No. 15-___

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

PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

In 1996, two doctors discovered cell-free fetal DNA (cffDNA) circulating in maternal plasma. They used that discovery to invent a test for detecting fetal genetic conditions in early pregnancy that avoided dangerous, invasive techniques. Their patent teaches technicians to take a maternal blood sample, keep the non-cellular portion (which was "previously discarded as medical waste"), amplify the genetic material within (which they alone knew about), and identify paternally inherited sequences as a means of distinguishing fetal and maternal DNA. Notably, this method does not preempt other demonstrated uses of cffDNA.

The Federal Circuit "agree[d]" that this invention "combined and utilized man-made tools of biotechnology in a new way that revolutionized prenatal care." Pet.App. 18a. But it still held that *Mayo Collaborative Servs. v. Prometheus Labs.*, 132 S. Ct. 1289 (2012), makes all such inventions patent-ineligible as a matter of law if their new combination involves only a "natural phenomenon" and techniques that were "routine" or "conventional" on their own. Multiple judges wrote separately below to explain that while this result was probably not intended by *Mayo*, it controlled, and only this Court could now "clarify" *Mayo*'s reach to prevent a "crisis" in life-science innovation.

The Question Presented is:

Whether a novel method is patent-eligible where: (1) a researcher is the first to discover a natural phenomenon; (2) that unique knowledge motivates him to apply a new combination of known techniques to that discovery; and (3) he thereby achieves a previously impossible result without preempting other uses of the discovery?

CORPORATE DISCLOSURE STATEMENT

Pursuant to Rule 29.6 of this Court's Rules, petitioner Sequenom, Inc. states that it has no parent company, and no publicly held corporation owns 10% or more of its stock.

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PETITION FOR A WRIT OF CERTIORARI

Petitioner respectfully seeks a writ of certiorari to review the judgment of the United States Court of Appeals for the Federal Circuit.

OPINIONS BELOW

The opinions below (Pet.App. 1a) are published at 788 F.3d 1371. The opinions respecting rehearing *en banc* (Pet.App. 70a) are published at 809 F.3d 1282. The district court's opinion (Pet.App. 25a) is published at 19 F. Supp. 3d 938.

JURISDICTION

The Federal Circuit entered judgment on June 12, 2015 and denied rehearing on December 2, 2015. Pet.App. 74a. The Chief Justice extended this petition's filing date to April 1, 2016, No. 15A871. The Court has jurisdiction under 28 U.S.C. §1254(1).

STATEMENT

1. In the 1990s, researchers were searching for non-invasive tests that might detect fetal genetic features early in pregnancy—including, most importantly, substantial abnormalities—without using dangerous techniques like amniocentesis. They knew some "nucleated cells" (that is, cells with their DNA core intact) passed from fetus to mother, and believed that finding even one such cell might permit diagnoses through analysis of the fetal DNA inside. *See* U.S. Patent No. 6,258,540 at 1:26-31. Researchers were thus meticulously combing the *cellular* portion of maternal blood for fetal cells, and routinely discarded the rest of their maternal blood samples—the plasma and serum—as waste. Pet.App. 3a; Patent 1:51-55.

Drs. Dennis Lo and James Wainscoat revolutionized this field. Pet.App. 18a. They discovered that "cell-free" fetal DNA (cffDNA) was circulating in pregnant women's plasma in surprising concentrations. *Id.* 13a. Their experiments further determined that relatively new genetic-research tools like "polymerase chain reaction" (PCR) would allow them to reliably detect that cffDNA in a sample otherwise dominated by nearly identical maternal DNA. This was a profound breakthrough; their *Lancet* article describing it has since been cited over a thousand times. *Id*. 18a.

This discovery, however, replaced one scientific problem with another. Researchers had been searching for a fetal-cell-shaped needle in a billions-of-maternal-cells-sized haystack, because that cell could yield a pure fetal sample. Lo and Wainscoat now had a ready source of fetal DNA, but it was "cell-free" fetal DNA mixed up with cell-free maternal DNA that would confound their diagnostic testing.

Lo and Wainscoat devised a solution that turned their discovery into a practical, non-invasive, early-prenatal test. Pet.App. 3a. They realized that, by identifying genetic fragments containing *paternally inherited* sequences the mother did not share, they could reliably identify fetal DNA, which would in turn allow them to diagnose certain fetal genetic conditions. For example, they recognized that fetal aneuploidies like Down Syndrome would cause predictable variations in the amount of identifiably fetal DNA associated with certain chromosomes in a given

maternal blood sample. Pet.App. 4a; Pet.App. 23a (Linn, J.); Patent 3:44-52.[1] In sum, these inventors had devised an early-prenatal genetic test whose key steps—never previously combined in this way—were to take a maternal blood sample, keep only the long-discarded *non*-cellular fraction, amplify the cell-free DNA only they had discovered therein, and search for paternally inherited sequences whose presence or quantity indicated diagnostically relevant conditions.

The '540 patent teaches this invention. Claim 1 teaches that the critical steps are amplification and detection of "paternally inherited nucleic acid[s] of fetal origin" in a "maternal serum or plasma sample." Patent 23:60-67. Claim 21 situates these steps within a larger diagnostic method that up-ended conventional practice:

> 21. 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 non-cellular fraction;
>
> (iii) detecting the presence of nucleic acid of fetal origin in the non-cellular fraction according to the method of claim 1 [that is, by (i) amplifying and (ii) detecting paternally inherited nucleic acids, and];

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[1] "Aneuploidies" are disorders involving the wrong *number* of chromosomes, and they affect the expected amount of cffDNA from those chromosomes in a given sample by altering the relative amount of source material.

(iv) providing a diagnosis based on the presence and/or quantity and/or sequence of the fetal nucleic acid.

Patent 26:4-14.

Beyond this particularized method, the patent discloses several even-more-concrete diagnostic tests. For example, in addition to the aneuploidy-detection case above, it explains how to use the method to determine fetal gender by searching for Y-chromosome material in maternal plasma (a "particularly useful" application, because mothers necessarily lack Y-chromosomes). *See* Patent 2:49-51. This test, separately claimed through dependent Claims 5 and 12, Patent 25:1-3, 25:18-20, is now often used to determine fetal gender using nothing more than a blood sample from a ten-week-pregnant mother.

