data that must remain widely available if physicians are to provide sound medical care." *Ibid.* (internal quotation marks omitted).

The ramifications in this instance are profound: As a result of competition from Natera and Ariosa, pregnant women have more options for prenatal care at lower prices than they would under the monopolistic structure that Sequenom seeks. The beneficiaries of the decision below are mothers, families, and children. Reversal would benefit only Sequenom.

The peroration of the petition is that "[t]his Court should take this opportunity to … avoid a result neither it nor Congress could have intended." Pet. 36. That statement evidences a stunning failure to grasp the reality of the past decade's developments in patent-eligibility. This Court and Congress *absolutely* intended that claims like these should *not* be eligible for patenting. That is why this Court established the *Mayo* framework and why Congress has not intervened to disturb it. The Federal Circuit's decision is not just compelled by *Mayo*, but correct as a matter of Section 101 jurisprudence and patent policy. As a result, if the Court were to grant review in this case, it would only affirm the judgment.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

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