No. 15-1182

IN THE

Supreme Court of the United States

SEQUENOM, INC.,

Petitioner,

v.

ARIOSA DIAGNOSTICS, INC., *et al.*,

Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF FOR A *AMICUS CURIAE* INTELLECTUAL PROPERTY OWNERS ASSOCIATION IN SUPPORT OF PETITION

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INTEREST OF *AMICUS CURIAE*

The Intellectual Property Owners Association (IPO) is a trade association representing companies and individuals in all industries and fields of technology who own or are interested in intellectual property rights.[1] IPO's membership includes more than 200 companies and over 12,000 individuals who are involved in the association either through their companies or as inventor, author, executive, law firm, or attorney members. Founded in 1972, IPO represents the interests of all owners of intellectual property. IPO regularly represents the interests of its members before Congress and the United States Patent and Trademark Office (USPTO) and has filed *amicus curiae* briefs in this Court and other courts on significant issues of intellectual property law. The filing of this brief was approved by the IPO Board of Directors. A list of IPO Board members can be found in the Appendix.[2]

As owners of intellectual property, the members of IPO believe that intellectual property rights promote the innovation, creativity, and investment necessary to address major global challenges and improve lives. We strive to maximize innovation across all industries and

1. No counsel for a party authored this brief in whole or in part, and no such counsel or party made a monetary contribution intended to fund the preparation or submission of this brief. No person other than the *amicus curiae* or its counsel made a monetary contribution to its preparation or submission. Parties consented to the filing of amicus briefs through blanket consent letters filed on March 28, 30, and 31.

2. IPO procedures require approval of positions in briefs by a two-thirds majority of directors present and voting.

improve lives throughout the world by fostering high quality rights and effective, harmonized systems to obtain and enforce them, on behalf of all our members.

IPO's corporate membership constitutes companies with valuable patent portfolios protecting their investment in research and development, as well as significant patent litigation dockets with claims of infringement lodged both by and against them. They also are engaged in numerous *inter partes* reviews. As such, IPO provides an important perspective on the development and enforcement of patent rights before both the USPTO and the courts.

INTRODUCTION AND SUMMARY OF ARGUMENT

IPO supports granting Sequenom's Petition for a Writ of Certiorari to clarify the confused state of patent eligibility under 35 U.S.C. § 101. Lower courts now believe they are compelled to apply this Court's instruction in *Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 134 S. Ct. 2347, 2355 (2014) and *Mayo Collaborative Servs. v. Prometheus Labs, Inc.*, 132 S. Ct. 1289, 1296-97 (2012), in a manner such that even groundbreaking, novel, non-obvious, and highly useful innovations are no longer patent eligible. In particular, there is an urgent need for the Supreme Court to clarify that section 101 analysis must consider the whole claim and not just each claim feature separately. In this case of an invention that revolutionized prenatal care, the analysis did not focus on the method claim as whole, but dissected features out of the patent claim that in isolation included patent-ineligible naturally occurring DNA. The new combination of claimed steps, however, was not considered. Also, evidence that the claim does not unduly

preempt use of the naturally occurring DNA was not considered. The Federal Circuit judges candidly reported their struggle with formulating a coherent analysis to apply in patent-eligibility disputes. Patent examiners attempt daily to identify the dividing line between eligibility and ineligibility that bedevils judges. The result has been to decimate patents and pending patent applications directed to previously eligible patentable subject matter, including those directed to diagnostic methods. IPO urges the Supreme Court to grant certiorari in this exemplary case to address widespread uncertainty as to the scope of exclusions from patent eligibility.

ARGUMENT

I. UNCERTAINTY AS TO PATENT ELIGIBILITY PRESENTS AN URGENT NEED FOR FURTHER CLARIFICATION FROM THIS COURT

This Court described a two-step test to determine claimed inventions' patent eligibility. First, claims are reviewed to determine if they are directed to one of the three categories of patent-ineligible subject matter: laws of nature, natural phenomena, and abstract ideas. *Alice,* 134 S. Ct. at 2355; *Mayo,* 132 S. Ct. at 1296-97. If so, the claims are then further reviewed to determine whether they contain an additional, inventive concept sufficient to transform them into a patent-eligible application of the ineligible subject matter. *Alice*, 134 S. Ct. at 2355; *Mayo*, 132 S. Ct. at 1296-97.[3]

