

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 OF FEDERAL CIRCUIT BAR
ASSOCIATION AS *AMICUS CURIAE* IN
SUPPORT OF PETITION FOR A WRIT OF
CERTIORARI**

EDGAR H. HAUG
PRESIDENT
FEDERAL CIRCUIT BAR
ASSOCIATION
1620 I Street, N.W.
Suite 900
Washington, D.C. 20006
(202) 558-2421

FRANK A. ANGILERI*
BROOKS KUSHMAN PC
1000 Town Center
Southfield, MI 48075
(248) 358-4400
(fangileri@brookskushman.com)

JORDAN A. SIGALE
JULIE L. LANGDON
DUNLAP CODDING PC
225 W. Washington Street
Suite 2200
Chicago, Illinois 60606

*Counsel of Record

Counsel for Amicus Curiae

TABLE OF CONTENTS

INTEREST OF <i>AMICUS CURIAE</i>	1
STATEMENT	2
SUMMARY OF THE ARGUMENT	6
ARGUMENT	8
I. The Court needs to at least clarify the <i>Mayo</i> approach to avoid applications of <i>Mayo</i> that fail to consider each claimed invention as a whole.....	8
A. The <i>Mayo</i> approach must be applied to the claimed invention as a whole.....	9
II. Applying the <i>Mayo</i> approach to the “claim as a whole” is consistent with this Court and the Federal Circuit’s interpretation of other sections of the patent statute	12
CONCLUSION	15

TABLE OF AUTHORITIES

Cases

<i>Alice Corp. Pty. Ltd. v. CLS Bank Int'</i> , 134 S.Ct. 2347	6, 7, 9, 10
<i>Ass'n for Molecular Pathology v. Myriad Genetics, Inc.</i> , 133 S. Ct. 2107 (2013).....	9
<i>Diamond v. Diehr</i> , 470 U.S. 175 (1987)...	5, 6,10,11,14
<i>Gottschalk v. Benson</i> , 409 U.S. 63 (1972).....	6
<i>Graham v. Deere Co.</i> , 383 U.S. 1 (1966).....	13
<i>KSR Int'l Co. v. Teleflex, Inc.</i> , 550 U.S. 398 (2007)..	13
<i>Mayo Collaborative Servs. v. Prometheus Labs., Inc.</i> , 566 U.S. ____; 132 S. Ct. 1289 (2012).....	2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 14
<i>Parker v. Flook</i> , 437 U.S. 584, 98 S.Ct. 2522, 57 L.Ed.2d 451 (1978).....	3, 6, 9, 10, 11, 14
<i>Richardson v. Suzuki Motor Co.</i> , 868 F.2d 1226 (Fed. Cir. 1989).....	14

Statutes

35 U.S.C. § 101	2, 6, 11, 12, 13, 14, 15
35 U.S.C. § 102	13, 14, 15
35 U.S.C. § 103	13, 14, 15

Rules

S. Ct. Rule 37.2(a)1
S. Ct. Rule 37.6.....1

INTEREST OF *AMICUS CURIAE*¹

Amicus Federal Circuit Bar Association (“FCBA”) is a national organization for the Bar of the United States Court of Appeals for the Federal Circuit. The FCBA unites the different groups across the country that practice before that court, seeking to strengthen and serve the court. One of the FCBA’s objectives is to provide the perspective of disinterested practitioners, including through *amicus curiae* briefs filed with this Court, on issues affecting practice before the Federal Circuit.²

The FCBA has a particular interest in the adjudication of matters falling within the exclusive jurisdiction of the Federal Circuit, including matters involving patent cases. Many members of the FCBA work in the area of patent law, and those members of

¹ Pursuant to Supreme Court Rule 37.6, counsel for amicus represent that they authored this brief in its entirety and that none of the parties or their counsel, nor any other person or entity other than amicus, its members, or its counsel, made a monetary contribution intended to fund the preparation or submission of this brief. Further, in the Association, no government board or association members participated in the decision to file the amicus brief or in shaping the contents of the brief.

