Nos. 2014–1139, 2014–1144

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

ARIOSA DIAGNOSTICS, INC., 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.

BRIEF OF PROFESSORS JEFFREY A. LEFSTIN AND PETER S. MENELL AS *AMICI CURIAE* IN SUPPORT OF REHEARING EN BANC

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CERTIFICATE OF INTEREST

Pursuant to Fed. Cir. Rule 47, counsel for *amici* certifies the following:

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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:

N/A

3. All parent corporations and any publicly held companies that own 10% or more of the stock of the parties represented by me are:

None

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

Professor Jeffrey A. Lefstin

Dated: August 26, 2015

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Statement Regarding Authorship and/or Funding

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1. No party's counsel took any part in authoring this brief.

2. No party or party's counsel contributed money that was intended to fund preparing or submitting the brief.

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STATEMENT OF INTEREST OF *AMICI CURIAE*

The authors of this brief are professors of law at the University of California who study and teach intellectual property law. *Amici* have both explored the patent-eligibility doctrine in their scholarship, and submit this brief to assist this Circuit in developing the law of patent-eligible subject matter.

Professor Jeffrey Lefstin holds a law degree and a doctorate degree in biochemistry. His scientific papers on molecular biology and genetics appeared in *Nature*, *Genes & Development*, and the *Journal of Molecular Biology*. Much of his research has focused on the historical development of patent law and its institutions.

Professor Peter Menell holds a law degree and a doctorate degree in economics. He co-founded the Berkeley Center for Law & Technology in 1995. Since 1998, he has organized more than 50 judicial education programs in conjunction with the Federal Judicial Center, circuit courts, and district courts on intellectual property law and is co-author of a widely used treatise on patent case management.

ARGUMENT

I. This Case Presents Vitally Important Issues at a Critical Juncture in the Development of Patent-Eligibility Law.

The past 40 years have witnessed the most rapid period of technological change in our nation's history. Advances in bioscience and digital technology have opened up vast new scientific fields. The patent system has struggled to keep pace. But much of this change has occurred in a policy vacuum. Congress has been reluctant to weigh in on the scope of patentable subject matter, and the Supreme Court stood on sidelines for much of this critical period. The Supreme Court cautiously reentered the discussion in 2010 and has since decided four patent-eligibility cases.

In *Bilski v. Kappos*, 561 U.S. 593 (2010) the Court explored the boundaries of the eligibility doctrine in general terms, emphasizing that 35 U.S.C. § 101 is a dynamic provision designed to encompass the unforeseeable progression of science and technology. *See id.* at 605.

Less than two years later, the Court again weighed in on the scope of patent-eligibility in *Mayo Collaborative Services v. Prometheus Laboratories*, 132 S. Ct. 1289 (2012). In contrast to *Bilski*, *Mayo* set forth a broader framework for evaluating patent-eligibility. *Mayo* explained that the distinction between an unpatentable law of nature and a patentable invention lay in the patentee's application: whether it evinced an "inventive concept" beyond the underlying law

of nature. The concise opinion glossed over several key issues, including how to reconcile prior discordant decisions (*Flook* and *Diehr*), and whether the requirement of "inventive concept" demands an unconventional application, or merely more than the generic instruction to "apply the law." Justice Breyer, the architect of *Mayo*, later commented that *Mayo* did no more than "sketch an outer shell of the content" [1] of the patent-eligibility test, leaving the content to be developed by the patent bar in conjunction with the Federal Circuit.[2]

The next year, in *Association for Molecular Pathology v. Myriad Genetics*, 133 S. Ct. 2107 (2013) ("*Myriad*"), the Court addressed claims to DNA sequences. While the Court rejected claims to purified DNA molecules corresponding directly to natural genes, the Court nonetheless upheld the eligibility of claims to cDNAs – DNA molecules derived from naturally occurring RNA by known, conventional, and routine laboratory procedures.

The Supreme Court returned yet again to patentable subject matter with *Alice Corp. v. CLS Bank Int'l*, 134 S. Ct. 2347 (2014). *Alice* confirmed that *Mayo*'s framework governs all patent-eligibility determinations under § 101. Like *Mayo* and *Bilski*, *Alice* sketched the outer limits of patent-eligibility in general terms. *Alice* made clear that a generic instruction to "apply it on a computer" could not

[1] Transcript of Oral Argument at 28, *Alice Corp. v. CLS Bank Int'l*, 134 S. Ct. 2357 (No. 13-298) (comment of Justice Breyer).

[2] *See id.*

transform a fundamental principle of business or economics into a patent-eligible invention.

The primary responsibility for developing patent-eligibility doctrine now rests with this Circuit, and this case presents an ideal vehicle for testing and explicating the proper boundaries.

The panel's decision uncritically accepts an expansive reading of *Mayo* that conflicts with insights from *Myriad* and *Alice*. The panel's holding could significantly upend patent protection for a critical field of scientific research. There is serious risk that failure to engage this issue at this juncture could set the patent system on a dire course. En banc review would provide perhaps the last clear chance to ventilate vital questions about patentability of diagnostic testing, one of the most important areas of biomedical research.

