Nos. 2014-1139, 2014-1144

IN THE UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

ARIOSA DIAGNOSTICS, INC., NATERA, INC.,

Plaintiffs-Appellees,

DNA DIAGNOSTICS CENTER, INC.,

Counterclaim Defendant-Appellee,

v.

SEQUENOM, INC., and SEQUENOM CENTER FOR MODULAR MEDICINE, LLC,

Defendants-Appellants,

ISIS INNOVATION LIMITED,

Defendant.

Appeals from the United States District Court
For the Northern District of California
In Nos. 3:11-cv-06391-SI, 3:12-cv-00132-SI and 3:12-cv-00865-SI
The Honorable Susan Y. Illston

RESPONSE TO PETITION FOR REHEARING EN BANC

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CERTIFICATE OF INTEREST

Counsel for Appellee Natera, Inc. certifies as follows:

1. The full name of every party or amicus represented by us is:

Appellee Natera, Inc. ("Natera")

2. The name of the real party in interest represented by us is:

Not applicable.

3. All parent corporations and any public companies that own 10 percent or more of the stock of the parties represented by us are:

Natera: None.

4. The names of all law firms and the partners or associates that appeared for the party now represented by us in the trial court or agency or are expected to appear in this Court are:

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Dated: October 19, 2015

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Natera, Inc. respectfully submits that the petition for rehearing en banc filed by Sequenom, Inc. *et al.* should be denied.

INTRODUCTION

The panel decision, which declared ineligible patent claims reciting the application of routine and conventional methods to a newly discovered natural phenomenon, was required by recent Supreme Court precedent. *See Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289 (2012); *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107 (2013); *Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 134 S. Ct. 2347 (2014).

Under the controlling framework for patent-eligibility established by these cases, courts first determine whether the patent is drawn to a law of nature, natural phenomenon, or abstract idea; and, if so, then ask whether the claims add significantly more to that ineligible subject matter. *Alice*, 134 S. Ct. at 2355. The asserted claims are drawn to the discovery that cell-free fetal DNA (cffDNA) circulates organically in maternal plasma, which is an ineligible natural phenomenon under *Myriad*, 133 S. Ct. at 2111. The claims apply only routine analytical methods (such as amplification and detection) to that natural phenomenon, which is insufficient to confer patent-eligibility under *Mayo*, 132 S. Ct. at 1297–98. Accordingly, the panel correctly held that the asserted claims are not eligible for patenting under 35 U.S.C. § 101 as authoritatively construed by the Supreme Court.

Sequenom and its *amici* express concern that the panel decision will deter investment and innovation in the biotechnology industry. Yet, they do not address the deleterious effects of over-expansive patent monopolies covering natural phenomena, including the economic and social costs to the health care system in general, and pregnant women and their families in particular. Here, the asserted claims, if eligible, would block doctor and patient access to non-invasive fetal diagnostics. Indeed, that is the result Sequenom ultimately seeks in this litigation.

The doctrinal and policy objections raised by Sequenom and its *amici* are not new. The very same arguments were presented, often by the same *amici*, to the Supreme Court in the *Mayo-Myriad-Alice* trilogy. The Supreme Court rejected those arguments, expressly or implicitly, in adopting its eligibility framework. Since this Court does not sit to check the Supreme Court's work, the recycled objections to that framework now presented by Sequenom and its *amici* cannot support review or revision, much less reversal, of the panel decision. This Court could not rule the asserted claims patent-eligible without defying the Supreme Court's recent, and unanimous, directives in this area. Accordingly, Natera respectfully submits that the petition for rehearing should be denied.

ARGUMENT

Part I of Sequenom's petition argues that the panel's decision is inconsistent with *Mayo*, *Myriad*, and *Diamond v. Diehr*, 450 U.S. 175 (1981)—the only three

cases cited in the entire petition. Pet. 7–13. Sequenom's argument is wrong for reasons explained in the separate response by Ariosa Diagnostics, Inc. (which Natera adopts by reference). *Myriad* establishes that cffDNA itself is not patent-eligible; *Mayo* holds that a diagnostic method applying routine analytical methods to ineligible subject matter is not patent-eligible; and Sequenom's reading of *Diehr* was *rejected* in *Alice* (*see* 134 S. Ct. at 2355 n.3), which Sequenom does not cite.