² Pursuant to Rule 37.2(a), counsel for amicus represent that all parties were provided notice of amicus’s intention to file this brief at least 10 days before its due date and that all parties have consented to the filing of this brief. Counsel for petitioner and respondents have filed letters with the Clerk granting blanket consent to the filing of amicus briefs. Those letters were filed on March 28, 2016, March 30, 2016 and March 31, 2016.

the FCBA share an interest in settled, reliable jurisprudence regarding important issues in patent law. This is overwhelmingly true in regards to establishing the proper scope for 35 U.S.C. § 101.

STATEMENT

Sequenom petitioned for a writ of certiorari from the Federal Circuit's ruling that application of the Supreme Court's opinion in *Mayo* mandated invalidity of Sequenom's claimed inventions under 35 U.S.C. § 101, notwithstanding Sequenom's revolutionary discovery that "combined and utilized man-made tools of biotechnology in a new way." Pet.App. 18a. Sequenom's question presented can be found in Petitioner's Writ. While agreeing with Petitioner's reasons, the FCBA independently presents its reasons this Court should grant certiorari.

Sequenom researchers discovered the existence of cell-free fetal DNA ("cffDNA") in maternal plasma, a biological material that was previously discarded by medical professionals. Their invention – disclosed in U.S. Patent No. 6,258,540 -- created diagnostic tools that tested for various fetal health issues (*e.g.* Down Syndrome, gender, RhD hemolytic disease) while avoiding the significant risks to the mother and the pregnancy that were inherent in the prior art techniques for obtaining such results. Pet.at 2-4.

After the district court invalidated the '540 patent under 35 U.S.C. § 101, Sequenom appealed to the

Federal Circuit, which affirmed the district court by applying *Mayo*³ and reasoned that the asserted patent claims “begin[] and end[] with a naturally occurring phenomena.” Pet.App. 9a-10a. Applying the second step of the *Mayo* framework, the Federal Circuit noted:

we examine **the elements** of the claim to determine whether the claim contains an inventive concept sufficient to “transform” the claimed naturally occurring phenomenon into a patent eligible application. 132 S.Ct. at 1294.

* * *

Mayo made clear that transformation into a patent-eligible application requires “more than simply stat[ing] the law of nature while adding the words ‘apply it.’” *Id.* at 1294. . . . For process claims that encompass natural phenomenon, **the process steps** are the additional features that must be new and useful. *See Parker v. Flook*, 437 U.S. 584, 591, 98 S.Ct. 2522, 57 L.Ed.2d 451 (1978) (“The process itself, not merely the mathematical algorithm, must be new and useful.”).

* * *

The method at issue here amounts to a general instruction to doctors to apply routine, conventional techniques when

³ *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. ___; 132 S. Ct. 1289 (2012).

seeking to detect cffDNA. Because **the method steps** were well-understood, conventional and routine, the method of detecting paternally inherited cffDNA is not new and useful. The only subject matter new and useful as of the date of the application was the discovery of the presence of cffDNA in maternal plasma or serum.

Pet.App. 12a-13a (emphasis added).

In concurring opinions to the merits panel decision and subsequent denial of *en banc* rehearing, Federal Circuit Judges Linn, Lourie, Moore, and Dyk expressed their beliefs that the framework set forth in *Mayo* may not yield the correct result for meritorious inventions, including the invention claimed in the '540 patent. *See* Pet.App. 20a- 24a and 75a-82a.

Judge Linn expressed concern that *Mayo*'s "blanket dismissal" of "post-solution activity that is purely conventional or obvious" makes some otherwise meritorious inventions patent-ineligible. Pet.App. 22a. To bolster his point, Judge Linn noted that the Supreme Court's blanket dismissal did not impact the invention at issue in *Mayo* because the claims "were the very steps that doctors were already doing;" yet that same "blanket dismissal of conventional post-solution steps leaves no room to distinguish *Mayo* from this case, even though here *no one* was amplifying and detecting paternally inherited cffDNA using the plasma or serum of

pregnant mothers.” Pet.App. 22a (emphasis in original).