It remains to be seen whether patent protection is the most appropriate regime for promoting this area of bioscience research. But given Congress's reluctance to take on these critical questions and the Supreme Court's less than lucid articulation of standards, the Federal Circuit has an especially important role in ensuring that this controversy receives thorough evaluation. At a minimum, such an effort would assist Congress, the Supreme Court, and the public in better understanding the issues. Failure to review this case en banc risks cementing a speculative interpretation of applicable law.

II. *Mayo* Does Not Condition Patent-Eligibility on Unconventional Application.

In setting forth the applicable legal standard, the panel opinion states that, for claims encompassing natural phenomena, "the process steps are the additional features that must be new and useful." *Ariosa Diagnostics, Inc. v. Sequenom Inc.*, 788 F.3d 1371, 1377 (Fed. Cir. 2015). Because the preparation of plasma and serum from blood was routine and conventional as of the filing date, as were general techniques for the amplification of DNA, *id.* at 1377-78, the panel opinion concluded that none of the claims in suit is patent-eligible under *Mayo*.

However, *Mayo* does not require that a new discovery be applied by unconventional means. Although some language in *Mayo* could be interpreted to set forth unconventional or inventive application as a possible test for patent-eligibility, *Mayo* suggests two other possibilities for an "inventive concept": *non-preemptive* application; and *non-generic* application – that is, more than a statement of a natural law coupled with an instruction to apply it.[3] While the panel was correct to perceive that *Mayo* describes preemption as the underlying justification for the patent-eligibility doctrine, not the operative test, the panel was incorrect to conclude that *Mayo* dictates a test of unconventional application.

A requirement for unconventional application is also inconsistent with the

[3] *See* Jeffrey A. Lefstin, *The Three Faces of Prometheus: A Post-Alice Jurisprudence of Abstractions*, 16 N.C. J .L. & TECH. 647, 663-77 (2015).

Court's post-*Mayo* opinions. In *Myriad*, the Court ruled that cDNA, which is simply a synthetic DNA copy of a naturally occurring mRNA molecule, is patent-eligible. There was no pretense in the case that the act of reverse-transcribing natural mRNA into cDNA was inventive, and indeed the production of cDNA was known, routine, and conventional when the Myriad patents were filed in 1994.[4] Had the Court required unconventional application over the natural phenomenon of mRNA, the Court could not have sustained the eligibility of the cDNA claims.

While *Alice* noted that the implementation of the claims in suit was "routine" and "conventional," the focus of the Court's analysis was whether the claim was to a *generic* application.[5] Unlike *Mayo*, the word "obvious" was conspicuously absent from *Alice*. The question, for the Court, was "whether the claims here do more than simply instruct the practitioner to implement the abstract idea of intermediated settlement on a generic computer." *Alice*, 134 S. Ct. at 2359. *Alice* clarified that the § 101 inquiry asks not whether a claim represents an unconventional application of a fundamental principle, but whether a claim does more than state a fundamental principle, plus a generic instruction to "apply it."

The *Mayo* claims, which recited only the diagnostic correlation, clearly failed that standard: they did nothing but reveal the underlying natural relationship.

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[4] The process of generating a cDNA from mRNA was conventional enough that one of the amici learned it as an undergraduate in the 1980s.

[5] *See id.* at 674-76 (discussing Court's emphasis on generic application).

But at least some of the claims in this case, which claim not cffDNA but the use of cffDNA as a *means* for diagnosing a genetic condition of the fetus, do more than simply claim the natural phenomenon of cffDNA. They might therefore satisfy *Mayo* and *Alice*'s standard of non-generic application.

In light of *Myriad* and *Alice*, the Court's interest in unconventional activity is best understood as a *sufficient* condition for patent-eligibility: claims are patent-eligible if they implement a fundamental principle by unconventional means. The Court in *Mayo* and *Alice* therefore scrutinized the claims for unconventional steps that would definitively confer patent-eligibility, and found none. But the panel opinion here goes well beyond that test by elevating unconventional activity to a sufficient *and necessary* condition for patent-eligibility: claims are patent-eligible if *and only if* they implement a fundamental principle by unconventional means. Given the potentially dire consequences of such an interpretation for biomedical research, the en banc court should reject that interpretation of *Mayo*.

III. *Mayo* and *Alice* Prohibit Dissection of Claims into Old and New Components.

Under the panel opinion's analysis, the § 101 inquiry requires process claims to be dissected into the underlying discovery and the steps by which that discovery is applied – and denies patent-eligibility if the individual steps were previously known in the art. That dissection was expressly forbidden by *Diamond v. Diehr*. 450 U.S. 175, 188 (1981). And *Diehr* further explained that a process may be

patent-eligible even if "all the constituents of the combination were well known and in common use before the combination was made." *Id.*

Diehr laid to rest *Flook*'s suggestion that fundamental principles ought to be treated as part of the prior art, and made clear that even processes consisting of previously known steps could be patent-eligible. Of course, matters are complicated by the Supreme Court's strained pretense that *Diehr* did not overrule *Flook*,[6] and the Supreme Court's reintroduction of *Flook*'s "inventive concept" language in *Mayo*. But it is surely clear that *Diehr*'s prohibition against dissecting claims has not been set aside by the Court's more recent decisions.

