No. 15-1182

IN THE

Supreme Court of the United States

SEQUENOM, INC.,

Petitioner,

v.

ARIOSA DIAGNOSTICS, INC., NATERA, INC., AND DNA DIAGNOSTICS CENTER, INC.,

Respondents.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

BRIEF OF JYANT TECHNOLOGIES, INC. AS *AMICUS CURIAE* IN SUPPORT OF PETITIONER SEQUENOM, INC.

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INTEREST OF *AMICI CURIAE*[1]

JYANT Technologies, Inc. (pronounced "giant"), located in Marietta, Georgia, is an early-stage biotechnology/pharmaceutical development company. JYANT leverages its strong proprietary intellectual property position to develop new therapies with companion diagnostics to bring medical products to the market faster. JYANT's patented technologies offer ground-breaking solutions to diagnosis and treat cancers and inflammatory diseases through the use of anti-chemokine and anti-chemokine receptor antibodies. JYANT has also developed a novel nano-compounding manufacturing methodology that allows for the targeted delivery of anti-cancer agents. Patent protection is critical to ensure the resources needed for its continued research and development. The decision of the Federal Circuit in the present appeal threatens to wreak havoc on patent law, and JYANT urges the Court to grant the petition for certiorari.

SUMMARY OF THE ARGUMENT

The Federal Circuit's decision is an errant attempt to navigate the murky jurisprudence of subject matter patent eligibility under 35 U.S.C. § 101. Without question, judicial efforts have fallen short of providing clear guidance for distinguishing

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[1] This brief was not authored, in whole or in part, by counsel for any party. No person or entity other than *Amici curiae*, their members, and their counsel made a monetary contribution to the preparation or submission of this brief. Counsel of record for each of the parties received timely notice of the intent to file this brief. Each party filed a blanket consent for all amicus briefs.

between a patent-ineligible "law of nature, natural phenomenon, and abstract idea" and an eligible "new and useful process, machine, manufacture, or composition of matter." The current uncertainty in the law demands that this Court again attempt to provide clear guidance concerning the confines of patent-eligibility, this time in the context of ground-breaking diagnostic and biotechnology inventions.

The Federal Circuit's opinion also fails to pay proper attention to the purpose of the patent laws: "To promote the Progress of . . . [the] useful Arts." U.S. Const. art. I, § 8, cl. 8. Patent protection for novel and nonobvious diagnostic methods achieves that objective. Importantly, patent protection for useful diagnostic tests does not preempt future research. On the contrary, it encourages the dissemination of ideas and enables others to invent improved or alternative diagnostic methods. For these reasons, the novelty and nonobviousness requirements of 35 U.S.C. §§ 102 and 103—and not the eligibility requirement of § 101—is the proper test for assessing the patentability of new diagnostic methods.

Finally, the Federal Circuit's reasoning threatens to abolish wide swaths of existing and future intellectual property. Almost every diagnostic test, whether medical, chemical, or agricultural, relies on some natural phenomenon. Those tests frequently apply known tools, such as reagents or procedures, to solve a specific problem. PCR itself—the basis of the 1993 Nobel Prize—used known reagents and protocols in a novel combination to produce a revolutionary result. Under the appeals court's reasoning, many diagnostic methods—no matter how novel and nonobvious—would be

ineligible for patent protection without any consideration of the merits of the invention under §§ 102 and 103.

ARGUMENT

I. The Current Uncertainty in the Law Requires This Court's Intervention

It is no secret that the state of the law concerning patent eligibility under 35 U.S.C. § 101 is far from ideal. *See, e.g.*, J. Jonas Anderson, *Applying Patent-Eligible Subject Matter Restrictions*, 17 Vand. J. Ent. & Tech. L. 267, 269 (2015) ("The Supreme Court's interest in, and difficulty with, promulgating a consistent standard for determining which inventions are patent-eligible has not gone unnoticed in the academy."); Christopher M. Holman, *Patent Eligibility Post-Myriad: A Reinvigorated Judicial Wildcard of Uncertain Effect*, 82 Geo. Wash. L. Rev. 1796, 1799 (2014) ("The Supreme Court's recent interest in the development of the patent eligibility doctrine appears to have raised more questions than it has answered.").