Judge Lourie, joined by Judge Moore, concurring with the denial of Sequenom’s petition for *en banc* rehearing, observed that *Mayo* specifically requires that we “divorce the additional steps from the asserted natural phenomenon to arrive at a conclusion that they add nothing innovative to the process.” Pet.App. 81a. En route to acknowledging the inescapable invalidity of Sequenom’s patent claims under that rubric, Judge Lourie noted this Court’s seemingly inconsistent statement from twenty-five years ago that “[a]pplications of natural phenomena or laws to a known process ‘may well be deserving of patent protection.’” Pet.App. 79a (quoting *Diamond v. Diehr*, 450 U.S. 175, 187 (1981)).

Judge Dyk expressed concern that “a too restrictive test for patent eligibility under 35 U.S.C. § 101 with respect to laws of nature . . . may discourage development and disclosure of new diagnostic and therapeutic methods” Pet.App. 84a.

SUMMARY OF THE ARGUMENT

Certiorari should be granted in this case because the substantial increase in patent invalidity judgments that has followed *Mayo and Alice* threatens to disrupt a significant segment of the American Economy: the medical/biotech industry. The overbreadth with which the lower courts have applied these precedents has also similarly disrupted the software industry. This Court found itself in a similar situation nearly twenty-five years ago in *Diehr*, 470 U.S. 175. At that time, the Court had recently issued rulings on 35 U.S.C. §101 in *Flook*, 437 U.S. 584 and *Gottschalk v. Benson*, 409 U.S. 63 (1972). Then, as now, the lower courts were broadly interpreting the judicial exception to § 101 as set forth in *Flook* and *Benson*. The importance to the United States economy of a well-defined, appropriately-drawn test for patent eligible subject matter cannot be overstated. Moreover, the facts presented by Sequenom's Petition, like the controversy in *Diehr*, provide an excellent opportunity for this Court to provide a navigation point for inventors, competitors, the Patent Office, and the lower courts, to assess patent-eligible subject matter under § 101.

The Federal Circuit stated that the broad application of *Mayo* led it to invalidate method patent claims that it believed “**combined and utilized man-made tools** of biotechnology **in a new way.**” Pet.App. 18a (emphasis added). The

varying Federal Circuit concurrence opinions highlight that the Judges believed *Mayo* permitted no other result, despite their agreement that the invention was inventive and of huge value in the field of prenatal medicine. These opinions from the Federal Circuit signal that *Mayo* has been misconstrued as prescribing a bright-line test for § 101 eligibility, discounting this Court's oft-stated reluctance to apply bright line tests in patent cases. It is hard to fathom that the Court intended for *Mayo* to be read in a vacuum as it is being interpreted by the lower courts (i.e. "blanket dismissal" of "post-solution activity that is purely conventional or obvious" Pet.App. 22a.) The lower courts continue to struggle with *Mayo* and incorrectly dissect the claims, even though in *Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, the Court noted that "the approach [] made explicit in *Mayo* considers all claim elements, both individually and in combination, [and] it is consistent with the general rule that patent claims 'must be considered as a whole.'" 134 S. Ct. 2347, 2355, n.3 (2014). Emphasizing this footnoted-nuance from *Alice* into the already existing *Mayo* framework would help the patent system regain its footing by clarifying the limits of patent-eligible subject matter.

For at least foregoing, this Court should grant certiorari to provide the Court with an opportunity to further guide the various stakeholders to a better understanding of this judicially-created exception to patentable subject matter.

ARGUMENT

I. THE COURT NEEDS TO AT LEAST CLARIFY THE *MAYO* APPROACH TO AVOID APPLICATIONS OF *MAYO* THAT FAIL TO CONSIDER EACH CLAIMED INVENTION AS A WHOLE

The opinion below explicitly states that the merits panel “examined the elements of the claim,” rather than considering each claim as a whole, as required by this Court’s precedent. Pet.App. 12a.

By erroneously viewing the claims element by element, and divorcing the “natural phenomenon” from the analysis, the Federal Circuit mis-applied *Mayo*. In so doing, the panel missed the impact sought by this Court from its preceding cases. The result would have been different had the Federal Circuit considered patent eligibility in view of the claimed invention as a whole: *i.e.*, the specific application of a natural phenomenon together with the process steps recited in the claimed invention. No one had ever amplified and detected paternally inherited cffDNA, thus the claim 1 **as a whole** was not well-understood, routine, or conventional. In fact, it was the unprecedented and counter-intuitive – prior to Sequenom’s invention, researchers would discard the maternal plasma as useless. Pet.at 5.