Mayo repeated *Diehr*'s statement that processes may be eligible under § 101 even if all the constituent steps were "well known and in common use." *Mayo*, 132 S. Ct. at 1298 (quoting *Diehr*). *Mayo*'s analysis evaluates claim steps "in context," *id.* at 1299, as an ordered combination. *See id.* at 1298. And *Alice* reiterated that the § 101 analysis must consider the claim as a whole, evaluating the significance of additional steps not in isolation, but in the ordered combination recited by claim. *See Alice*, 132 S. Ct. at 2355 n. 3 (quoting *Diehr* and *Flook*). Yet under the panel opinion's statement of the law, any process claim based on a natural phenomenon is ineligible for a patent unless the individual steps of the process are novel.

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[6] *See* John M. Golden, Flook *Says One Thing,* Diehr *Says Another: A Need for Housecleaning in the Law of Patentable Subject Matter*, 82 GEO. WASH. L. REV. 1765 (2014).

IV. The Panel's Rule Invalidates Claims that *Mayo* Deemed Patent-Eligible.

The reach of the test articulated by the panel opinion is difficult to overstate. It may be that *Mayo* and *Myriad*, at least if interpreted broadly, drastically curtail patent protection for new diagnostics.[7] But beyond such larger issues, en banc review is warranted in this case because the rule stated by the panel opinion would invalidate claims that *Mayo* deems to be patent-eligible applications of natural phenomena.

Consider, for example, Neilson's famous patent on the hot-blast smelting process, which disclosed the heating of air prior to its introduction into the blast furnace. The Court of Exchequer's opinion sustaining the patent has been the cornerstone of many of the Supreme Court's foundational cases, such as *O'Reilly v. Morse*, *Tilghman v. Proctor*, *Flook*, and *Mayo* itself.[8] *Mayo* deemed Neilson's invention to be eligible, representing "a particular, useful application" of an underlying principle. *Mayo*, 132 S. Ct. at 1300. Yet under the panel opinion's rule, Neilson's patent would have been invalid. For at the time of the invention, both the heating of air and the introduction of air into the blast furnace were well-known.[9] The only "subject matter new and useful" was the discovery that "hot air promotes

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[7] *See* Rebecca S. Eisenberg, *Diagnostics Need Not Apply*, 21 J. SCI. & TECH. L. (forthcoming 2015) (available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2631679).

[8] *See* Jeffrey A. Lefstin, *Inventive Application: A History*, 67 FLA. L. REV. 565, 593-601 (2105).

[9] *See id* at 586-87.

ignition better than cold air" – which, according the Supreme Court in *Mayo*, was a law of nature. *See id.* at 1300. Under the panel opinion's analysis, because Neilson implemented his discovery by old and known means, his patent would be invalid.

Likewise, *Mayo* states that a typical claim to a new use of an existing drug would be patent-eligible as a particular application of a natural law. *See id.* at 1302. Yet under the panel opinion's statement of the law, a claim to administering a known drug to treat a new condition would be ineligible, because the steps of administering the drug to a patient would be known and conventional at the time of filing. It would be no answer that a typical second medical use claim involves an artificial substance (a drug), versus a natural phenomenon (like cffDNA). For *Mayo* itself deems the response of the human body to an artificial substance to be a law of nature.[10] By focusing on the novelty of the additional steps, rather than on whether those steps represent a particular application of a law of nature as prescribed by *Mayo*, the panel opinion's approach would invalidate claims that the *Mayo* Court intended to preserve.

V. Conclusion.

This case presents critical issues for patent-eligibility jurisprudence, justifying granting the petition for rehearing en banc.

[10] In *Mayo*, the Court regarded the relationship between thiopurine drug dosage, levels of 6-thioguanine in a patient's blood, and therapeutic efficacy as a law of nature. *See Mayo*, 132 S. Ct. at 1296-97.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

Counsel for *amici curiae* certifies that:

1. The brief complies with the page limitation of Fed. Cir. R. 35(g) because, excluding the exempted portions as provided in Fed. R. App. P. 32(a)(7)(B)(iii) and Fed. Cir. R. 32(b), it does not exceed 10 double-spaced pages.

2. The 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)(5), because it has been prepared using Microsoft Word 2011 in a proportionally spaced typeface: Times New Roman, font size 14 point.

Aug. 26, 2015

/s/ Jeffrey A. Lefstin
Jeffrey A. Lefstin

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This is to certify that I have this day filed the foregoing brief via the Court's CM/ECF system, which will provide notification of such filing to all registered CM/ECF users.

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