The Federal Circuit's multiple opinions in the present case underscore the confusion surrounding patent eligibility in the context of biotechnology and diagnostic inventions. The panel opinion was accompanied by a concurrence by Judge Linn, who seemingly would have reversed the district court but felt constrained by broad statements in this Court's precedent. *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371, 1381 (Fed. Cir. 2015) (Linn, J., concurring) ("But for the sweeping language in the Supreme Court's *Mayo* opinion, I see no reason, in

policy or statute, why this breakthrough invention should be deemed patent ineligible.").

The denial of the rehearing petition brought further confusion, with three separate opinions accompanying the order denying the petition. *See Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 809 F.3d 1282 (Fed. Cir. 2015). Judge Lourie, joined by Judge Moore, concurred in the denial but, like Judge Linn, found themselves bound by *Mayo*, explaining that "it is 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, or that they claim abstract concepts." *Id.* at 1287. Judge Dyk also concurred, observing that, in his view, "*Mayo* may not be entirely consistent with the Supreme Court's decision in *Myriad*." *Id.* at 1289–90. Finally, Judge Newman dissented from the denial, urging that "patenting of this new diagnostic method preempt further study of this science, nor the development of additional applications." *Id.* at 1294.

While absolute certainty in patent law is unattainable, the current jurisprudential disarray cannot be acceptable in the world's leading intellectual property regime. Inventors, innovative companies, investors, and regulatory agencies all require a reasonable certainty about what is or is not eligible for patent protection. Our judicial system must provide sufficient guidance to the innovation and business communities so they can continue to create the inventions that raise our standard of living, provide groundbreaking medical advances, and increase quality of life for all.

II. The Federal Circuit's Unduly Narrow View of Patent-Eligibility Threatens Patent Protection For Innovative Diagnostic and Biotechnology Inventions

The Federal Circuit's panel opinion purports to apply the framework set forth in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 132 S. Ct. 1289 (2012), but the *Mayo* framework must be correctly understood in the context of precedent, which the appeals court overlooked. Taken in context, *Mayo* does not require the invalidation of a diagnostic method claim simply because it uses known techniques to achieve a useful result based on new scientific knowledge.

In *Association for Molecular Pathology v. Myriad Genetics, Inc.*, this Court rejected claims directed to the naturally-occurring human genes. 133 S. Ct. 2107, 2116–18 (2013). Applied here, *Myriad* ostensibly forecloses patent claims that would attempt to monopolize the naturally occurring, cell-free fetal DNA itself. That much is undisputed, and the inventors here did not seek such claims.

The *Myriad* Court also expressly recognized that methods utilizing human genes may qualify for patenting. The Court explained that the issue being decided "[did] not involve patents on new applications of knowledge about" the human genes. *Id.* at 2120. The unanimous Court also quoted Judge Bryson's apt observation that, "[a]s the first party with knowledge of the [gene] sequences, Myriad was in an excellent position to claim applications of that knowledge." *Id.* The Court specifically noted that many of the "unchallenged claims are limited to such applications." *Id.*

Even before *Myriad*, the Court in *Diamond v. Diehr* applied similar reasoning in affirming the patent-eligibility of a method for curing rubber. 450 U.S. 175, 193 (1981). The claim at issue in *Diehr* covered a method of operating a rubber-molding press, and the innovative aspect was using the Arrhenius equation to calculate "when to open the press and remove the cured product." *Id.* at 177–78. Each physical step was known, but the claim, assessed as a whole, was to the patent-eligible improvement of using a particular algorithm together with known steps to achieve an improved result. *Id.* at 188–89.

Consistent with *Diehr* and *Myriad*, the claimed method here—analyzed as a whole—uses known tools in a novel manner based on a unique scientific insight. The invention's improvement is to use known techniques, such as blood fractionation, PCR, and detection, to achieve a useful result in an improved manner.