A. The *Mayo* Approach Must Be Applied to the Claimed Invention as a Whole

The lower courts' application of the *Mayo* approach has gotten critically off-track by failing to consider this Court's *Mayo* and *Alice* opinions in combination with its § 101 opinions preceding *Mayo*. This Court has consistently recognized that all inventions are likely to incorporate a law of nature, natural phenomena, or abstract idea to some degree, and that a claimed process is not patent ineligible simply because it involves patent ineligible subject matter. *Mayo*, 132 S. Ct. at 1293. This Court has also consistently recognized that claims that incorporate ineligible subject matter can be transformed into patent eligible subject matter by the addition of other claim elements, such as additional steps in a process claim. *Id.* at 1294. For example, in *Myriad*, which was decided after *Mayo*, this Court agreed with Federal Circuit Judge Bryson that "as the first party with knowledge of the [genes], *Myriad* was in an excellent position to claim applications of that knowledge." *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107, 2120 (2013). Thus, this Court appreciates that process claims incorporating patent ineligible subject matter may be patent eligible.

Mayo set forth an approach to determine when ineligible subject matter is "transformed" into patent eligible subject matter. Specifically, in applying the second part of the *Mayo* framework, the Court analyzed the additional steps of the claim

individually **and as an ordered combination** to determine whether those steps added anything to or transformed the “law of nature.” *Mayo*, 132 S. Ct. at 1297 (emphasis added). As the Court indicated:

“[t]he question before us is whether **the claims** do significantly more than simply describe these natural relations. To put the matter more precisely, **do the patent claims add enough** to their statements of the correlations to allow the processes they describe to qualify as patent-eligible processes that apply natural laws?”

Id (emphasis added). The Federal Circuit has construed this statement as an over-arching “test” for patent eligibility. In *Alice Corp.*, this Court characterized this statement, not as a “test” but as an “approach [] made explicit in *Mayo* [that] considers all claim elements, both individually and in combination [and] is consistent with the general rule that patent claims ‘must be considered as a whole.’” 134 S. Ct. at 2355, n.3. Thus, if there was any doubt, this Court made clear that a proper § 101 analysis must be applied to the claim as a whole.

Furthermore, the precedents cited within *Mayo* also explicitly note that the claim must be considered as a whole. *See Flook*, 437 U.S. at 592 and *Diehr*, 450 U.S. at 184-185, 188. In *Diehr*, the Court made particularly pertinent comments:

In determining the eligibility of respondents’ claimed process for patent protection under

§ 101, **their claims must be considered as a whole. It is inappropriate to dissect the claims into old and new elements** and then to ignore the presence of the old elements in the analysis. This 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.** The “novelty” of any element or steps in a process, or even of the process itself, is of no relevance in determining whether the subject matter of a claim falls within the § 101 categories of possibly patentable subject matter.

Id. at 188 (emphasis added). Also, in a footnote, the Court criticized the *Diehr* petitioner for suggesting that the Court, in *Flook*, held that the abstract idea could not be considered in a § 101 analysis. *Id.*, n. 12. The Court reasoned that the petitioner’s position would “make all inventions unpatentable” and “would also undermine our earlier decisions regarding the criteria to consider in determining the eligibility of a process for patent protection.” *Id.* Without clarity on the proper way to apply the *Mayo* framework to the claim (as a whole vs. an element-by-element basis), the lower courts may adopt the same rejected position of the *Diehr* petitioner.

Nothing in the *Mayo* opinion squarely instructs the courts to separate the claims into parts (the patent ineligible part and the remaining steps part) and analyze those parts separately and independently from the claim as a whole. And, nothing suggests that the second step of the *Mayo* approach should be conducted in the absence of the law of nature, natural phenomena, or abstract idea. But, to be fair, nothing in *Mayo* says not to do that either, and thus, it is easy to appreciate the Federal Circuit's approach.