3. Significantly, the Court did not require this two-step formulation as the *only* mechanism for evaluating patent eligibility. Rather, this Court has eschewed overly rigid rules for analyzing

This Court has long held that claimed inventions must be analyzed as a whole in order to determine their patent eligibility. *Diamond v. Diehr*, 450 U.S. 175, 188, 101 S. Ct. 1048, 1058 (1981) (stating that "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."). In *Mayo*, the Court reiterated the importance of considering claims as a whole as part of the eligibility analysis. 132 S. Ct. at 1298 (analyzing all the steps of a claimed method "as an ordered combination" when evaluating eligibility); *see also Alice*, 134 S. Ct. at 2355 n.3 ("Because the approach we made explicit in *Mayo* considers all claim elements, both individually and in combination, it is consistent with the general rule that patent claims 'must be considered as a whole.'" (quoting *Diehr*, 450 U.S. at 188, 101 S. Ct. at 1057-58)). Thus, the *Mayo* Court did not establish some new, heightened requirement that individual elements of an invention must themselves be "inventive." Nevertheless, since *Mayo,* courts and the USPTO faced with questions of patent eligibility have not consistently considered claimed inventions in their totality, thereby improperly denying patent protection to deserving inventions.

The claimed methods at issue here, which the panel agreed "revolutionized prenatal care," involve making copies of cell-free fetal DNA (cffDNA) from a pregnant woman's blood and testing it for the presence of fetal genes inherited from the father. *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371, 1373-74, 1379 (Fed. Cir.

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patent eligibility in favor of inquiries more attuned to the specific circumstances of each case. *Bilski v. Kappos*, 561 U.S. 593, 605, 130 S. Ct. 3218, 3227 (2010).

2015) (internal quotation marks omitted). In the first step of its patent-eligibility analysis, the panel held the claims were directed to patent-ineligible natural phenomenon – cffDNA in pregnant women's blood.[4] *Id.* at 1376. As to its second step, the panel acknowledged the requirement to consider claim elements both individually and as an ordered combination but then failed to do so. *Id.* at 1376-77. Rather, after characterizing "*the method steps* [as] well-understood, conventional and routine" (*id.* at 1377 (emphasis added)), the panel explicitly dismissed the argument that the inventiveness required to confer patent eligibility lay in the inventors' new *ordered combination of steps* (*id.* at 1379-80).

A concurring opinion stated that the claimed method was "truly meritorious," "groundbreaking," a "breakthrough invention," "deserving of patent protection," and "nothing like the invention at issue in *Mayo*," in large part because, as an ordered combination, it had "never been done before." 788 F.3d at 1381 (Linn, J., concurring). The concurring opinion noted there was "no room to distinguish *Mayo* from this case," despite acknowledging the untoward consequences such a broad reading of *Mayo* would have on the patent regime. *Id.* at 1381 ("[D]espite *Mayo's* declaration that a claim to 'a new way of using an existing drug' is patentable, . . . it is unclear how a claim to new uses for existing drugs would survive *Mayo's* sweeping test." (quoting *Mayo*, 132 S. Ct. at 1302)).

4. Considering that the claims recite a method of *detecting and analyzing* cffDNA from pregnant women's blood, not its *existence*, the panel's unnecessarily broad view of when a claim is "directed to" a natural phenomenon in the first step of this analysis also deviates from the analytic framework established by the Supreme Court.

The Federal Circuit produced three more opinions in response to Sequenom's request for *en banc* rehearing of the panel's decision, further reflecting the multiple views of this Court's precedent. In so doing, the Federal Circuit itself calls upon this Court to clarify the morass of conflicting judicial interpretations of patent-eligible subject matter for method claims in life sciences technologies. One opinion stated it would be "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." 809 F.3d 1282, 1287 (Lourie, J., concurring). *Mayo* was interpreted as "unfortunately oblig[ating the court] to divorce the additional steps from the asserted natural phenomenon to arrive at a conclusion that they add nothing innovative to the process" and, despite misgivings, compelling the finding that the invention is ineligible. *Id.*, at 1286.

