

No. 2014-1139, -1144

United States Court of Appeals
for the
Federal Circuit

ARIOSIA DIAGNOSTICS, INC. and NATERA, INC.,

Plaintiffs-Appellees,

DNA DIAGNOSTICS CENTER, INC.,

Counterclaim Defendant-Appellee,

– v. –

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

Defendants-Appellants,

ISIS INNOVATION LIMITED,

Defendant.

APPEALS FROM THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT
OF CALIFORNIA IN NOS. 3:11-cv-06391-SI, 3:12-cv-00132-SI,
JUDGE SUSAN Y. ILLSTON

**AMICUS CURIAE BRIEF OF THE NEW YORK INTELLECTUAL
PROPERTY LAW ASSOCIATION IN SUPPORT OF
PETITION FOR REHEARING EN BANC**

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CERTIFICATE OF INTEREST

Pursuant to Fed. Cir. R. 29 and 47.4, counsel for *amicus curiae* New York Intellectual Property Law Association certifies the following:

1. The full name of the parties I represent: New York Intellectual Property Law Association
2. The name of the real parties in interest I represent: New York Intellectual Property Law Association
3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the parties I represent: N/A/
4. The names of all law firms and the partners or associates that appeared for the party now represented by me who appeared in the trial court or are expected to appear in this Court:

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INTEREST OF *AMICUS CURIAE*

This *amicus curiae* brief is submitted on behalf of the New York Intellectual Property Law Association ("NYIPLA").¹

The NYIPLA is a professional association of approximately 1,300 attorneys whose interests and practices lie in the area of patent, trademark, copyright, trade secret and other intellectual property law. The NYIPLA's members include a diverse array of attorneys specializing in patent law, including in-house counsel for businesses that own, enforce and challenge patents, as well as attorneys in private practice who represent entities in various proceedings before the U.S. Patent and Trademark Office ("PTO"). Many of the NYIPLA's member attorneys participate actively in patent litigation, representing both patent owners and accused infringers.

A primary concern of the NYIPLA is that the law applicable to intellectual property be developed in a way that enhances the ability of the clients of its members to conduct their businesses with reasonable certainty concerning the predictability of whether certain patent claims covering inventions developed by them are patent eligible.

¹ Sequenom, Inc., Sequenom Center for Molecular Medicine, LLC (collectively, "Sequenom"), Isis Innovation Limited, Natera, Inc. and DNA Diagnostics Center, Inc., have consented to the submission of this brief. Ariosa Diagnostics, Inc. has indicated that it will not agree to the submission of this brief until after it is filed, at which point it will make a determination. Accordingly, *Amicus Curiae* files concurrently with this brief a motion requesting leave to file.

The arguments set forth in this brief were approved on August 26, 2015 by an absolute majority of the total number of officers and members of the Board of the NYIPLA (including such officers and Board members who did not vote for any reason including recusal), but do not necessarily reflect the views of a majority of the members of the Association or of the firms with which those members are associated.

No party's counsel authored this brief in whole or in part. No party or party's counsel contributed money that was intended to fund preparing or submitting this brief. No person other than *Amicus Curiae*, its members, or its counsel contributed money that was intended to fund preparing or submitting this brief.

After reasonable investigation, the NYIPLA believes that no member of the Board or Amicus Committee who voted to prepare this brief on its behalf, or any attorney in the law firm or corporation of such a Board or Committee member, or attorney who aided in preparing this brief, represents a party with respect to this litigation. Some Committee or Board members or attorneys in their respective law firms or corporations may represent entities which have an interest in other matters which may be affected by the outcome of this litigation.

**THIS CASE PRESENTS A FUNDAMENTAL ISSUE
THAT SHOULD BE REHEARD EN BANC**

The NYIPLA submits this *amicus curiae* brief in support of Sequenom's Petition for Rehearing En Banc, primarily to address the role of preemption in the patent eligibility analysis mandated by *Mayo* and *Alice*. *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289 (2012); *Alice Corp. v. CLS Bank Int'l*, 134 S. Ct. 2347 (2014).

The Supreme Court has long recognized that the proper test for determining patent eligibility is whether the claimed subject matter falls within one of the four statutory classes of subject matter *and does not preempt what this Court has called a "fundamental principle"* (i.e., abstract idea, natural phenomena or law of nature). *See Diamond v. Diehr*, 450 U.S. 175, 185 (1981) (citing *Parker v. Flook*, 437 U.S. 584 (1978); *Gottschalk v. Benson*, 409 U.S. 63, 67 (1972); *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948)). Neither *Mayo* nor *Alice* changed this.

While *Mayo* and *Alice* presented a two-part "framework" to address when a particular claimed invention preempts a "fundamental principle," neither case purported to have that framework replace a preemption inquiry nor authorize a court to ignore the ultimate question, i.e., does the claim preempt a fundamental principle instead of merely claim a practical application of such a principle?

The NYIPLA does not address here whether the claims in Sequenom's patent are patentable. However, the NYIPLA believes that the Panel erred in concluding that if claims are patent ineligible under the two-part framework of *Mayo* and *Alice*, then the preemption inquiry is rendered moot. For at least this reason, rehearing en banc should be granted.