The patent also describes how to use its method to achieve a breakthrough in avoiding RhD hemolytic disease. Briefly, when RhD-negative women carry RhD-positive fetuses (who inherit the RhD blood-antigen gene from their fathers), the mother's antibodies can attack the fetus's blood, leading to fetal illness, and even death. Despite possible complications, the main previous option was indiscriminately treating RhD-negative women just in case the fetus was positive. But because (like the Y-chromosome) the RhD gene is necessarily absent in the RhD-negative mother, the patent's method works perfectly for testing the fetus's RhD status. Patent 2:62-3:3. This test is separately claimed through dependent Claims 8 and 11; Claim 9 covers using the same method for other blood-antigen tests. Patent 25:8-12, 25:16-17.

In the Federal Circuit's words, this "invention, commercialized by [petitioner] Sequenom as its MaterniT21 test, created an alternative for prenatal diagnosis of fetal DNA that avoids the risks of widely-used techniques." Pet.App. 3a. This, if anything, undersells the benefit: Previously, accurate early-prenatal diagnosis of such conditions required dangerous techniques like amniocentesis, carrying a material risk of heartbreaking miscarriage or fetal injuries. These inventors replaced a long needle invading the amniotic sac—and a terrifying moment for expecting parents—with a simple and safe blood draw, solving a problem that frustrated their field for years.

Notably, Lo and Wainscoat did not try to patent cffDNA itself, nor preempt all uses of it by others. *Id.* In fact, peer-reviewed research in the record below has demonstrated practical uses for cffDNA that do not (i) fractionate maternal blood, (ii) amplify DNA in the sample; or (iii) detect paternally inherited DNA at all. Pet.App. 55a-56a. And the patent does not preempt such practices because it nowhere claims the use of the cffDNA itself. Instead, it is infringed only if *all* its steps are practiced in combination.

Indeed, what was so novel about the '540 patent was precisely that combination of techniques it first disclosed. Researchers in the 1990s surely knew how to fractionate blood, amplify DNA, look for genetic sequences, and make diagnoses from them. But it is undisputed that no one was previously practicing these steps in the '540 patent's combination because, evocatively, they were discarding the relevant materials as waste. Pet.App. 3a. In short, the '540 patent's *combined* steps were anything but "conventional" because the "convention" was the opposite.

2. Petitioner Sequenom exclusively licensed the '540 patent and invested enormously in bringing it to market as a viable medical test. As the pioneer, Sequenom spent heavily on clinically validating the method, obtaining regulatory approvals, and educating clinicians. *See* N.D. Cal. #11-6391, Dkt. 36, ¶¶15-21, 36-43. When MateriT21 launched in late 2011, Sequenom had already spent about $70 million developing it, *id.* ¶41, and expected to double that in 2012. And, of course, it committed substantial royalties to license the technology.

Respondents launched their price-competing products shortly thereafter, targeting the same markets and affirmatively trying to free-ride on Sequenom's investment. *Id.* ¶¶45, 54. Respondent Ariosa candidly told its investors that it would "draft on Sequenom's efforts to go after the same geographies," N.D. Cal. #11-6391, Dkt. 114, Ex. 16, and its Chairman testified about Ariosa's "strategies of being a fast follower and letting your competitor educate the market around advantages to cell-free DNA," Dkt. 114, Ex. 3, pp.117-18. This predictably caused "price and market erosion," *Aria Diagnostics v. Sequenom*, 726 F.3d 1296, 1304-05 (Fed. Cir. 2013), and so Sequenom has yet to achieve profitability on its investment.

3. As a heavily-invested practicing entity, Sequenom refused to license competitors. Respondents sued petitioner seeking a declaratory judgment; Sequenom counterclaimed and sought a preliminary injunction. After construing the '540 patent's claims, the district court denied the injunction. But, in an initial appeal, the Federal Circuit corrected the district court's claim constructions, found significant

risks of irreparable harm to Sequenom's patent-protected product, and so vacated and remanded "with additional guidance" regarding an injunction. *See id.* On remand, however, the district court invalidated the patent under Section 101. Pet.App. 68a.

This time, a different Federal Circuit panel affirmed (with a remarkable concurrence from Judge Linn, *see infra* p.8-9). The majority concluded that the '540 patent fails the two-step test this Court first developed in *Mayo* for when a method patent impermissibly claims a natural law or phenomenon. First, it said, the claims "are directed to a patent-ineligible concept" because the "method begins and ends with a natural phenomenon" (*i.e.*, cffDNA). Pet.App. 9a-11a. Second, it said, the claimed method did not "'transform' the claimed naturally occurring phenomenon into a patent-eligible application." *Id.* 12a. The core reasoning was that, "[f]or process claims that encompass natural phenomen[a], the process steps … must be new and useful." *Id.* And because researchers already knew how to accomplish the *individual* steps of (1) fractionating blood; (2) amplifying DNA; and (3) detecting characteristics in amplified DNA, the combined method impermissibly added only "well-understood, routine, and conventional activity" to the natural phenomenon Lo and Wainscoat had discovered—rendering it patent-ineligible as a matter of law. *Id.* 13a.

The majority then rejected "Sequenom's remaining argument[]" that "before the '540 patent, *no one* was using the plasma or serum of pregnant mothers to amplify and detect paternally-inherited cffDNA." Pet.App. 18a. This argument, it said, "implies that the inventive concept lies in the discovery of cffDNA

in plasma or serum." *Id.* The majority's evident rationale was that, because the discovery of cffDNA in maternal plasma directly motivated the '540 patent's new combination of known techniques, that invention merely reflected that patent-ineligible discovery itself. According to the majority, that rendered the patent ineligible under Section 101 as a matter of law, even though it "agree[d]" that the patent "*combined* and utilized man-made tools of biotechnology *in a new way* that revolutionized prenatal care." *Id.* (emphasis added).

Finally, without disputing that alternative inventions not preempted by the '540 patent had put cffDNA to practical use, *supra* p.5, the majority simply waived this critical fact away. Pet.App. 17a. It acknowledged that, under longstanding Section 101 precedent, "the principle of preemption is the basis for the judicial exceptions to patentability." *Id.* But it regarded preemption as a one-way ratchet: It "may signal patent ineligible subject matter," but "the absence of complete preemption does not demonstrate patent eligibility." *Id.* Indeed, the panel held that, once a court concludes that the claims involve only natural phenomena and "conventional" techniques, "preemption concerns are fully addressed and made moot." *Id.*

Judge Linn wrote separately, explaining in very direct terms that he joined "only because [he was] bound by the sweeping language of the test set out in *Mayo*." Pet.App. 20a. In his view, "[t]his case represents the consequence—perhaps unintended—of that broad language in excluding a meritorious invention from the patent protection it deserves and should have been entitled to retain." *Id*. 20a-21a. He noted

that the patent appeared eligible under *Diamond v. Diehr*, 450 U.S. 175, 188 (1981), which *Mayo* reaffirmed and the majority did not discuss. Pet.App. 21a-22a. Nonetheless, he concluded that certain language in *Mayo*, though unnecessary to its holding, seemed to compel a finding of ineligibility, *id.* 22a—even though "Sequenom's invention is nothing like the invention at issue in *Mayo*," and there was "no reason, in policy or statute" to invalidate it. *Id.* 24a.