Another concurrence agreed with the panel's holding that Sequenom's invention is not patent eligible, yet opined that a patent-eligibility test that is overly restrictive might "discourage development and disclosure of new diagnostic and therapeutic methods in the life sciences, which are often driven by discovery of new natural laws and phenomena." *Id.* at 1287, 1293 (Dyk, J., concurring). Judge Dyk worried that, "in the life sciences, where development of useful new diagnostic and therapeutic methods is driven by investigation of complex biological systems … claims that apply newly discovered natural laws and phenomena in somewhat conventional ways are screened out by the *Mayo* test." *Id.* at 1289. He also expressed that the holding in *Mayo* might be inconsistent with this Court's recognition in *Association for Molecular Pathology v. Myriad Genetics, Inc.,* 133 S. Ct. 2107, 186 L. Ed. 2d 124

(2013), "that an inventive concept can sometimes come from discovery of an unknown natural phenomenon, not just from unconventional application of a phenomenon." *Ariosa*, 809 F.3d at 1290. Notwithstanding these concerns as to the current state of patent-ineligibility jurisprudence, he stated that "*any further guidance must come from the Supreme Court.*" *Id.* at 1287 (emphasis added).

Dissenting from the denial of Sequenom's request for rehearing, Judge Newman agreed with her colleagues insofar as she characterized them as believing the invention should be patent eligible, but further stated that the facts of this Court's precedents diverge from those present here such that precedent does not compel a holding of patent ineligibility. *Id.* at 1293 (Newman, J., dissenting). Unlike in *Mayo*, Judge Newman stated, here "the claimed method was not previously known, nor the diagnostic knowledge and benefit implemented by the method." *Id.* at 1294. Observing that this Court has cautioned against generalizing "all discoveries of natural phenomena or their application in new ways or for new uses a[s] ineligible for patenting," Judge Newman recognized the invention's "profound public benefit" and that patenting "facilitate[d] the public benefit of provision of this method through medical diagnostic commerce, rather than remaining a laboratory curiosity." *Id*. at 1249.

The claimed methods at issue in *Mayo* are distinguishable from the claims at issue here, because even as an ordered combination as a whole, those claims amounted to nothing more than enunciating a natural law in the context of a process that was already routine practice. *See* 132 S. Ct. at 1298. The *Mayo* claims recited administering a drug to a patient and measuring the

resulting metabolite levels, wherein metabolite levels outside a defined range indicated a need to change the dose administered. *Id.* at 1297-98. Because it was already routine for doctors to administer the drug and measure metabolite levels to determine appropriate dosing, with the claims involving nothing more, the Court found the claims ineligible. *Id.* at 1297-98. That method differs starkly from the one claimed here, which even the panel agreed was revolutionary. 788 F.3d at 1379.

The claims at issue here, when considered as a whole, are also distinguishable from the claims that were held to be patent ineligible in *Myriad,* 133 S. Ct. 2107 (2013). Although agreeing with Sequenom that its claimed method revolutionized prenatal care, the panel stated that "'[g]roundbreaking, innovative, or even brilliant *discovery* does not by itself satisfy the § 101 inquiry.'" 788 F.3d at 1379 (quoting *Myriad*, 133 S. Ct. at 2117 (emphasis added)). However, in *Myriad*, this Court held that isolated genes were laws of nature, such that claims merely reciting them *and nothing more* were drawn to patent-ineligible subject matter. 133 S. Ct. at 2117. In contrast, the claims here recite *a use of* cffDNA in pregnant women's blood, not merely its existence. In applying *Myriad*'s admonition against patenting even a "groundbreaking" discovery of a law of nature, the panel overlooked the real question here: whether the groundbreaking *application* of a natural phenomenon, as described in a method claim as a whole, is patent eligible. Indeed, the *Myriad* court suggests it is. *Id.* at 2120 ("[A]s the first party with knowledge of the [ineligible subject matter, the patentee] was in an excellent position to claim applications of that knowledge." (internal quotation marks omitted)).

To assist courts and the USPTO in the proper analysis of patent eligibility, IPO urges this Court to emphasize that claimed methods must be evaluated as a whole when determining patent eligibility. Preventing the continuing trend of judicial and USPTO decisions holding claimed methods to be ineligible for patenting beyond what this Court envisioned, let alone required, is an issue of exceptional importance to the patent-owning community, and this case presents an ideal opportunity for this Court to curb that harmful trend. *See, e.g., Mayo*, 132 S. Ct. at 1293 (acknowledging that "all inventions at some level embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas").

