

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.

Appeal from the U.S. 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 *AMICI CURIAE* AMARANTUS BIOSCIENCE HOLDINGS,
INC., PERSONALIS, INC., AND POPULATION DIAGNOSTICS, INC. IN
SUPPORT OF APPELLANTS' PETITION FOR REHEARING EN BANC**

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August 27, 2015

CERTIFICATE OF INTEREST

Counsel for *amici curiae* Amaranthus Bioscience Holdings, Inc., Personalis, Inc., and Population Diagnostics, Inc. certify the following:

1. The full name of every party represented by me is: Amaranthus Bioscience Holdings, Inc., Personalis, Inc., and Population Diagnostics, Inc.
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: Amaranthus Bioscience Holdings, Inc., Personalis, Inc., and Population Diagnostics, Inc.
3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party or *amici curiae* represented by me are: None.
4. The names of all law firms and the partners and associates that have appeared for the party or *amici curiae* in the lower trial court or agency or are expected to appear for the party or *amici curiae* in this Court are:

Gideon A. Schor, Maya Skubatch, Richard Torczon, and Charles J. Andres, Jr. of Wilson Sonsini Goodrich & Rosati.

Date: August 27, 2015

/s/ Gideon A. Schor
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STATUTES

35 U.S.C. § 112(b)4

STATEMENT OF INTEREST OF *AMICI CURIAE*¹

Amici Amarantus Bioscience Holdings, Inc., Personalis, Inc., and Population Diagnostics, Inc. discover and provide diagnostic tests that use exomes, genomes, and genetic biomarkers. The ability of *amici* to attract investment and to continue operations depends on ensuring that claims to such tests recite patentable subject matter. *Amici* have an interest in ensuring that the legal standard for determining whether those claims recite patentable subject matter does not predispose courts to find patent ineligibility.

ARGUMENT

I. The Lower Courts and the USPTO Need Better Guidelines on How to Determine Patent-Eligible Subject Matter

This Court, in its special role as the only Federal appeals court for patents, should take this opportunity to provide workable § 101 guidance. The first *Alice* test step is being applied too subjectively by courts and the USPTO, leading to unpredictability. The Court has authority to set guidelines within Supreme Court precedent that provides a flexible, workable framework for guideline construction. Greater predictability for courts, the USPTO, patentees, and patent applicants will come from requiring that claims be construed as a whole before validity is determined.

¹ No counsel for any party authored this brief in whole or in part. No party, no party's counsel, and no person other than *amici* and their counsel made a monetary contribution intended to fund the preparation or submission of this brief. A motion for leave to file the within brief has been filed.

A. *The Supreme Court Has Consistently Required Considering the Claims as a Whole*

In *Alice Corporation Pty. Ltd. v. CLS Bank International*, the Supreme Court formalized a framework to determine whether a patent claims a judicial exception (*i.e.*, an abstract idea, natural phenomenon, or law of nature). 134 S. Ct. 2347, 2355 (2014). Under the *Alice* test, a court must first ask “whether the *claims* at issue are *directed to* one of those patent-ineligible concepts”; if so, then the court must ask, “[w]hat else is there in the *claims* before us?” *Id.* (emphasis added). While the Supreme Court did not explicitly define the phrase “directed to,” the wording of the *Alice* test confirms that the focus must be on what is actually claimed, not a single element of a claim. The claim focus of the *Alice* test codifies earlier Supreme Court decisions.

In *Parker v. Flook*, the Supreme Court concluded that the claims at issue attempted to patent a mathematical algorithm. The Court explained:

Our approach . . . is, however, not at all inconsistent with the view that *a patent claim must be considered as a whole*. Respondent’s process is unpatentable under § 101, not because it contains a mathematical algorithm as one component, but because once that algorithm is assumed to be within the prior art, *the application, considered as a whole*, contains no patentable invention.