Part II of Sequenom's petition warns breathlessly that the panel's decision poses an "existential threat" to the patent system. Pet. 13–15. Its *amici* sound variations on this theme, arguing that the panel's decision will have adverse effects on the biotechnology industry. Yet while Sequenom and its *amici* train their fire on the panel decision, their real disagreement is with the Supreme Court's decisions in *Mayo*, *Myriad*, and *Alice*. As explained below, the panel decision correctly implemented both the doctrinal framework and the policy balance laid down in this recent trilogy. Accordingly, rehearing is not warranted.

I. The Panel Faithfully Applied Binding Law Regarding Section 101.

Sequenom and its *amici* propose an approach to assessing patent-eligibility that cannot be reconciled with the framework articulated by the Supreme Court in *Mayo*, *Myriad*, and *Alice* in three significant respects. *First*, they contend that the asserted claims are eligible because the existence of cffDNA in maternal plasma was newly discovered; but the Supreme Court has held both that naturally occur-

ring DNA is unpatentable and that the novelty and non-obviousness requirements do not substitute for a proper eligibility analysis. *Myriad*, 133 S. Ct. at 2111; *Mayo*, 132 S. Ct. at 1303–04. *Second*, they insist that all specific applications of natural phenomena are patent-eligible; but the Supreme Court has unequivocally ruled that only *inventive* applications that add "significantly more" than the phenomenon itself are eligible. *Mayo*, 132 S. Ct. at 1294; *see also Alice*, 134 S. Ct. at 2355. *Third*, they suggest that only complete preemption should bar eligibility; but the Supreme Court has made clear that preemption concerns are the rationale, not the focus, of the inquiry. *Mayo*, 132 S. Ct. at 1303. These same arguments, often by the same entities, did not prevail in *Mayo*, *Myriad*, or *Alice*; nor can they here.

A. Subject-Matter Eligibility Is An Independent Requirement.

Sequenom concedes, as it must, that the discovery of cffDNA in maternal plasma is not *itself* patent-eligible. Pet. 2. The Supreme Court in *Myriad* held that naturally occurring genetic material is not patentable, and that holding applies fully here. 133 S. Ct. at 2111. Accordingly, the cffDNA discovery itself—regardless of how "groundbreaking" it might have been—does not confer patentability.

Sequenom and its *amici* contend, however, that the asserted claims are eligible because they recite a new method of using the discovery that cffDNA exists in maternal plasma. *See*, *e.g.*, Pet. 7–10; Novartis Br. 5; NYIPLA Br. 6. Similar arguments were presented to the Supreme Court in *Mayo* and *Alice*, to no avail. *See*,

e.g, Brief for Novartis Corp. as *Amicus Curiae* at 9, in *Mayo*, 2011 WL 5373697 (arguing that "[p]rocess claims involving [] laws of nature, natural phenomena, or abstract ideas are patent-eligible if the claims are to a new and useful application of those laws"); Brief for United States as *Amicus Curiae* at 32, in *Mayo*, 2011 WL 4040414 ("To hold that the method nevertheless falls outside Section 101 … would cast doubt on a host of patents for transformative medical processes that *are* novel and non-obvious"). This argument fares no better here.

Novelty and non-obviousness are necessary, but not sufficient, preconditions to patentability. They do not substitute for the independent (and antecedent) requirement of patent-eligibility. These analyses are inadequate for evaluating the independent requirement of patent-eligibility because "§§ 102 and 103 say nothing about treating laws of nature as if they were part of the prior art when applying those sections." *Mayo*, 132 S. Ct. at 1304. If novelty and non-obviousness were all that is required, patentees would be able to monopolize natural phenomena where, as here, the existence or utility of the phenomenon was not known or obvious before the discovery. *Id.* The proper Section 101 eligibility inquiry, by contrast, assumes that knowledge of the phenomenon is in the public domain, where it rightfully belongs. *See Parker v. Flook*, 437 U.S. 584, 594 (1978) (concluding that "once [the ineligible concept] is assumed to be within the prior art, the application, considered as a whole, contains no patentable invention"); *Diehr*, 450 U.S. at 204

(explaining that, under *Flook*, "the algorithm is treated for § 101 purposes as though it were part of the prior art; the claim is then examined to determine whether it discloses 'some other inventive concept'").