II. EVIDENCE RELATING TO WHETHER A CLAIMED INVENTION UNDULY PREEMPTS INELIGIBLE SUBJECT MATTER IS ALWAYS RELEVANT TO A PATENT ELIGIBILITY INQUIRY

This Court must address the evidence of whether a patent claim does not unduly preempt the use of patent-ineligible subject matter by others. This Court has consistently couched its patent-eligibility jurisprudence as designed to prevent the undue preemption of laws of nature, natural phenomena, and abstract ideas. *Alice*, 134 S. Ct. at 2355 (stating that inventions that do not pose a risk of undue preemption are patent eligible); *Myriad*, 133 S. Ct. at 2116; *Mayo*, 132 S. Ct. at 1302; *Diamond v. Chakrabarty*, 447 U.S. 303, 309, 100 S. Ct. 2204, 2208 (1980). Here, the Federal Circuit acknowledged that "the principle of preemption is the basis for the judicial exceptions to patentability." 788 F.3d at 1379. Paradoxically, however, the panel called preemption concerns in this case

"moot" because it had already "deemed [the claims] only to disclose patent-ineligible subject matter under the *Mayo* framework." *Id.* This statement begs the question and conflicts with this Court's guidance on patent eligibility.

Taken to its logical conclusion, the Federal Circuit's decision would mean that under the *Mayo* test for patent eligibility, an invention may be found patent ineligible no matter how much evidence there is that it does not unduly preempt a law of nature, natural phenomenon, or abstract idea. This result undermines the entire stated purpose of this Court's patent-eligibility jurisprudence: to prevent undue preemption. The approach taken by the Federal Circuit is not what this Court said and cannot be what it intended in view of its goal of preventing preemption. *Bilski*, 561 U.S. 593, 605, 130 S. Ct. 3218, 3227 (2010) (rejecting rigid rules that frustrate the purposes of the Patent Act). And yet, it has become a common, but misguided, refrain in district court litigation (*see, e.g.*, *Open Text S.A. v. Box, Inc.*, 78 F. Supp. 3d 1043, 1049 (N.D. Cal. 2015) (stating that this "Court has in fact considered the preemption concern because it is already baked into the *Mayo/Alice* test."), and the USPTO instructs its patent examiners that "questions of preemption are inherent in the two-part framework from *Alice Corp.* and *Mayo*."[5]

Here Sequenom presented substantial evidence that its claims do not unduly preempt the use of cffDNA found in pregnant women's blood. The claims at issue require separating, or "fractionating," components of blood (serum

5. U.S. Patent and Trademark Office, July 2015 Update: Subject Matter Eligibility 8 (2015), available at http://www.uspto.gov/sites/default/files/documents/ieg-july-2015-update.pdf.

or plasma), making multiple copies of, or "amplifying," the cffDNA it contains, then identifying paternally inherited genes therein. 788 F.3d at 1373-74. To demonstrate that its claims do not unduly preempt use of cffDNA and do recite patent-eligible subject matter, Sequenom showed that other groups have analyzed cffDNA without fractionating the pregnant women's blood containing it, without amplifying it, or without using it to identify paternally inherited genes. All those other methods of using cffDNA fall outside of Sequenom's claims.[6] Contrast this with *Mayo*, where the only use of the ineligible subject matter (the mathematical relationship between drug metabolism and dosing) was covered by the claims (measuring metabolite levels to determine appropriate dosing levels). Yet the Federal Circuit improperly disregarded all such evidence here as "moot." 788 F.3d at 1379.

Evidence of a lack of undue preemption, the heart of this Court's patent-eligibility jurisprudence, should not be excluded from the analysis, and can be accommodated within the two-step framework described in *Mayo*.[7] For example, if a claim is deemed directed to patent-ineligible subject matter under "step one," evidence that such subject matter may also be used outside the claim--*i.e.*, that the claim does not unduly preempt use of the patent-ineligible subject matter--may constitute evidence that the claim contains an inventive concept that transforms it into a patent-eligible application under "step two."

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6. Consolidated Opening Brief of Appellant Sequenom, Inc. at 10-11, Nos. 14-1139, 14-1142, 14-1144 (Fed. Cir. Jan. 22, 2014).

7. This is not to suggest that evidence of lack of undue preemption should be required to demonstrate patent eligibility, however.