By not considering the claim as a whole, the lower courts give no consideration to the disclosure of a natural phenomenon used in a manner which is not well-understood, routine, or conventional. Unfortunately, the Federal Circuit reasoned that *Mayo* compelled that approach, and thus, it is imperative to grant certiorari to correct and eliminate the misimpression under which the lower courts continue to operate.

II. APPLYING THE *MAYO* APPROACH TO THE “CLAIM AS A WHOLE” IS CONSISTENT WITH THIS COURT AND THE FEDERAL CIRCUIT’S INTERPRETATION OF OTHER SECTIONS OF THE PATENT STATUTE

The current application of the *Mayo* approach to determine what is patent eligible under 35 U.S.C. § 101 is in conflict with related sections of the Patent Act, and with the Court and Federal Circuit's

interpretation of the related sections of the Patent Act. 35 U.S.C. Chapter 10 specifically deals with patentability, and is broken up into sections, including 101 (inventions patentable), 102 (conditions of patentability, novelty), and 103 (conditions of patentability, non-obvious subject matter.) Sections 102 and 103 have always required consideration of the claim as a whole. Section 103 specifically indicates:

A patent for a claimed invention may not be obtained, notwithstanding that the claimed invention is not identically disclosed as set forth in section 102, if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains.

35 U.S.C. § 103 (emphasis added). In analyzing this section, the Court has indicated that an invention may be found obvious if “there existed at the time of invention a known problem for which there was an obvious solution **encompassed by the patent’s claims.**” *KSR Int’l Co. v. Teleflex, Inc.*, 550 U.S. 398, 420 (2007) (emphasis added); *see also, Graham v. Deere Co.*, 383 U.S. 1, 13 (1966) (reasoning that the subject matter as a whole is that which is defined in the claims.) Thus, the Court’s position is that

obviousness must be analyzed in the context of a claim as a whole.

Likewise, § 102 has been interpreted as requiring a similar and consistent analysis. The Federal Circuit has reasoned an invention is anticipated when a single prior art reference contains “each and every element of a claimed invention” and those elements are “literally present, arranged as in the claim.” *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236 (Fed. Cir. 1989). As such, in determining whether a prior art reference anticipates a claimed invention, the court must consider the prior art reference in view of the whole claim (including the elements and the arrangement of those elements). Ironically, although this language is very similar to the language set forth in *Mayo* (consider the steps separately, and as an ordered combination), the lower courts are not applying it as they would in a § 102 analysis where they would analyze the claimed invention as a whole.

It is logical that, just as §§ 102 and 103 require that the prior art reference(s) teach the claim as a whole in order to bar patentability, a consistent statutory interpretation of § 101 also requires an analysis of the claim as a whole to determine whether patent eligible subject matter is claimed. In fact, this interpretation comports with this Court’s earlier § 101 analysis. *See e.g. Flook*, 437 U.S. at 592; *Diehr*, 450 U.S. at 188. A contrary interpretation leads to inconsistency, conflict, and uncertainty in this area of patent law. As such, the Court should

grant certiorari to take this opportunity to align the test applied under 35 U.S.C. § 101 with those tests applied under §§ 102 and 103.

CONCLUSION

Because it raises an important question of patent law that impacts many inventors, patent owners, competitors, the Patent Office, and the lower courts, the petition for a writ of certiorari should be granted.

EDGAR H. HAUG
PRESIDENT
FEDERAL CIRCUIT BAR
ASSOCIATION
1620 I Street, N.W.
Suite 900
Washington, D.C. 20006
(202) 558-2421

FRANK A. ANGILERI*
BROOKS KUSHMAN PC
1000 Town Center
Southfield, MI 48075
(248) 358-4400
(fangileri@brookskushman.com)

JORDAN A. SIGALE
JULIE L. LANGDON
DUNLAP CODDING PC
225 West Washington Street,
Suite 2200
Chicago, Illinois 60606
(312) 651-6744
(jsigale@dunlapcoddington.com)

Counsel for Amicus Federal Circuit Bar Association

April 20, 2016