Petitioner sought rehearing *en banc*, supported by twelve *amicus* briefs, but it was denied with three further opinions. Building on Judge Linn's concurrence, their basic thrust was that, despite this patent's inventive merit, the case would have to be resolved in this Court because *Mayo* tied the Federal Circuit's hands. For example, Judge Lourie, joined by Judge Moore, explained that the patent's claims merely "rely on or operate by, but do not recite, a natural phenomenon," Pet.App. 79a, and that barring such inventions under Section 101 would mean that "nothing in the physical universe would be patent-eligible," *id.* 77a. He emphasized that this patent claimed "innovative and practical *uses* for" cffDNA through methods that, as a whole, were "*not* routine and conventional," and did not foreclose "other methods of prenatal diagnostic testing using cffDNA." *Id.* 81a. He thus concluded that it was "unsound to have a rule that takes inventions of this nature out of the realm of patent-eligibility on grounds that they only claim a natural phenomenon plus conventional steps." *Id.* 82a. But because, "applying *Mayo*, we are unfortunately obliged to divorce the additional steps from the asserted natural phenomenon," he agreed the court was bound to affirm. *Id.* 81a.

Judge Dyk made similar points. He highlighted "a problem with *Mayo* insofar as it concludes that inventive concept cannot come from discovering something new in nature," especially "in the life sciences, where development of useful new diagnostic and therapeutic methods is driven by investigation of complex biological systems." Pet.App. 89a-90a. He worried that "*Mayo* may not be entirely consistent with the Supreme Court's decision in" *Association for Molecular Pathology v. Myriad Genetics*, 133 S. Ct. 2107, 2112-13 (2013). Pet.App. 90a. And, critically, while he emphasized his belief that "some further illumination as to the scope of *Mayo* would be beneficial," he concluded that, given "the language of *Mayo* … any further guidance *must come from the Supreme Court*, not this court." *Id*. 84a (emphasis added).

Judge Newman would have granted rehearing. She noted that her colleagues all seemed to "agree … that this case is wrongly decided," Pet.App. 100a, because the "diagnostic method here is novel and unforeseen, and is of profound public benefit." *Id.* 102a. But she did not "share the view that this incorrect decision is required by Supreme Court precedent," *id.* 100a, reasoning that the distinction between patenting "new applications" of knowledge and patenting knowledge itself could have allowed the Federal Circuit to save this meritorious invention. *Id.*

REASONS FOR GRANTING THE WRIT

This is as straightforward a certiorari candidate as any patent case can be. It is manifestly important: A host of judges and *amici* have stressed that the result below is untenable—invalidating previously irreproachable inventions and precipitating what Judge Lourie called "a crisis of patent law and medi-

cal innovation." Pet.App. 78a. Those judges have likewise emphasized that the only clarifications that can avoid such results "must come from the Supreme Court." Pet.App. 84a (Dyk, J.); Pet.App. 20a-21a (Linn, J.). And this is the vehicle this Court needs to provide that clarification: Every opinion below agrees that this case tests *Mayo*'s uncertain limits by invalidating an otherwise *plainly* meritorious invention. As *Mayo*'s author has acknowledged, that case could only "sketch an outer shell" of its test, Arg. Tr. 28, *Alice v. CLS Bank Int'l*, 134 S. Ct. 2347 (2014) (No. 13-298) (Breyer, J.), partly because it was hard to "figure out much … to go beyond … an obvious case." *Id.* 10-11. Here, unlike *Mayo*, every intuition points towards patent-eligibility. And yet the Federal Circuit felt compelled by *Mayo* to condemn this meritorious patent—and, *a fortiori*, the patents underlying an entire, vital field of American healthcare innovation. If, as several judges below observed, that cannot be what *Mayo* intended, this is precisely the case in which this Court needs to say so.

The case itself shows why. Sequenom invested enormously in developing and validating a recognized "breakthrough" for clinical use, only to see that investment radically undermined by fast-following competitors trading on an uncertain legal doctrine. As several judges below explained, even they find it hard to reconcile *Mayo*'s test with other language in the opinion, Pet.App. 23a-24a (Linn, J.), let alone other language in other opinions, Pet.App. 90a-91a (Dyk, J.). It is infinitely harder for businesses to decipher where the doctrine now stands, especially because it (now) seems divorced from intuitions about patent-eligibility for "revolutionary" inventions like

this one. Right now, Section 101 doctrine lacks any discernable limits, and so no company can trust in the patent system when deciding whether to invest in bringing an invention to market. This issue has become particularly life-threatening to life-science innovators. Pet.App. 77a-78a (Lourie, J.); Pet.App. 90a (Dyk, J.). And so unless this Court clarifies some limits on Section 101, a doctrine that was meant to be a narrow exception will become the rule by default in at least this industry, and likely beyond.

This is a perfect case in which to provide that clarification; here, the Court can confirm the eligibility of inventions like the '540 patent by merely making explicit a distinction the cases already contain. In particular, the Court can brighten the line between a method that merely adds a new discovery to what practitioners were already doing, *see Mayo*, 132 S. Ct. at 1299, and one that, by the Federal Circuit's own description, "*combine[s]* … man-made tools … *in a new way*" to achieve a revolutionary result. Pet.App. 18a (emphasis added). Put otherwise, this case allows the Court to emphasize that a *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 phenomenon. That is precisely why, in *Mayo* itself, this Court said that discovering a "new way of using an existing drug" should remain patent-eligible, even though such an invention only combines a newly discovered natural phenomenon with otherwise known substances and techniques. 132 S. Ct. at 1302. And it is why, in *Myriad*, this Court endorsed Judge Bryson's view that "the first party with knowledge of [a natural phenomenon]" should be "in an excellent

position to claim applications of that knowledge." 133 S. Ct. 2120. That, of course, is an excellent description of these inventors: They were "the first parties with knowledge of" cffDNA, and should have been "in an excellent position to claim applications of that knowledge"—like previously impossible blood tests for fetal gender or Down Syndrome—by teaching others the new combination of available techniques that would enable such revolutionary results.