437 U.S. 584, 594 (1978) (emphasis added). *Flook* also quoted the Court of Customs and Patent Appeals: “if *a claim is directed essentially to* a method of calculating, using a mathematical formula, even if the solution is for a specific purpose, the claimed method is non-statutory.” *Id.* at 595 (quoting *In re Richman*, 563 F. 2d 1026,

1030 (CCPA 1977)). Thus, in making its determination, the *Flook* Court considered the claim and the application as a whole, as well as what the claim was “directed essentially to.” *Id.*

In *Diamond v. Diehr*, the Supreme Court again examined the claims as a whole. The claimed invention was directed to a process for molding rubber into cured precision products. The Court stated:

*Analyzing respondents’ claims . . . we think that a physical and chemical process for molding precision synthetic rubber products falls within the § 101 categories of possibly patentable subject matter. * * * Our conclusion regarding respondent’s claims is not altered by the fact that in several steps of the process a mathematical equation and a programmed digital computer are used.*

450 U.S. 175, 184-85 (1981) (emphasis added).

Considering what the claims as a whole are “directed to” produces a flexible, workable analysis that allows for fact-driven, nuanced decisions of patent-subject matter eligibility. Employing ordinary claim construction, the Supreme Court was able to distinguish the patent subject-matter ineligibility of the algorithm-employing claims in *Flook* from the eligible claims in *Diehr*.

B. Failure to Consider Each Claim as a Whole Leads to Arbitrary and Inconsistent Results

Lack of consistency in the *Alice* test’s application is a problem that this Court has the ability to cure. Lack of predictability harms parties trying to obtain and defend good patents, harms parties trying to invalidate bad patents, and harms innovation in

large technology sectors including personalized medicine, diagnostics, and software. The first *Alice* test step has become so untethered from the actual claim language that the second *Alice* test step has become meaningless. Untethering of the analysis from the claim language is inconsistent with every other form of invalidity analysis and is not what the Supreme Court intended.

This Court once identified claim construction as “an important first step in a § 101 analysis,” *In re Bilski*, 545 F.3d 943, 951 (Fed. Cir. 2008) (en banc) (skipping claim construction only because no claim terms were in dispute), yet this Court subsequently adopted a more permissive approach, allowing courts to proceed without a claim construction. *Bancorp Servs., L.L.C. v. Sun Life Assurance Co.*, 687 F.3d 1266, 1273 (Fed. Cir. 2012) (“we perceive no flaw in the notion that claim construction is not an inviolable prerequisite to a validity determination under § 101”). Untethering claim validity from claim construction leaves the courts (and the USPTO) without any predictable constraints on how the determination will be conducted. This approach is wrong as a matter of controlling statutory authority: a patent must conclude with a claim that particularly and distinctly defines the subject matter of the invention. 35 U.S.C. § 112(b). The claim provides notice both for the patentee on the scope of its exclusive rights and for the rest of the world on what is not within that scope. As this Court has summarized: the name of the game is the claim. *In re Hiniker*, 150 F.3d 1362, 1369 (Fed. Cir. 1998).

Because of this untethering, lower courts and the USPTO have *not* properly applied the plain meaning of “*claims . . . directed to*” in *Alice*’s first test step. Instead, the analysis has become little more than a determination of whether a judicial exception is present in the claim. This determination is made without a consideration of the claim as a whole in light of the specification, and, as such, the first step is improperly deemed satisfied without any rigorous examination of the essence of the claim. For example, lack of proper claim construction led to the following analysis and conclusion:

[T]he asserted claims of the ’540 patent are directed to a multistep method that starts with cffDNA . . . a naturally occurring non-cellular fetal DNA that circulates freely in the blood stream of a pregnant woman. *See, e.g.*, ’540 patent claims 1, 24, 25. . . . The method ends with paternally inherited cffDNA, which is also a natural phenomenon. The method therefore begins and ends with a natural phenomenon. Thus, the claims are directed to matter that is naturally occurring.

