

**United States Court of Appeals
for the Federal Circuit**

ARIOSIA DIAGNOSTICS, INC., and NATERA, INC.,

Plaintiffs-Appellees,

and

DNA DIAGNOSTICS CENTER, INC.,

Counterclaim Defendant-Appellee,

v.

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

Defendants-Appellants,

and

ISIS INNOVATION LIMITED,

Defendant.

Appeals from the United States District Court for the Northern District of California in Nos. 3:11-cv-06391-SI, and 3:12-cv-00132-SI, Judge Susan Y. Illston.

**BRIEF OF INTELLECTUAL PROPERTY OWNERS ASSOCIATION
AS *AMICUS CURIAE* SUPPORTING APPELLANTS AND IN FAVOR
OF REHEARING EN BANC**

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August 27, 2015

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

Ariosa Diagnostics, Inc v. Sequenom, Inc.

Nos. 2014-1139, -1144

CERTIFICATE OF INTEREST

Counsel for the Amicus Curiae, Intellectual Property Owners Association, certifies the following (use “None” if applicable; use extra sheets if necessary):

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2. The name of the real party in interest (if the party named in the caption is not the real party in interest) represented by me is:

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

Philip S. Johnson, Kevin H. Rhodes, and Herbert C. Wamsley,
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TABLE OF CONTENTS

TABLE OF AUTHORITIES *ii*

INTEREST OF *AMICUS CURIAE* 1

SUMMARY OF ARGUMENT 2

ARGUMENT 3

 I. The *En Banc* Court Should Clarify That a Claimed Invention Must Be
 Analyzed as a Whole to Determine Its Patent Eligibility..... 3

 II. The *En Banc* Court Should Hold That Evidence of a Lack of Undue
 Preemption Supports a Finding of Patent Eligibility..... 8

CONCLUSION 10

TABLE OF AUTHORITIES

Cases

<i>Alice Corp. Pty. v. CLS Bank Int'l</i> , 134 S. Ct. 2347 (2014).....	3, 4, 8
<i>Ariosa Diagnostics, Inc. v. Sequenom, Inc.</i> , 788 F.3d 1371 (Fed. Cir. 2015).....	<i>passim</i>
<i>Ass’n for Molecular Pathology v. Myriad Genetics, Inc.</i> 133 S. Ct. 2107 (2013).....	6, 7, 8
<i>Bilski v. Kappos</i> , 561 U.S. 593, 130 S. Ct. 3218 (2010)	n.3
<i>Diamond v. Chakrabarty</i> , 447 U.S. 303, 100 S. Ct. 2204 (1980).....	8
<i>Diamond v. Diehr</i> , 450 U.S. 175, 101 S. Ct. 1048 (1981).....	3-4
<i>Mayo Collaborative Servs. v. Prometheus Labs., Inc.</i> , 132 S. Ct. 1289 (2012).....	<i>passim</i>

Statutes and Rules

35 U.S.C. § 101	2, 7, 9
Fed. R. App. P. 29	1
Fed. R. App. P. 35(a)(2).....	2
Fed. Circ. R. App. P. 29	1

The Intellectual Property Owners Association (IPO) submits this brief as *amicus curiae* pursuant to Fed. R. App. P. 29 and Rule 29 of this Court. IPO supports the petition for rehearing *en banc* filed by Sequenom Center For Molecular Medicine, LLC and Sequenom, Inc. (Sequenom) to clarify the analysis for determining the patent-eligibility of a claimed invention in view of the evolving Supreme Court jurisprudence on patent-eligible subject matter.

INTEREST OF AMICUS CURIAE

Amicus curiae IPO is a trade association representing companies and individuals in all industries and technology fields who own or are interested in intellectual property.¹ IPO's members include over 200 companies and 12,000 individuals involved in the association through their companies or as inventor, author, executive, law firm or attorney members. Founded in 1972, IPO represents the interests of all intellectual property owners. IPO regularly represents its members' interests before Congress and the United States Patent and Trademark Office (PTO) and has filed *amicus curiae* briefs in this and other courts on

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. A Motion for Leave to File as Amicus is being filed with this brief.

significant intellectual property issues. The Appendix lists IPO's Board of Directors, which approved filing this brief.²

SUMMARY OF ARGUMENT

This appeal presents a question of exceptional importance: how to determine, in view of the extensive recent Supreme Court jurisprudence on the subject, whether a claimed invention includes sufficiently more than patent-ineligible subject matter and thus is eligible for patenting under 35 U.S.C. § 101, including whether evidence that a claim at issue does not unduly preempt ineligible subject matter is relevant to such an analysis? *En banc* review is therefore appropriate, *see* Fed. R. App. P. 35(a)(2), and is of great interest to the patent owning community represented by IPO. IPO urges this Court, sitting *en banc* to hold that a claimed method must be considered as a whole for purposes of determining patent eligibility, and may not be dissected into its individual steps when considering whether it claims more than routine, conventional, and well-understood activity. Further, IPO urges the Court to clarify that evidence that a claim does not unduly preempt use of ineligible subject matter strongly supports a finding that it recites a patent-eligible invention.