Unfortunately, the Federal Circuit reached the opposite conclusion by adopting a reading of *Mayo* so broad that it demands this Court's intervention. Indeed, the rote version of *Mayo*'s two-part test endorsed below invalidates any method patent combining a natural discovery with "conventional" techniques—even if those techniques are admittedly "new" in combination and that new combination admittedly does not preempt all uses of the discovered phenomenon. Pet.App. 13a. Recognizing that "all inventions at some level embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas," *Mayo* promises that its test is not meant to "eviscerate patent law." 132 S. Ct. at 1293. But the Federal Circuit's version of *Mayo*'s test does exactly that—gutting protections for a host of meritorious inventions, especially in the life-sciences, where almost all inventions come from combining existing techniques in new ways to capitalize on new insights from basic research. Pet.App. 84a (Dyk, J.).

Indeed, the Federal Circuit's version of *Mayo* undermines just about any biomedical breakthrough you can conceive. Vaccines? They combine the natural fact of immune response with known methods of drug administration. Even for previously unstudied

diseases like Zika? Yes. Aspirin—perhaps the world's most successful patented medicine? It combined a natural plant product with basic chemistry techniques. Gene amplification by PCR—the Nobel-winning method that respondent Ariosa's parent (Roche) has earned billions licensing? By its inventor's description, a simple idea that "lay unrecognized for more than 15 years after *all the elements for its implementation were available*." Mullis, *The Unusual Origin of the Polymerase Chain Reaction,* SCIENTIFIC AMERICAN, Apr. 1990, at 56 (emphasis added). If combining a new insight about the natural world with "available elements" to achieve extraordinary new results is unpatentable subject matter—as is now U.S. law absent this Court's intervention—no such breakthroughs are patent-eligible. That means anyone who would invest in making, validating, or commercializing inventions like these for human medical use must invite others along for the free ride, with predictably unfortunate results.

Even worse, the decision below exacerbates this confusion by jettisoning the one reliable compass this Court had identified for Section 101 cases—the patent's "preemptive" scope. As *Alice* made clear, preemption is "the concern that drives" the Section 101 exceptions, 134 S. Ct. at 2354-55, and so 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. But the Federal Circuit expressly held below that such concerns are "made moot" whenever a legalistic application of *Mayo*'s test identifies only "routine" or "conventional" techniques in a patent that builds on a natural phenomenon or

law. Pet.App. 17a. That unbounded application of *Mayo*'s "outer shell" leads directly to untenable and unintended results like those below. It is undisputed here that the '540 patent does not preempt *multiple*, demonstrated uses of cffDNA. An approach to Section 101 that reduces such a critical fact to a "moot" afterthought is too badly broken to let lie. And this case is a perfect vehicle for fixing it.

Ultimately, it is clear that the Federal Circuit has turned *Mayo*'s somewhat ambiguous language into a "crisis of patent law and medical innovation," Pet.App. 78a (Lourie, J.), while affirmatively disclaiming any ability to stop it. This case thus requires this Court's review, while also providing an ideal vehicle through which to provide some clarity in an area of law that badly needs it.

I. The Decision Below Has Dangerously Overextended *Mayo*.

A. This Court now needs to clarify that its precedents permit patenting meritorious inventions like this one.

This Court's Section 101 cases recognize a deep jurisprudential tension. On the one hand, patents should not preempt the fundamental building-blocks of human ingenuity. Thus, abstract ideas (like "hedging risk"), natural phenomena (like actual human DNA), and natural laws (like $E=mc^2$) are ineligible for patenting. On the other hand, as this Court has recognized, all inventions at bottom "reflect, rest upon, or apply" those kinds of discoveries, *Mayo*, 132 S. Ct. at 1293. Accordingly, the law must distinguish between eligible *applications* of fundamental discov-

eries, and ineligible patents on discoveries themselves. *Id.* at 1294.

That limitation on Section 101 jurisprudence is critical because the categories above are exceptions to a broad statute that, on its face, allows patents on "anything under the sun that is made by man." *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980). The Patent Act provides that "[w]hoever invents *or discovers* any new and useful process … may obtain a patent." 35 U.S.C. §101 (emphasis added). Accordingly, as the Court has acknowledged, the Section 101 exceptions are judicial carve-outs whose only purpose is to ensure that patents do not "tend to impede innovation more than [they] would tend to promote it." *Mayo*, 132 S. Ct. at 1293. The Court should thus be very skeptical about using Section 101 precedents to invalidate patents on apparently meritorious inventions—especially where those patents serve the Act's policies by encouraging those who achieve previously impossible results to invest in bringing them to market. Put otherwise, those who (like respondents here) invoke Section 101 against a recognized "breakthrough" that solved long-standing practical problems in their field should have a very steep hill to climb. *See Microsoft Corp. v. i4i Ltd.*, 131 S. Ct. 2238, 2242 (2011) (statute presumes patents valid, puts burden on challenger, and requires clear evidence for invalidation).

But while practical applications like the invention here should be easily eligible, this Court has struggled to articulate a pragmatic legal rule that allows it to distinguish this invention and others like it from far-less-meritorious patents. That is because, as the Court recognized in *Mayo*, it cannot allow cre-

ative drafters to circumvent Section 101 by "simply stat[ing] the law of nature while adding the words 'apply it.'" 132 S. Ct. at 1294. The Court in *Mayo* and *Alice* thus sketched a two-part test that first asks if the patent incorporates one of the excepted categories (like a natural law) and, if so, whether the "patent claims add *enough* … to allow the processes they describe to qualify as patent-eligible processes that *apply* natural laws." *Id.* at 1297. If the "additional steps consist of well-understood, routine, conventional activity already engaged in by the scientific community," both individually and "as an ordered combination," the method is patent-ineligible. *Id.* at 1298.

It should be obvious that—as *Mayo*'s author has acknowledged—this two-part "test" was not intended to serve as a fully developed legal rule that could be easily or mechanistically applied to all future cases. Instead, *Mayo* had merely "sketched the outer shell of the content" for its test in an "obvious case," requiring careful elucidation through further examples. *See supra* p.11. That is partly why it is so critical to review cases like this one, which test *Mayo*'s uncertain boundaries with seemingly meritorious inventions (rather than "obviously" problematic patents like the one in *Mayo* itself). But it also recommends looking to the several concrete examples this Court has invoked—in and after *Mayo*—to see why an invention like this one need not be found ineligible.