Ariosa Diagnostics, Inc. v. Sequenom, Inc., 788 F.3d 1371, 1376 (Fed. Cir. 2015).

This characterization of the invention is inapposite at least for Sequenom’s claim 25. Claim 25 is directed to a:

method for *performing a prenatal diagnosis on a maternal blood sample* [comprising] . . . [A] *obtaining* a non-cellular fraction of the blood sample [B] *amplifying a paternally inherited nucleic acid* from the non-cellular fraction and [C] *performing nucleic acid analysis* on the amplified nucleic acid *to detect paternally inherited fetal nucleic acid*.

Clearly, claim 25 includes in it numerous limitations, *i.e.*, [A]-[C], that do not start and end with the same product.

In reducing this claim to a method that “begins and ends with a natural phenomenon,” the panel abstracts the claimed invention to a general concept in a way that is unprecedented for claim construction and that opens a Pandora’s box for claim analysis in general. It also misses the essence of the invention. Claim 25 is expressly directed to, and solves problems in the field of, prenatal diagnosis by enabling the use of a maternal blood sample in a totally new way. Indeed, the patent’s focus on this revolutionary improvement starts with its title “Non-invasive prenatal diagnosis.” US 6,258,540 B1 at 1:12-17.

Focusing on the claimed invention as a whole is not a panacea for patentees. Some claims will not include the inventive features that might have avoided excessive abstraction. *In re Roslin Inst. (Edinb.)*, 750 F.3d 1333, 1338 (Fed. Cir. 2014) (differences from natural product not in claims). However, the lower courts and the USPTO cannot be permitted to expand the scope of ineligibility by improperly ignoring claim limitations from the outset.

C. This Court Has Addressed Similar Improper Abstraction in Other Contexts and Has Required Focus on the Claims and Specification

A similar abstraction can occur in obviousness analysis of design patents. The first step of the analysis involves translating the design figures into words—a kind of abstraction. *Durling v. Spectrum Furniture Co., Inc.*, 101 F.3d 100, 103 (Fed. Cir. 1996). The Court has struggled with a tendency in the lower courts “to view the

various designs from too high a level of abstraction” such that they define a “general concept” that leaves out the very features that make the design original. *Apple, Inc. v. Samsung Elecs. Co.*, 678 F.3d 1314, 1331-32 (Fed. Cir. 2012) (rejecting abstraction of claimed design to “a rectangular table with four evenly rounded corners and a flat back”); *Durling*, 101 F.3d at 104 (rejecting abstraction to “a sectional sofa with integrated end tables”); *High Point Design LLC v. Buyers Direct, Inc.*, 730 F.3d 1301, 1314 (Fed. Cir. 2013) (rejecting abstraction to “[t]he slipper shown has a smooth exterior and a fuzzy interior”). The remedy is to insist that the courts “add sufficient detail to [the] verbal description of the claimed design to evoke a visual image consonant with [the claimed] design.” *High Point Design*, 730 F.3d at 1314.

The specification provides another invaluable resource in regulating abstraction. For analogous art determinations, this Court’s predecessor recognized a similarly unbounded abstraction problem: without reasonable constraints all art is analogous. The solution was to look to the field of the invention and the nature of the problem solved. If the art in question was not within the same field as the claimed invention and was not solving a reasonably pertinent problem, then it was not analogous. *In re Wood*, 599 F.2d 1032, 1036 (CCPA 1979). As with analogous art, tethering the subject-matter eligibility analysis to what the inventor actually discloses and claims (as it would have been understood by those skilled in the art) maintains a proper focus for the abstraction step.