The facts of this case illustrate the wisdom of this dichotomy. Once it was discovered that maternal plasma contains cffDNA, the application of routine analytical methods to that plasma and its contents was a simple step. *Cf. Funk Brothers Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 132 (1948) ("The application of this newly-discovered natural principle to the problem of packaging inoculants may well have been an important commercial advance. But once nature's secret of the non-inhibitive quality of certain [bacteria] was discovered, the state of the art made the production of a mixed inoculant a simple step."); *see also Myriad*, 133 S. Ct. at 2117 (endorsing *Funk*). If such analytical methods were novel and non-obvious, they might be patentable; but they still would have to clear *Mayo*'s eligibility threshold. While Sequenom and *amici* would rather skip that requirement, Supreme Court precedent forecloses that option.

Some *amici* have previously gone so far as to ask the Supreme Court to "break from the *Funk Brothers*, *Flook*, and *Mayo* line of cases and focus attention on whether a claimed invention applies a discovery or invention to technological ends." Brief for Lefstin and Menell as *Amici Curiae* at 16, in *Alice*, 2014 WL 828045. They even cited the district court decision *in this case* to exemplify how

"revival of the inventive application test casts doubt on the patent-eligibility of many claims" where the "application was evident in light of patentee's discovery." *Id.* at 13. The Supreme Court, of course, declined this invitation and reaffirmed *Mayo* in *Alice*. This Court cannot grant "rehearing" of that decision, even though that is what Sequenom and its *amici* seek in suggesting that a new use of a natural phenomenon is alone sufficient for patent-eligibility.

B. Application Claims Must Provide An Inventive Concept.

Sequenom and its *amici* contend that the asserted claims recite an eligible *application* of the natural phenomenon that fetal DNA exists in maternal plasma. *See*, *e.g*, Pet. 11–13; BIO Br. 10; Leftsin Br. 5; IPO Br. 7. But the asserted claims amount to prototypical "apply it" instructions, which *Mayo* squarely forecloses. *Mayo*, 132 S. Ct. at 1294 ("one must do more than simply state the law of nature while adding the words 'apply it'"). All members of the panel recognized as much. *See* Panel Op. 11 ("The method at issue here amounts to a general instruction to doctors to apply routine, conventional techniques when seeking to detect cffDNA"); Concurring Op. 3 ("The Supreme Court's blanket dismissal of conventional post-solution steps leaves no room to distinguish *Mayo* from this case").

Amici have repeatedly argued to the Supreme Court that any application of a natural phenomenon should be patentable. *See*, *e.g*, Brief for BIO as *Amicus Curiae* at 25–26, in *Mayo*, 2011 WL 5373695 ("where a claimed process does include

tangible, transformative steps that limit the claim to a particular application … the claim is patent-eligible"); Brief for Lefstin as *Amicus Curiae* at 22, in *Myriad*, 2013 WL 1099166 (arguing that claims that provide a "specific mode of application" should be patent-eligible). And the Supreme Court has consistently rejected this "any application" argument.

The "any application" argument ignores the Supreme Court's repeated warning "against interpreting § 101 in ways that make patent eligibility depend simply on the draftsman's art." *Alice*, 134 S. Ct. at 2360 (quotation omitted). If any application of newly discovered natural phenomena were patentable, an artful draftsman could avoid the prohibition against patenting ineligible subject matter by adding "well-understood, routine, conventional activity, previously engaged in by those in the field" to the discovery. *Mayo*, 132 S. Ct. at 1299. Thus, in order to recite an eligible invention, the claims must "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.

To be sure, both *Mayo* and *Myriad* recognized that *some* applications of a natural phenomenon may be patent-eligible. *See* 132 S. Ct. at 1299 (explaining that eligible claims add steps or combinations of steps that are not "in context obvious, already in use, or purely conventional"); 133 S. Ct. at 2119 (explaining that

claims to "an innovative method of manipulating genes" would be patent-eligible). Sequenom sets up a false conflict between these statements and the panel decision by suggesting that the panel has ruled that *no* applications of the cffDNA phenomenon are eligible for patenting. Pet. 1, 12. But the panel did no such thing; rather, the panel only ruled that the *particular* applications recited *in the asserted claims* were not patent-eligible.

As the panel recognized, the asserted claims add nothing inventive to the natural phenomenon that cffDNA exists in maternal plasma, whether the steps are viewed alone or in combination. Indeed, the district court explained: "The 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." Dkt. 254 at 18; *see also* Panel Op. 11 ("Using methods like PCR to amplify and detect cffDNA was well-understood, routine, and conventional activity in 1997"). Because these steps viewed as a whole "add nothing significant beyond the sum of their parts taken separately," *see Mayo*, 132 S. Ct. at 1298, the asserted claims are ineligible.