1. This Court's cases already demonstrate why this and similar inventions are patent-eligible.

As explained below, principles and examples described in this Court's precedents disclose an im-

portant limitation on *Mayo* that the Federal Circuit missed and this Court should reinforce through this vehicle. That limitation is that even if the techniques in a method motivated by a natural law are known separately, they can be unconventional "as an ordered *combination*"—that is, the method might not involve "conventional activity already engaged in by the scientific community … when viewed *as a whole*." 132 S. Ct. at 1298 (emphases added).

Begin with *Diehr*, which *Mayo* reaffirmed but the panel below ignored. *Diehr* considered a patent for a method of curing rubber that relied on an unpatentable mathematical equation and a computer to constantly measure the temperature inside a rubber mold and recalculate curing time using that equation. Each separate technique was already known and practiced, but not the combination. Critically, *Diehr* explained that "[i]t is inappropriate to dissect the claims into old and new elements and then to ignore the presence of the old elements," and that "[t]his is particularly true in a process claim because a new combination of steps in a process may be patentable even though all the constituents of the combination were well known and in common use before the combination was made." 450 U.S. at 188.

Diehr emphasized that the patent at issue did "not seek to pre-empt the use of th[e] [unpatentable] equation," but "[r]ather … only to foreclose from others the use of that equation in conjunction with all of the other steps in the[] claimed process." *Id.* at 187. This emphasis that, "[i]n determining the eligibility of respondents' claim[s] … under §101, their claims must be considered as a whole," *id.* at 188, is what the Federal Circuit missed below. Indeed, the Feder-

al Circuit's (mis)reading of this Court's decisions does in fact "dissect the claims into old and new elements" and then ignore both the new discovery and any old elements, thereby invalidating the kind of "new combination of steps" that *Diehr* specifically holds patent-eligible.

Mayo reaffirmed *Diehr* on this very point. In holding that the claims in *Mayo* were unlike those in *Diehr*, the Court stressed that the three method steps involved, considered together, merely specified "well-understood, routine, conventional activity *previously engaged in by those in the field*," 132 S. Ct. at 1299 (emphasis added), and that "[t]he process in *Diehr* was not so characterized," *id.* As Judge Linn explained, the "'conventional activities' in *Mayo* were the very steps that doctors were already doing [in combination]—administering the drug at issue, measuring metabolite levels, and adjusting dosing based on the[m]." Pet.App. 22a; *see* Pet.App. 89a-90a (Dyk, J.). Accordingly, the addition of the unpatentable natural law in *Mayo* did not change anything beyond informing doctors of the law itself.

By contrast, the '540 patent's method is just like *Diehr*'s and not at all like *Mayo*'s: The phenomenon Lo and Wainscoat discovered motivated them to teach a new method that *no one* was practicing, and whose combined steps were in fact the opposite of a "conventional" approach that had previously treated the key materials as waste. Pet.App. 3a; *see id.* 18a (agreeing patent "combined" existing "tools of biotechnology in a new way").

A second, no-less-critical example comes from *Mayo* itself. There, the Court intimated that "a new way of using an existing drug" would be patent-

eligible. Pet.App. 24a (Linn, J.) (quoting *Mayo*, 132 S. Ct. at 1302). But that can be true only if patent-eligibility extends to new combinations of routine steps that would be self-evident to researchers who knew about a new discovery: After all, the drug is known, the means of administering it are known, and the only new insight is the natural law that the drug treats a disease no one previously knew it treated. So, unless the "inventive concept" that *Mayo* requires can be found in combining existing techniques in a new way to capitalize on a newly discovered natural phenomenon, *Mayo* itself is wrong about the patent-eligibility of new uses for existing drugs. Conversely, if *Mayo* (like *Diehr*) is better understood to permit patenting unconventional *combinations* of known techniques and materials to accomplish new results that capitalize on newly discovered natural phenomena, the invention at issue here is patent-eligible, because that description fits it to a T.

Finally, there is this Court's endorsement of Judge Bryson's view in *Myriad* that, "as the first party with knowledge of [a natural phenomenon], Myriad was in an excellent position to claim applications of that knowledge," even though it could not claim the knowledge or phenomenon itself. 133 S. Ct. 2120. Again, this proposition would be false if the law forecloses patenting new combinations of already-known steps motivated by a patentee's unique discovery, as the Federal Circuit believed. In that case, the "first party with knowledge" of a natural phenomenon would be 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.

This case is thus a perfect vehicle to clarify *Mayo* and its limits. Correctly understood, *Mayo* does not prohibit claiming new methods assembled by combining previously known techniques even when those methods are motivated by or incorporate new insights into nature and its laws. Instead, it prohibits taking a series of steps "already engaged in by the scientific community" and claiming them for oneself by merely adding new *knowledge* of a natural law (like the correct correlations between thiopurine metabolite levels and drug dosages). *See* 132 S. Ct. at 1298-99. The Court should take this opportunity to make this distinction clear.

2. A proper preemption analysis confirms this patent's eligibility.

The Court should also take this unique opportunity to reiterate the centrality of preemption to Section 101 analysis. Drawing on 150 years of authority, *Alice* affirmed that preemption is "the concern that drives" the Section 101 exceptions. 134 S. Ct. at 2354-55. The very reason we distinguish "patents that claim the building blocks of human ingenuity" from "those that integrate the building blocks into something more," is that the "latter pose no comparable risk of pre-emption." *Id.* Section 101 thus forecloses claims that preempt essentially *all* uses of a natural phenomenon—not claims foreclosing only *particular* methods of using them that the inventor has disclosed. *Id.*

In this case, however, we know the inventors made only the latter kinds of claims, because re-

searchers have undisputedly identified practical uses for cffDNA *not preempted* by the patent. Demonstrated methods show that cffDNA may be used without practicing each of the patent's core steps: One need not fractionate the sample; one may forego amplification; and one can use cffDNA without distinguishing paternally inherited sequences at all. These non-preempted innovations are conclusive evidence that petitioner's patent does not claim the natural phenomenon itself—instead claiming merely one set of applications then known only to the inventors. This should have strongly signaled to the Federal Circuit that its analysis was amiss.