Furthermore, the claims here do not present the preemption risk of which this Court has frequently warned. The method's ultimate utility is analyzing fetal DNA to determine characteristics of the fetus, such as gender, Rh type, and certain genetic abnormalities. The claims do not prevent others from making those very same determinations using traditional means for analyzing fetal DNA. The claims therefore do not present the preemption concern the *Myriad* Court considered with the patenting of human genes, which might have tied up the basic informational building blocks of the human genome.

The further flaw of the appeals court's analysis is how it avoids the novelty and obviousness

determinations under §§ 102 and 103 by skipping to a cursory conclusion on patent eligibility under § 101. In particular, § 103 provides the preferred analytical framework with which a court can objectively determine whether a claimed diagnostic test is a significant enough advance so as to warrant patent protection. *See KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 427–28 (2007); *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966). Section 101 offers no such objective framework. Instead, it employs undefined and abstract terms such as "abstract" and "preemption."

The Federal Circuit's incorrect application of the law threatens to undermine patent protection for a wide variety of inventions, including diagnostic tests. No informed application of § 101 should decimate the very legal protection that incentivizes the development of so many useful tools that improve the human condition. *See* Rebecca S. Eisenberg, *Diagnostics Need Not Apply*, 21 B.U. J. Sci. & Tech. L. 256, 285 (2015); Christopher M. Holman, *Mayo, Myriad, and the Future of Innovation in Molecular Diagnostics and Personalized Medicine*, 15 N.C. J. L. & Tech. 639, 677 (2014) (identifying the Federal Circuit's decision as "pos[ing] substantial impediments to the patenting of innovations in personalized medicine, an increasingly promising application of diagnostic testing").

Indeed, even Judge Dyk expressed his concern, shared by some of his colleagues, that

> a too restrictive test for patent eligibility under 35 U.S.C. § 101 with respect to laws of nature (reflected in some of the language in

> *Mayo*) may 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.

Ariosa Diagnostics, 809 F.3d at 1287 (Dyk, J., concurring in denial of the petition for rehearing en banc).

Under the Federal Circuit's reasoning, one can make a strong argument that the invention of PCR itself would not be eligible for patent protection, even though it revolutionized biotechnology and was the basis for the 1993 Nobel Prize. PCR used pre-existing materials, such as DNA, primers, DNA polymerase, and deoxynucleoside triphosphates, along with known heating and cooling steps. *See Hoffman-La Roche v. Promega Corp.*, 323 F.3d 1354, 1358 (Fed. Cir. 2003). PCR exploited the natural phenomenon of how DNA replicates to create a revolutionary process, yet no one could reasonably contend that PCR is not eligible for patent protection.

The invention at issue in the present petition can be considered a new, specific use of existing technology, similar to PCR. Considering the claims as whole, they should be patent-eligible. The merits of the claimed invention ought to be considered under the proper analytic framework of § 103.

Patent protection has facilitated the development of medical diagnostic tests of all types, thereby

improving the standard of care in the vast majority of medical decisions. *See* Jim Kling, *Diagnosis or Drug? Will Pharmaceutical Companies or Diagnostics Manufacturers Earn More From Personalized Medicine?*, 8 EMBO Reports 903, 904 (2007) (reporting that "approximately 70% of the decisions made by physicians in the USA are based on the results of a diagnostic test"). Diagnostic tests are ubiquitous, and they provide guidance for the detection and treatment of medical conditions and diseases, such as infectious diseases, HIV infection, cancers, inflammatory disorders, stroke, Alzheimer's, and many others. All of these tests, at their base, are specific applications relying on some natural phenomenon. Absent patent protection, companies will be less inclined to invest in research for new diagnostic tests.

CONCLUSION

For the foregoing reasons, *Amicus Curiae* JYANT Technologies, Inc. respectfully submits that the Court should grant the petition for certiorari.

Respectfully submitted,

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