This is the right case to address this error because there is no preemption on the facts of this case and, as Judge Linn's concurrence acknowledges, the Panel's application of the Supreme Court's framework in *Mayo* deprived "a meritorious invention from the patent protection it deserves and should have been able to retain" and that "Sequenom 'effectuate[d] a practical result and benefit not previously attained,' so its patent would traditionally have been valid." Concurring Op. at 4. This error warrants review en banc because, *inter alia*, the PTO and district courts have repeated this error in their guidelines and holdings.²

² Whether the Supreme Court eventually may be asked to reconsider the framework of *Mayo* and *Alice* as a result of this or another case is beyond the scope of this brief. Nevertheless, this Court can and should determine that the *Mayo* and *Alice* framework do not limit the patent eligibility of otherwise meritorious inventions in the absence of preemption.

THE *MAYO* FRAMEWORK DOES NOT MOOT PREEMPTION

The claims in Sequenom's U.S. Patent No. 6,258,540 ("the '540 patent") are directed to noninvasive detection of paternally inherited cell-free fetal DNA ("cffDNA") in the blood or plasma of pregnant women,³ allowing for early detection of certain genetic traits without the serious risks posed by prior procedures, such as amniocentesis. Sequenom offered evidence that there are other uses of cffDNA other than those claimed in the '540 patent and thus, preemption did not exist.

In this case, the Panel held that several claims in the '540 patent were invalid because they were not directed to patent-eligible subject matter under the *Mayo* framework. The Panel further concluded that "[w]here a patent's claims are deemed only to disclose patent ineligible subject matter under the *Mayo* framework, as they are in this case, ***preemption concerns are fully addressed and made moot.***" Op. at 14-15 (emphasis added). The Panel did so while acknowledging that "[t]he Supreme Court has made clear that the principle of preemption is the basis for the judicial exceptions to patentability." *Id.* at 14

³ Claim 1 of the patent reads: "A method for detecting a paternally inherited nucleic acid of fetal origin performed on a serum or plasma sample from a pregnant female, which method comprises amplifying a paternally inherited nucleic acid from the serum or plasma sample and detecting the presence of a paternally inherited nucleic acid of fetal origin in the sample."

(citing *Alice*, 134 S. Ct. at 2354). *Amicus Curiae* respectfully submits that the Panel's conclusion is clear error and needs to be corrected.

The Panel erroneously applied the *Mayo* framework in a mechanical manner (much like the machine or transformation test, Friedman-Walter-Abele and technological arts tests had been applied in the past), ignoring the goal of the inquiry—to determine if the claim includes enough "something more" to avoid preempting the fundamental principle in question. This type of rigid analysis of prior Supreme Court patent-eligibility frameworks was rejected in *Bilski v. Kappos*, 561 U.S. 593 (2010) and is likewise incorrect here.

It is well-settled that the proper test for determining patent eligibility is whether the claimed subject matter falls within one of the four statutory classes of subject matter *and does not preempt* a so called fundamental principle. *Diehr*, 450 U.S. at 185. In *Diehr*, the Supreme Court acknowledged these as "long-established standing principles." *Id.* (referring to *Parker*, 437 U.S. 584 and *Gottschalk*, 409 U.S. 63).

The Supreme Court has also made clear that patents that "pose no comparable risk of pre-emption ... remain eligible for the monopoly granted under our patent laws":

In applying the § 101 exception, we must distinguish between patents that claim the "'buildin[g] block[s]'" of human ingenuity and those that integrate the building blocks into something more, *Mayo* 566 U.S., at ___, 132

S. Ct. at 1303, thereby "transform[ing]" them into a patent-eligible invention, *id.*, at ___, 132 S. Ct. at 1294. ... ***The latter pose no comparable risk of pre-emption, and therefore remain eligible for the monopoly granted under our patent laws.***

Alice, 134 S. Ct. at 2354-55 (emphasis added).

The failure to consider preemption has resulted in courts and the PTO over-using §101 in a gatekeeper or threshold fashion for which it was never intended to be used, either as enacted by Congress or as interpreted by the Supreme Court. *Cf. Dann v. Johnston*, 425 U.S. 219, 221 (1976) (avoiding a §101 determination in favor of a §103 analysis).

Accordingly, *Amicus Curiae* respectfully submits that the Panel should have considered preemption when applying the framework of *Mayo*. The full Court should grant rehearing to correct this legal error en banc.

Since this error has made its way into the PTO's Patent-Eligibility Guidelines and into decisions of the district courts, it is important that it be addressed promptly by this Court.

CONCLUSION

For the reasons set forth above, this Court should order rehearing en banc to hold that preemption is a necessary consideration when analyzing claims in a patent eligibility determination.

Dated: August 27, 2015

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B). The brief contains 1,553 words, according to the word processing system used in preparing it, excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii) and Fed. Cir. R. 32(b).

This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6). The brief has been prepared in a proportionally spaced typeface using Microsoft Word in 14 point Times New Roman font.

Dated: August 27, 2015

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CERTIFICATE OF FILING AND SERVICE

United States Court of Appeals for the Federal Circuit

Ariosa Diagnostics Inc. v. Sequenom, Inc., et al., 2014-1139,-1144

I, Maryna Sapyelkina, hereby certify that on this 27th of August, 2015, I caused the foregoing ***Amicus Curiae* Brief of The New York Intellectual Property Law Association in Support of the Petition for Rehearing *En Banc*** to be filed with the Clerk of the Court using the CM/ECF system. I also caused a true and correct copy of the foregoing Notice of Appearance to be electronically served on counsel of record for Appellants and Appellees, and Counsel for *Amici Curiae*, registered as CM/ECF users.

Upon acceptance by the Court of the e-filed document, six paper copies of the Brief will be filed with the Court, via Federal Express, within the time provided in the Court's rules.

August 27, 2015

/s/ Maryna Sapyelkina
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