The Federal Circuit missed that signal, however, because it reduced preemption to a one-sided afterthought. On its view, "[w]hile preemption may signal patent ineligible subject matter, the absence of complete preemption does not demonstrate patent eligibility." Pet.App. 17a. Instead, once a formalistic application of *Mayo*'s two-part test suggests that the claims combine an unpatentable discovery with conventional techniques, "preemption concerns are fully addressed and made moot." *Id.* This kind of rote legalism is not what this Court envisioned when it "sketched" out *Mayo*'s rationale: A patent's preemptive scope is not just some dispensable consideration; it is this Court's best-tested way of knowing when a patent claims only an application of a newly discovered phenomenon, rather than the whole phenomenon itself.

Indeed, if preemption is a one-way ratchet (as the Federal Circuit evidently believed), it should ratchet the other way. Sometimes, a meritorious patent will appear to preempt all currently-known ways

of using a revolutionary insight, especially at the moment of the invention itself. That's because, as *Myriad* recognizes, the first person with knowledge of a newly discovered phenomenon is in an excellent position to claim its applications. At that moment, she (alone) can claim every straightforward application she (alone) can teach the world, 133 S. Ct. at 2120, and that is exactly what you would expect her to do.

In other words, the preemption concern is not that the patent covers all the immediately useful ways in which an insight known only to the inventor can be harnessed *right now*. As this Court explicitly recognized in *The Telephone Cases*, 126 U.S. 1, 535 (1888), that fact may "show more clearly the great importance of [a] discovery, but it will not invalidate [a] patent."[2] Instead, the concern is that a patent covers all the ways a natural discovery might *ever* be put to use, including highly innovative ones the patentee does not know and cannot teach. *See* Pet.App. 93a (Dyk, J.) (endorsing alternative Section 101 approach limiting patentees to applications of natural laws they fully reduce to practice and disclose). That is precisely why this Court allowed Samuel Morse to patent the telegraph, but not "the use of the motive power of the electric or galvanic current … *however developed*, for making or printing intelligible charac-

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[2] The district court thus erred by discounting the evidence of non-preemption here on the ground that the other, undisputed uses of cffDNA arose only after the patent was granted. Pet.App. 57a. Not even the Federal Circuit endorsed this reasoning, which is incoherent: If non-preempted uses of a natural discovery are *ever* created, then—by simple logic—the patent had *never* claimed the ineligible discovery itself.

ters." *Mayo*, 132 S. Ct. at 1301 (quoting *O'Reilly v. Morse*, 56 U.S. 62, 86 (1853)).

To be sure, even the clarifications outlined above cannot render Section 101 jurisprudence into an exact science, and *Mayo* may remain a barrier to even some seemingly meritorious inventions. But whatever the outcome might be for the '540 patent, this case remains an indispensable vehicle for clarifying *Mayo*'s breadth, so that at least the biomedical community and its investors will know which breakthrough inventions—many of which are already patented—provide no actual guarantee of exclusivity to those who would bring them to market. The Court needs now to reconcile the analytic tensions in its case law, and provide some semblance of predictability in an area of law that depends vitally upon it. This alone recommends review.

B. The Federal Circuit's contrary reading of *Mayo* poses far-reaching dangers.

The need for this Court's intervention multiplies, however, when one considers the breadth the Federal Circuit gave *Mayo* below. It agreed that the '540 patent was a "breakthrough"; that it "combined and utilized man-made tools of biotechnology in a new way that revolutionized prenatal care"; and that "no one was using" its method in combination before because they were in fact discarding the relevant material as waste. Pet.App. 18a. But it still held the patent ineligible because it interpreted *Mayo* to require invalidating patents whenever they incorporate a natural law or phenomenon and recite techniques that are separately "well-known," "conventional," or "routine." As explained, *Mayo* need not be read that way, and

that confusion merits clarification. But the Federal Circuit has now unambiguously adopted that reading, and it has thereby "eviscerate[d] patent law" in the very way this Court and the Solicitor General warned against in *Mayo* itself. *See Mayo*, 132 S. Ct. at 1293; Brief of U.S., *Mayo*, No. 10-1150, at 31-32.

To begin, the Federal Circuit's version of *Mayo* plainly swallows all three examples above. *Supra* pp.18-21. *Diehr*'s invention combined an unpatentable law of nature and otherwise conventional techniques like "measuring" temperature and "recalculating" curing time. A new use for a known drug combines a natural law (that the drug treats a new disease), a known substance (by hypothesis), and conventional methods of administration (like taking a pill). And the only way someone with unique knowledge of a new discovery would be in an "excellent position" to claim new applications of that discovery is if using that discovery to motivate new combinations of known techniques suffices for eligibility. The Federal Circuit's approach to *Mayo*'s test is thus irreconcilable with principles and examples this Court has already recognized, and—as in the case of new drug applications—have long been critical to biomedical research.

It gets worse. The Federal Circuit's version of *Mayo* would invalidate even the very first patent, signed by George Washington on July 31, 1790, after a review headed by Thomas Jefferson. That patent was granted to Samuel Hopkins for an improved method of making potash, whose innovation involved burning the ashes in a furnace before undertaking the conventional steps of dissolving and boiling them in water, drawing off the lye, and boiling it down into

salts. *See* U.S. Patent X1, https://goo.gl/fIFfsg. Of course, burning ashes in a furnace and boiling water were not, themselves, unknown techniques—even in 1790. But combining these ancient steps led to an improved result, and so a patentable invention.

Hopkins's patent—like all inventive methods—relied on an insight about the natural world that motivated him to combine available tools in new ways to do something previously impossible. Hopkins discovered that you get purer potash if you first burn ashes in a furnace, just like Lo and Wainscoat discovered that you get detectable paternally inherited sequences if you amplify the DNA in maternal plasma. To be sure, any trained artisan who knew what these inventors had discovered might also have known how to put those discoveries to practical use, because the necessary techniques were readily available. But that didn't stop the Founders who wrote Section 101's precursor from granting Hopkins his patent on his new combination of routine techniques (literally, "burning," "boiling" and "drawing off"), and it shouldn't have stopped the Federal Circuit here.