III. CHILLING ECONOMIC IMPLICATIONS OF A CONFUSED TEST FOR PATENT ELIGIBILITY EXIST

Patents are especially important for the viability of life sciences ventures to support exploration for new technologies. Obtaining a patent significantly and substantially increases a company's ability to obtain essential investment, hire employees, bring its products to market, and to innovate further.[8] Conversely, delays in obtaining a patent significantly blunt--and, if long enough, eliminate--the salutary effects patents have on startups' viability and prolificacy.[9]

The cost of developing and commercializing a diagnostic test is estimated to be at least $20 million and can run as high as $100 million or more, depending on the underlying technology.[10] Companies would be unlikely to invest so much to create, obtain regulatory approval of, and commercialize a new diagnostic test without an expectation that they could recoup costs during a time-limited period of exclusive use of their inventions via patent protection (after which, of course, the intellectual property embodied in the diagnostic becomes freely available).

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8. *See* U.S. Patent and Trademark Office, Economic Working Paper No. 2015-5, The Bright Side of Patents 2 (2016).

9. *Id.* at 3 (finding that, all other things being equal, a delay of as little as two years in a startup's ability to obtain a patent effectively nullifies the foregoing benefits).

10. Diaceutics Group., *Mystery Solved! What Is the Cost to Develop and Launch a Diagnostic?* (2013), available at http://diaceutics.com/mystery-solved-what-cost-develop-and-launch-diagnostic?ref=iceutics

Patent protection can also aid the translation of research done in a university setting into publicly available innovations, such as new diagnostic tests, by promoting business partnerships between universities and private industry, as occurred here.[11] For example, it is estimated that, from 1996 to 2013, licensing of patented technology by universities, hospitals, and research institutions accounted for up to $518 billion of U.S. gross domestic product and $1.18 trillion of U.S. gross industrial output and was responsible for creating as many as 3.8 million jobs.[12] Consequently, nearly 10,000 patented products that originated from work done in academic research laboratories, including blockbuster medical treatments, are currently on the market.[13] Without any belief that patent protection was available for, the invention at issue here, it might well have remained just a "laboratory curiosity" without the "profound public benefit" it ultimately provided. *Ariosa*, 788 F.3d at 1294, (Newman, J., dissenting).

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11. The claimed invention was created by professors at the University of Oxford, patented, then licensed to Sequenom which brought it to market. *See* Sequenom, Inc., *Sequenom Secures Rights to Key Non-Invasive Prenatal Diagnostic Intellectual Property* (2005), available at http://sequenom.investorroom.com/press_releases?item=65.

12. Lori Pressman *et al.*, The Economic Contribution of University/Nonprofit Inventions in the United States: 1996-2013, at 3 (Biotechnology Industry Organization 2015), available at https://www.bio.org/sites/default/files/BIO_2015_Update_of_I-O_Eco_Imp.pdf.

13. Association of University Technology Managers, Highlights of AUTM's U.S. Licensing Activity Survey FY 2014, at 5-6 (2015), available at http://www.autm.net/resources-surveys/research-reports-databases/licensing-surveys/fy-2014-licensing-survey/.

Confusion about the scope of exclusions from patent eligibility undermines these societal benefits of the patent protection regime. Considering the severe consequences on the development and commercialization of diagnostic tests and other biomedical inventions, IPO respectfully submits that further guidance from this Court on patent eligibility is urgently needed before the United States' ability to promote scientific progress sustains long-term damage.

CONCLUSION

The patent eligibility doctrine is intended to serve the patent regime's greater purpose of promoting scientific progress, but a breakdown in its careful application frustrates that objective. By focusing on well-understood, routine, and conventional claim elements in isolation rather than examining claims as a structured whole, courts are too often missing the forest for the trees and improperly excluding deserving inventions from patent eligibility. The resulting harm to the patent system is real, it is significant, and it is not going away. The narrow, rigid, and restricted test applied by the lower courts and the USPTO has decimated patents and pending patent applications directed to diagnostic methods and needs to be reviewed by this Court so that "truly meritorious" inventions "deserving of patent protection" remain patent eligible. This Court has the opportunity to clearly enunciate that new methods, even those utilizing naturally occurring substances, are patent eligible. Also, a review of evidence that the claims do not unduly prevent others from using a patent-ineligible natural substance is required in the analysis. For all the foregoing reasons, IPO respectfully requests that this Court grant Sequenom's petition for a Writ of Certiorari.

Respectfully submitted,

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