Sequenom and its *amici* repeat the bromide that this analysis improperly "dissects" the claims into old and new elements. *See Diehr*, 450 U.S. at 189. But, in both *Mayo* and *Alice*, the Supreme Court rejected the view that *Diehr* permits

patenting of well-known and conventional (in a word, old) applications of ineligible concepts. *See Mayo*, 132 S. Ct. at 1298–99 (distinguishing *Diehr* on the basis that it "was nowhere suggested that all these steps, or at least the combination of all those steps, were in context obvious, already in use, or purely conventional"); *Alice*, 134 S. Ct. at 2355 n.3 (explaining that *Mayo* is "consistent with the general rule that patent claims must be considered as a whole") (quotation omitted). *Diehr* itself recognized that "insignificant post-solution activity will not transform an unpatentable principle into a patentable process." 450 U.S. at 191–92. Otherwise, the first discoverer of an ineligible phenomenon could monopolize it by asserting "apply it" claims utilizing conventional methodologies. The result that Sequenom seeks thus contradicts controlling Supreme Court precedent. *See* Pet. 1.

The patent's claim that routine methods of analysis may be applied to cffDNA in maternal plasma is only a restatement of the discovery that maternal plasma contains cffDNA. These methods inform skilled artisans of no more than disclosure of the ineligible discovery itself, and as such, the patent-in-suit would effectively confer a monopoly over the discovery that cffDNA exists in maternal plasma. Because that newly discovered phenomenon itself is not patent-eligible, as *Myriad* held, and because recitation of routine steps does not supply the inventive concept necessary to transform the discovery into an eligible invention, as *Mayo* held and *Alice* reiterated, the panel's decision that the asserted claims are ineligible

was dictated by Supreme Court precedent. The full Court could not reach a contrary conclusion without contravening the *Mayo*-*Myriad*-*Alice* trilogy.

C. Complete Preemption Is Not Required.

Another recurring objection from Sequenom and its *amici* is that the panel failed to analyze whether the asserted claims completely preempt all applications of the natural phenomenon. *See*, *e.g.*, Pet. 12; NYIPLA Br. 7; IPO Br. 9. Once again, this argument establishes only *amici*'s persistence in maintaining a position despite consistent rejection by the Supreme Court. *See*, *e.g.*, Brief for NYIPLA as *Amicus Curiae* at 4, in *Alice*, 2014 WL 458989 (arguing that claims should be eligible unless "the claim as a whole preempts the use of the abstract idea"); Brief for IPO as *Amicus Curiae* at 12, in *Myriad*, 2013 WL 1122810 (arguing that the claims were "specific and concrete and as such do not implicate the policy concerns enunciated by [the Supreme] Court" regarding preemption).

The policy concern "that drives [Section 101's] exclusionary principle is one of preemption." *Alice*, 134 S. Ct. at 2354. Laws of nature are "the basic tools of scientific and technological work." *Myriad*, 133 S. Ct. at 2116. Because "monopolization of those tools through the grant of a patent might tend to impede innovation more than it would tend to promote it," the Supreme Court has "repeatedly emphasized this … concern that patent law not inhibit further discovery by improperly tying up the future use of" these tools. *Mayo*, 132 S. Ct. at 1293, 1301.

Contrary to *amici*'s suggestion, however, *complete* preemption has never been required to hold claims ineligible. *See Flook*, 437 U.S. at 597; *Diehr*, 450 U.S. at 204; *Mayo*, 132 S. Ct. at 1303. Rather, "the underlying functional concern here is a *relative* one: how much future innovation is foreclosed relative to the contribution of the inventor." *Mayo*, 132 S. Ct. at 1303. In this case, the patent contributes no invention: the newly discovered natural phenomenon is in the public domain, and the asserted methods were well-known in the prior art. Thus, any preemption would be too much preemption.

This case would be a particularly bad vehicle for rethinking preemption analysis, even if that path were not foreclosed by *Mayo* and *Alice*, because the claims asserted here, in fact, broadly preempt all known methods for detecting cffDNA in maternal plasma and making diagnoses therefrom. This point was made vividly by the district court, which concluded that "the effect of issuing the '540 patent was to wholly preempt all known methods of detecting cffDNA at that time." Dkt. 254 at 19–20. This determination—which Sequenom does not challenge and its *amici* ignore—is more than sufficient to establish that the asserted claims are preemptive enough to preclude eligibility.