Indeed, only arbitrary distinctions can prevent the Federal Circuit's version of *Mayo* from eventually swallowing all of patent law. As *Mayo* notes, almost every patent can be expressed as an unpatentable idea combined with conventional techniques. The light bulb is a natural law—that electrified filament glows without burning in an oxygen-free environment—plus glass, gas, and wire. And this is why discovering practical natural phenomena must be allowed to contribute to taking the "inventive step" that *Mayo* requires. *See* Pet.App. 89a (Dyk, J.). The point is that, while Edison could not patent the *fact* that a

filament will glow without burning in an oxygen-free environment, he could patent all the applications that were obvious (only to him) after that discovery, even if others might easily have done the same things if they knew what he knew. *See Myriad*, 133 S. Ct. at 2120. And yet, as academic commentators have observed, Edison and several other famous inventors would likely have been denied their iconic patents under the Federal Circuit's version of *Mayo*'s test. *See* Risch, *Nothing Is Patentable,* 67 Fla. L. Rev. 45, 51-53 (2015) (because each invention applied previously-known techniques to newly-discovered natural phenomena, current law would invalidate patents for cotton gin, electric motor, telegraph, telephone, airplane, and radio antenna, many of which this Court itself had approved).

Indeed, it would be exhausting to list all the world-altering inventions the courts would have invalidated under the Federal Circuit's new regime. As the first-patent example indicates, industrial processes would fare poorly. But, as this case even-more-vividly shows, biomedical innovations are uniquely vulnerable to the Federal Circuit's interpretation of *Mayo* because of their inherent connection to basic biological research, *see* Pet.App. 90a (Dyk, J.). And that is ironic, because these kinds of inventions also uniquely depend on investments that are readily susceptible to free-riding, and that no first-mover will make without an assurance of patent protection—among them, clinical validation, regulatory approval, and (of course) the invention itself.

Consider vaccines. Inoculation is, quite simply, a natural phenomenon involving the body's inherent immune response to pathogens. For every new vac-

cine, the hard part is discovering the natural law—that a particular protein or attenuated germ will provoke immunity without serious illness. Edward Jenner invented smallpox vaccine after discovering that cowpox exposure led to smallpox immunity. Apart from that discovery, creating a smallpox inoculant involved no unknown or unconventional techniques. This is true for essentially every vaccine subsequently produced, no matter the massive private outlay that may be required to research and clinically validate it for widespread human use. But under the rule of this case, all are patent-ineligible because all rely on known techniques and natural phenomena—even if those techniques and phenomena had never been combined in this life-saving way before.

Or consider PCR—the Nobel-winning invention that birthed almost all modern genetic medicine. As its inventor Kary Mullis has acknowledged, PCR is just the application of a "simple idea" to a set of chemical reagents that had been in conventional use for years. All Mullis realized was a natural law whereby combining those reagents in a repeated procedure would exponentially redouble a particular genetic sequence in a sample. The only techniques involved were heating, cooling, adding reagents, and starting over. The separate steps were thus "well-understood"; Mullis's genius lay in an insight into the natural world he had on a moonlit drive, which motivated him to combine these long-available materials and techniques. *See* Mullis, *supra*, at 56.

Moreover, the most important (and valuably patented) improvement to PCR occurred when Mullis and his coworkers realized that using DNA polymerase from a *naturally-occurring*, heat-resistant bacte-

ria (called Taq) would make the process more efficient, because you would no longer need to add fresh enzyme after every cycle. *See Hoffman-La Roche v. Promega Corp.,* 323 F.3d 1354, 1358 (Fed. Cir. 2003). Natural phenomenon; known techniques; new combination; massive practical improvement. Before this case, everyone understood that these were patent-eligible inventions (on which Ariosa's parent reaped incalculable returns). But as *amici* attest, this decision turns those settled expectations upside-down.

Finally, the Federal Circuit's reading of *Mayo* leads to two ironic and unacceptable results.

First, it inexplicably punishes the most valuable inventions—namely, those that recombine only "well-understood" and readily available techniques to achieve breakthrough results. It is far more valuable to devise a way of turning lead to gold with a high-school chemistry set than with a redesigned particle accelerator. No intelligible patent policy supports deeming only the former method patent-ineligible.

Second, the Federal Circuit's rule punishes inventors for understanding how their inventions work. Imagine that, instead of discovering and understanding the diagnostic relevance of cffDNA, Lo and Wainscoat had serendipitously discovered that running maternal serum through a sequencer and looking for certain outputs predicted fetal gender or Down Syndrome, but they didn't know why. They plainly have a patentable method in hand—they have a new set of steps that leads to a new practical result, and mentions no natural law or phenomenon. But once they explain why this method works, and the Federal Circuit determines that it involves a set of available techniques others would have performed if they too

had understood the existence of cffDNA, their patent disappears. Plainly, this rule does not "promote the Progress of Science," U.S. Const. art. I, § 8, cl. 8.

Ultimately, the Federal Circuit's interpretation of *Mayo* is not only erroneous but unacceptably dangerous—discarding patented inventions recognized by everyone from the Founders to this Court to the Nobel Committee, and treating the most useful inventions as suspect only because of the profound scientific understanding and breakthroughs of their inventors. This error will fatally undermine the biomedical field and this entire area of law, making this Court's immediate intervention to clarify *Mayo* all the more necessary and appropriate.

II. This Issue is Vitally Important.

Were anything more required, we add three simple indicia of this case's importance.

First is the overwhelming support of trustworthy *amici*. Twelve different briefs supported rehearing below and more are expected here. The *amici* encompass the largest biotech and pharmaceutical associations, companies, professors, practitioners, universities, international interests, and more. The Solicitor General sounded a similar alarm about unintended consequences as an *amicus* in *Mayo*. *See* Brief of U.S., *Mayo*, at 31-32. And these varied voices only join the chorus of judges who warned below that only this Court can clarify *Mayo* and prevent it from swallowing the field of life-science innovation.

Indeed, there is widespread agreement that the concerns above are real, including in the relevant press. *See, e.g.*, Marandett, *Ariosa v. Sequenom Signals Trouble Ahead For Life Sciences*, LAW360 LIFE

SCIENCES, Nov. 3, 2015 ("*Ariosa* portends ominous consequences for patents … in the life sciences. … [It] puts at risk such inventions as immunodiagnostics, molecular diagnostics, and method patents directed to therapeutic uses of antibodies, vaccines, gene therapy, and biologics and biosimilars[.]"). And, as *amici* attest, this public perception alone has already changed market realities, along with the practices of their companies and university researchers.

Second, the decision below threatens to destroy the predictability and certainty the patent system needs to do its job. At a minimum, the biomedical community is now adrift in determining whether or not patents will ever be available in these or related fields. And that's essentially the ballgame, because once you must seriously question the availability of patent protection, you cannot: (1) confidently invest in research; (2) confidently invest in clinical validation and commercialization of existing patents; or (3) confidently predict that it is better to disclose your discoveries through the patent system than it is to keep them a trade secret.