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

ARGUMENT

I. The *En Banc* Court Should Clarify That a Claimed Invention Must Be Analyzed as a Whole to Determine Its Patent Eligibility

The Supreme 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 Corp. Pty. v. CLS Bank Int'l*, 134 S. Ct. 2347, 2355 (2014); *Mayo Collaborative Servs. v. Prometheus Labs, Inc.*, 132 S. Ct. 1289, 1296-97 (2012). 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. at 2355; *Mayo*, 132 S. Ct. at 1296-97.³

The Supreme 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

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

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 PTO faced with questions of patent-eligibility have not consistently considered claimed inventions in their totality, improperly denying patent protection to deserving inventions. The panel’s decision suffers from the same infirmity of missing the forest for the trees, which will likely proliferate if its decision stands.

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. 788 F.3d 1371, at 1373-74, 1379 (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.⁴ 788 F.3d 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.* 1379-80).

In a concurring opinion, Judge Linn 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. Nevertheless, concurring with the panel’s holding, Judge Linn read language from *Mayo* very broadly, divorced from the claims at issue therein, as “leav[ing] 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. Judge Linn further cautioned that applying an overly broad interpretation of language from *Mayo* could deny patent protection to inventions the *Mayo* Court

⁴ Considering that the claims recite a method of *detecting and analyzing* cfDNA from pregnant women’s blood, not its *existence*, the panel’s unnecessarily broad conception 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.

itself explicitly characterized as patent-eligible, a clearly incongruous result. *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).

Judge Linn’s concerns are very well-founded, but the *Mayo* decision does not compel the result he laments. The claimed methods at issue in *Mayo* are distinguishable from the claims at issue here, because even as an ordered combination as a whole, they 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.* 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, also are distinguishable from the claims that were held to be ineligible for patenting in *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.* (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.” (quoting *Myriad*, 133 S. Ct. at 2117 (emphasis added)). However, in *Myriad*, the 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. *Myriad*, 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 the *Myriad* Court’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 claimed method 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)).

The panel’s misapplication of the Supreme Court’s jurisprudence on this issue is representative of the difficulties courts and the PTO are often having in properly evaluating patent eligibility since *Mayo*. As a result, many inventions are improperly being denied protection and there is significant uncertainty among patentees and patent applicants as to the breadth of the judicially created exclusions from patent eligibility. To assist courts and the PTO in the proper analysis of patent eligibility, IPO urges this Court to emphasize how claimed

methods must be evaluated as a whole when determining patent eligibility.

Preventing the continuing trend of judicial and PTO decisions holding claimed methods to be ineligible for patenting beyond what the Supreme 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 unfortunate 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. The *En Banc* Court Should Hold That Evidence of a Lack of Undue Preemption Supports a Finding of Patent Eligibility

Another aspect of the “question of exceptional importance” at issue in this appeal is whether evidence that a claim does not unduly preempt use of patent-ineligible subject matter is relevant to the analysis of the claimed invention’s patent eligibility. The Supreme 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 patents 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). The panel here 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 ultimate question and conflicts with the Supreme Court’s guidance on patent eligibility.

Taken to its logical conclusion, the panel decision in this case would mean that under the test for patent eligibility described by the Supreme Court in *Mayo*, 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 is not a result compelled by *Mayo* or the other the recent § 101 decisions by the Supreme Court. Indeed, it undermines the entire stated purpose of the Supreme Court’s patent-eligibility jurisprudence: to prevent undue preemption. The approach taken by the panel is not what the Supreme Court said and cannot be what it intended in view of its focus on preventing preemption.

In fact, 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 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 therefore 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, and without using it to identify paternally inherited genes. All those other methods using cffDNA fall outside Sequenom's claims. Dkt. 30-1, Sequenom's Consolidated Opening Brief, at 10-11. Yet the panel improperly disregarded all of this evidence as "moot." 788 F.3d at 1379.

Evidence of a lack of undue preemption, the heart of the Supreme Court's patent-eligibility jurisprudence, should not be excluded from the analysis, and can be accommodated within the two-step framework described in *Mayo*.⁵ 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." IPO urges this Court to rehear this case *en banc* as an opportunity to clarify that evidence of a lack of preemption is never "moot" under the Supreme Court's two-step test for patent eligibility.

CONCLUSION

For all of the foregoing reasons, IPO respectfully requests that this Court rehear this appeal *en banc*.

⁵ This is not to suggest that evidence of lack of undue preemption should be required to demonstrate patent eligibility, however, as the Supreme Court has not imposed such a requirement.

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APPENDIX¹

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CERTIFICATE OF SERVICE

I, Robyn Cocho, being duly sworn according to law and being over the age of 18, upon my oath depose and say that:

Counsel Press was retained by counsel for *Amicus Curiae*, Intellectual Property Owners Association, to print this document. I am an employee of Counsel Press.

On **August 27, 2015**, Counsel for *Amicus Curiae* has authorized me to electronically file the foregoing **Motion** with the Clerk of Court using the CM/ECF System, which will serve via e-mail notice of such filing to any of the following counsel registered as CM/ECF users:

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Additionally, paper copies will also be mailed to the above principal counsel for the parties at the time paper copies are sent to the Court.

Sixteen paper copies will be filed with the Court within the time provided in the Court's rules.

August 27, 2015

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