To avoid untethered abstraction, courts and the USPTO should consider: (i) the claims as a whole, (ii) in light of the specification, (iii) from the perspective of a skilled artisan, as well as (iv) the problem being solved by, (v) and the state of the art at the time of, the claimed invention. Moreover, the above factors should be analyzed on a claim-by-claim basis. A detailed focus on the claim language is the norm in determining patent invalidity, *e.g.*, *Akamai Techs, Inc. v. Cable & Wireless Internet Svs.*, 344 F.3d 1186, 1192, 1195 n.4 (Fed. Cir. 2003) (anticipation); *Abbott Labs. v. Andrx Pharm., Inc.*, 452 F.3d 1331, 1335-36 (Fed. Cir. 2006) (obviousness), making the present application of *Alice*'s first step an unexplained departure from the norm.

Failure to consider a claim as a whole in light of the specification from the perspective of the skilled artisan strips the claim of its inherent context, making it easy to oversimplify the claimed invention as a mere judicial exception. Proper claim construction avoids this de-contextualization and instead forces attention on what was actually claimed. Giving effect to the actual claim language is consistent with the Supreme Court's caution that "we tread carefully in construing this exclusionary principle lest it swallow all of patent law." *Alice Corp.*, 134 S. Ct. at 2354.

II. Excessive Abstraction in Alice's First Step Makes the Second Step a Foregone Conclusion

Alice's second step asks, "[w]hat else is there in the claims before us?" *Id.* Unfortunately, in practice, once a claim is characterized as being "directed to" a judicial exception, the remaining elements are dismissed as merely conventional.

Again, the solution is to look at the claim as a whole. Applying the permissive application of the *Alice* test to *Diehr* claim 1 is instructive because the permissive approach yields the wrong result.

In a permissive analysis, use of a judicial exception in a claim is enough to demonstrate that a claim is directed to the judicial exception. For example, *Sequenom* claim 25, a method of prenatal diagnosis, was held to be directed to “a multistep method that starts with cffDNA . . . [and] ends with paternally inherited cffDNA, which is also a natural phenomenon.” *Ariosa Diagnostics*, 788 F.3d at 1376. Because the *Sequenom* method claims used (*e.g.*, started and ended with) a natural phenomenon, the *Sequenom* claims were held to be “directed to matter that is naturally occurring.” *Id.* at 9.

Similarly, *Diehr* claim 1 is a method claim that operates a rubber molding press with the aid of a digital computer, using an algorithm (based on the Arrhenius equation) to determine when to open the rubber molding press. The computer, employing the algorithm, monitors the rubber curing at frequent intervals from cure beginning to cure end, so *Diehr* claim 1 starts and ends with the judicial exception. Using a permissive interpretation of *Alice*'s first step, *Diehr* claim 1 would be directed to a judicial exception.

The second test step is now foregone because one cannot conclude that the remaining “process steps are the additional features that must be new and useful.”

Ariosa Diagnostics, slip op. at 10. The additional elements in *Diehr* claim 1 (e.g., a computer, rubber molding press, molded articles, rubber) were all long known – that is, these elements were not new and useful. Accordingly, a permissive application of the *Alice* test analysis of *Diehr* claim 1 would hold claim 1 to be patent ineligible subject matter. Because the Supreme Court held *Diehr* claim 1 to be patent eligible subject matter, the permissive application of the *Alice* test must be incorrect.

III. Conclusion

There is a lack of consistency in how courts and the USPTO have been applying the *Alice* test. The permissive approach, which allows scant attention to the actual claim language, has created a chaotic situation in which the lower court’s characterization of the invention is untethered from the claimed invention. The resulting unpredictability is bad for all stakeholders in the patent system. The Court should act to restore greater predictability.

Date: August 27, 2015

Respectfully submitted,

/s/ Gideon A. Schor

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CERTIFICATE OF COMPLIANCE

I hereby certify that this *amicus* brief complies with the page limit requirements of Federal Circuit Rule 35(g) because it is no more than ten pages 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 2010 in 14 point Times New Roman.

Date: August 27, 2015

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CERTIFICATE OF SERVICE

I hereby certify that counsel for the parties have been served with a true and correct copy of the above and foregoing document via the Court's CM/ECF system on August 27, 2015.

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