That last result is a deeply ironic place for this area of law to end up. While regulatory approval processes may preclude absolute secrecy forever, the current regime now affirmatively encourages researchers to keep as secret as possible those very "basic tools of scientific and technological work" that Section 101 doctrine is designed to render into a public good for the benefit of scientific progress. *Mayo*, 132 S. Ct. at 2193. Before, those engaged in such research could freely disclose their findings, secure in the knowledge that—as *Myriad* put it—they remained in an excellent position to claim practical ap-

plications of that knowledge. 133 S. Ct. at 2120. Now, secrets look much more valuable than patents. And that benefits no one, especially in fields like these, where sharing research is so fundamental to the timely development of life-saving interventions.

The realistic consequence is that the bottom may well fall out of life-science innovation. *See* Pet.App. 78a (Lourie, J.) ("It is said that the whole category of diagnostic claims is at risk. It is also said that a crisis of patent law and medical innovation may be upon us, and there seems to be some truth in that concern."). After the decision below, those seeking new vaccines, new uses for existing drugs, and even holy-grail insights like early, non-invasive cancer screens, may conclude that the game isn't worth the candle. And who could blame them: They could revolutionize their field, teach their colleagues a method that is the diametric opposite of conventional wisdom, create a practical, non-invasive test that confers enormous medical benefits on society, have their research cited a thousand times, and yet still lose their patent (after incurring a huge expense in reliance on its protection) because their previously unknown method relies on too fundamental an insight *they alone had* into the natural world. If this is the permanent reality, neither aspiring scientists nor venture capitalists may see much to gain in developing or commercializing biomedical research.

Finally, the decision below places the United States out of step with the international community regarding the patent-eligibility of biomedical methods—perhaps even breaching our treaty obligations. Other authorities, including the European Patent Office, have bars on patenting natural laws. But none

has invalidated an invention anything like this one; indeed, the EPO upheld this very patent. *See* Technical Board of Appeal Decision, No. T0146/07, ¶35 (Dec. 13, 2011). As various *amici* explain, the now-governing U.S. approach to eligibility is far more restrictive than the rest of the world's, runs afoul of international treaties that oblige us to conform our patent rules to international standards, and can impermissibly place international applicants at a unilateral disadvantage. In addition to the factors above, this kind of international legal tension strongly recommends this Court's review.

III. This Case Is An Ideal Vehicle.

Many of this case's vehicle strengths appear above, including—most critically—the intuitive patent-eligibility of this "breakthrough" invention, and the many opinions below holding that *only* this Court can save it by clarifying *Mayo*. *Supra* p.9-12. Moreover, this is the exceptionally rare case in which the Federal Circuit will have expressly "agree[d]" that the patent "*combined* and utilized man-made tools … in a *new way* that revolutionized" a field. Pet.App. 18a (emphasis added). No future case could frame the question presented more precisely than that.

To this, we add three final points.

First, this is an extremely well-ventilated patent, with a far-more-developed record than is usual for Section 101 cases. Because of the preliminary-injunction appeal, the Federal Circuit already construed the '540 patent's claims. *See* 726 F.3d at 1300-04. There is also a well-established factual record based on peer-reviewed scientific publications conclusively establishing that the patent has not preempted

all uses of cffDNA. Pet.App. 55a-56a. And because respondents have already challenged the '540 patent in *inter partes* review, there's no real question whether, for example, Claim 21 is novel and non-obvious,[3] which is rarely true of patents with alleged 101 infirmities. The EPO has even upheld this patent against allegations that it lacked an "inventive step" and did not enable testing for Down Syndrome and other conditions. *Supra* p.33. Its meaning and background are thus uniquely clear.

Second, this patent involves not only broader independent claims, but also narrower dependent claims. The independent claims (like Claim 21) describe one particular diagnostic application of cffDNA, where fractionation, amplification, and detection of paternally inherited sequences enable fetal diagnoses. But the dependent claims refine that down to the level of *individual tests*, like using the method to detect Down Syndrome, RhD status, or gender. And, notably, respondents' infringing tests are for precisely those conditions.

This is a pertinent detail, because one judge below suggested a novel doctrine under which the inde-

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[3] *See* Final Written Decision, IPR2012-00022, at 46 (upholding Claim 21, among others). This decision did hold that Claim 1 was "inherently" anticipated by a Russian paper, even though that paper failed to detect (or even express any awareness of) paternally inherited cffDNA. *Id.* at 36. But that is immaterial here both because Claim 21 covers all the products at issue, and because that holding depends on the very district court decision this petition seeks to reverse, *see id.* at 50-52; CAFed. #15-01691, Order (July 22, 2015) (granting stipulated stay of IPR appeal pending this petition).

pendent claims here might fail for being too broad, even though they are "inventive" in the sense Section 101 jurisprudence had previously required. *See* Pet.App. 98a (Dyk, J.). Were the Court interested in such a test, this patent would allow it to draw a line between broader and narrower claims actually presented in the case.

Finally, while this issue is important in numerous cases,[4] this may be the Court's last good chance to clarify this aspect of *Mayo*, because the decision below will incentivize behaviors precluding future vehicles. The press reactions and *amicus* briefs demonstrate that the entire biomedical field (and even those beyond it) have gotten the message. Unless this Court intervenes now, many companies will decline to patent, exclusively license, or commercialize similar inventions in a way that would permit a suit to reach this Court. Moreover, given the threat of invalidation the decision hangs over every diagnostic method patent, patentees will just settle or grant cheap licenses to avoid risking a catastrophic loss.

In sum, this is the perfect case for this Court to clarify *Mayo* and articulate a principled line in this now-severely-muddied area of law. That line can embrace existing precedent and continue to reject patents that purport to claim natural phenomena, while still protecting meritorious patents (like petitioner's) from being collateral damage in what is properly a war on overbroad claims on facially dubious inven-

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[4] For example, a similar question is presented in another pending petition, *see Hemopet v. Hill's Pet Nutrition, Inc.*, No. 15-1062 (filed Nov. 10, 2015).

tions often brought by abusive, non-practicing entities. This Court should take this opportunity to provide the guidance the Federal Circuit is openly seeking, and avoid a result neither it nor Congress could have intended.

CONCLUSION

This Court should grant certiorari.

Respectfully submitted,

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