The patent here purports to block future innovators from applying standard tools of genetic analysis to cffDNA in maternal plasma. As in *Mayo*, preemption analysis "reinforces [the] conclusion that the processes described in the patent[] are

not patent eligible, while eliminating any temptation to depart from case law precedent." *Mayo*, 132 S. Ct. at 1302. The panel correctly held the claims ineligible.

II. The Panel Decision Is Consistent With The Policy Of Section 101.

Congress struck a delicate balance in Section 101, and the Supreme Court has maintained that balance in its recent trilogy of eligibility decisions. As with their doctrinal arguments, the policy arguments advanced by Sequenom and its *amici* reflect no more than their disagreement with the Supreme Court's precedents in this area. They are free to take up their differences (once again) with the Supreme Court, or they may use these arguments to urge legislative change, but under the extant statute as authoritatively construed by the Supreme Court, the panel could not—and this Court cannot—adopt their policy agenda.

The principal policy argument advanced, in varying guises, by Sequenom and its *amici* is that applying the Supreme Court's test for patent-eligibility to diagnostic methods could discourage investment and innovation in biotechnology. *See*, *e.g.*, Pet. 13–15; Novartis Br. 1–4; BIO Br. 7; Coalition Br. 1–2. This is a surpassingly odd argument given that *Mayo* involved diagnostic testing and *Myriad* involved genetic material; the panel did not *extend* the law to some new area, but rather *applied* recent cases to a similar invention in the same field.

Many of these same *amici* predicted the same dire consequences in *Mayo* and *Myriad*. *See*, *e.g.*, BIO as *Amicus Curiae* at 27, *supra*, in *Mayo* (ineligibility of

the *Mayo* patents would "pose[] grave risks to the biotechnology industry and the future of personalized medicine"); Novartis as *Amicus Curiae* at 8, *supra*, in *Mayo* (same "would endanger the pharmaceutical and biotechnological industries, patients throughout the United States, and the American economy"); Brief for Coalition *et al.* as *Amici Curiae* at 7, in *Mayo*, 2011 WL 5439047 ("it would be a devastating blow to the promise of personalized medicine to compromise patent protection for this industry"); Brief for BIO as *Amicus Curiae* at 35, in *Myriad*, 2013 WL 1209142 ("the list of potentially life-enhancing therapeutics and diagnostics that die in the pipeline might never be known").

The Supreme Court, however, declined to declare "whether, from a policy perspective, increased protection for discoveries of diagnostic laws of nature is desirable." *Mayo*, 132 S. Ct. at 1305. Rather, it held that "patent law's general rules must govern inventive activity in many different fields of human endeavor, with the result that the practical effects of rules that reflect a general effort to balance these considerations may differ from one field to another." *Id.* at 1303. As the Court later made crystal clear, the same test for subject-matter eligibility governs all "patents that claim the 'building blocks' of human ingenuity." *Alice*, 134 S. Ct. at 2354 (quoting *Mayo*); *see also Le Roy v. Tatham*, 55 U.S. (14 How.) 156, 175 (1853) ("The same [rationale for excluding a patent on steam power] may be said of electricity, and of any other power in nature, which is alike open to all").

Moreover, *amici* tell only half the story when it comes to the interests at stake here. Patent protection is a "two-edged sword" under which the "promise of exclusive rights provides monetary incentive that lead to creation, 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 would result 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." *Id.* (internal quotation omitted). And, here, it would mean that women have fewer and more expensive options in prenatal care. In view of such competing interests, the Supreme Court has deferred to "the role of Congress in crafting more finely tailored rules where necessary." *Id.* This Court should—and must—follow this guidance.

CONCLUSION

At bottom, Sequenom and its *amici* disagree with the Supreme Court's jurisprudence on patent-eligibility. This Court, however, is constrained to follow precedent. The panel faithfully applied *Mayo*, *Myriad*, and *Alice* to conclude that the asserted claims are ineligible for patenting. The very same doctrinal and policy arguments that the Supreme Court has rejected in case after case cannot lead to a determination of eligibility here. The petition for rehearing should be denied.

Dated: October 19, 2015

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CERTIFICATE OF SERVICE

I hereby certify that on October 19, 2015, I caused a copy of the foregoing to be served on counsel of record via CM/ECF.

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