Nos. 2014–1139, 2014–1144

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

ARIOSA 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. Ilston.

BRIEF OF NOVARTIS AG AS *AMICUS CURIAE* IN SUPPORT OF REHEARING *EN BANC*

Corey A. Salsberg*
NOVARTIS INTERNATIONAL AG
Novartis Campus
CH-4002 Basel
Switzerland
+41 61 324-4320
corey.salsberg@novartis.com

Counsel for Amicus Curiae Novartis AG
**Admitted in California, Massachusetts and to this Court*

CERTIFICATE OF INTEREST

Counsel for *Amicus Curiae* Novartis AG certifies the following:

1. The full name of every party or *amicus curiae* represented by me is:

   Novartis AG.

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

   Not applicable.

3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party or *amicus curiae* represented by me are:

   None.

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

   Corey A. Salsberg (admitted to practice in California, Massachusetts, and in this Court. Appearing as counsel for amicus curiae in this Court).

Date: August 27, 2015

Respectfully submitted,

/s/ Corey A. Salsberg

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INTEREST OF *AMICUS CURIAE*[1] AND INTRODUCTION

Novartis is a global healthcare company whose mission is to discover, develop and successfully market innovative products to prevent and cure diseases, to ease suffering and to enhance the quality of life for patients across the world. Our products, which include innovative medicines, eye-care, high-quality generic medicines and biosimilars, reach more than 1 billion patients around the world every year, treating diseases that range from cancer, to heart disease, to diabetes, Alzheimer's, macular degeneration, malaria, and many more. As the breadth of our portfolio and the span of our patient impact demonstrate, we are at heart an innovation company, relying primarily on our substantial investment in our own research and development (R&D)—$9.9 billion in 2014 alone—to fuel the ingenuity and high-stakes work that it takes to invent, develop and deliver new medicines.

Like others in our industry, to make all of this possible in spite of the high costs and risks inherent in biopharmaceutical R&D, we rely heavily on the strong incentives of the patent system. For over 220 years, those incentives have been available to encourage innovation in all of its forms—for "'anything under the sun that is made by man,'" as Congress reminded us in 1952—subject only to limited judicial exceptions. *Diamond v. Diehr*, 450 U.S.175, 182 (1981) (quoting S. Rep. No. 1979, 82d Cong., 2d Sess., 5 (1952)). In framing the patent-eligibility thresh-

[1] Pursuant to Rule 29(c)(5), *amicus* states that no counsel for a party authored this brief in whole or in part, no party or its counsel contributed money that was intended to fund preparing or submitting the brief, and no one but *amicus* and its counsel contributed financially to the brief's preparation and submission.

old so broadly, Congress plainly understood the pivotal role that 35 U.S.C. §101 plays not only as the system's statutory gatekeeper, but, in practical terms, as technology's "Janus," with the power to begin entire fields of useful Arts—or, if the gates are closed, to end them as abruptly. *See Diamond v. Chakrabarty*, 447 U.S. 303, 315, 308 (1980) (The breadth of Section 101 "embodie[s] Jefferson's philosophy that 'ingenuity should receive a liberal encouragement'" in order "to fulfill the constitutional and statutory goal of promoting 'the Progress of Science and the useful Arts.'") (internal citations omitted).

As a business that depends upon the system every day, we too understand that critical role, and the magnitude of what is at stake every time a court considers narrowing the gates. We have therefore followed every recent court decision closely—*Mayo, Myriad, Alice Corp.*—with concern over the certain and uncertain ways that it might impact the direction of our R&D. We have commented extensively on the USPTO's Subject Matter Eligibility Guidance, urging the Office to proceed with caution and to apply the judicial exceptions no more broadly than the case law requires.[2] And we have actively voiced our concerns in a variety of public fora, from roundtables to public hearings to panel discussions. Though, without doubt, each new decision has raised questions as to precisely where the boundaries lie between patentable human invention and ineligible natural phenomena, we have

[2] *See* Novartis Comments to USPTO Subject Matter Eligibility Guidance (available at http://www.uspto.gov/sites/default/files/patents/law/comments/mm-e-novartis20140731.pdf; and http://www.uspto.gov/sites/default/files/documents/2014ig_e_novartis_2015mar14.pdf).

found reassurance in the Supreme Court's consistent holdings that its seminal cases (*Diehr*, *Chakrabarty*, etc.) remain good law, in its limitation of its holdings to the "particular claims before us," and in its repeated admonitions to interpret those holdings narrowly, lest they "eviscerate patent law." *Mayo Collaborative Services v. Prometheus Labs., Inc.*, 566 U.S. __, 132 S. Ct. 1289, 1293-94 (2012); *see also Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107, 2119-2120 (2013) ("It is important to note what is not implicated by this decision . . . .")

That reassurance has slipped away with the panel's erroneous decision in this case, which ignores the case "most directly on point" (*Diehr*), misinterprets the framework of the principal case on which it relies (*Mayo*), and dangerously expands the judicial exceptions further than any decision in history. *Mayo*, 132 S. Ct. at 1298. As a threshold, purposefully "cast in broad terms" *Chakrabarty*, 447 U.S. at 315, Section 101 and the precedents interpreting it cannot be given the *narrowest* reading when they are readily (and more logically) amenable to a far broader one. As a threshold, intended only as a "general statement" of the categories of "*possibly* patentable subject matter," *Diehr*, 450 U.S. at 189 (emphasis added), the door to the United States patent system cannot foreclose that which the stricter patent laws inside allow. And, as a threshold, designed to "liberal[ly] encourage[]" human ingenuity, *id.*, such a door cannot be correctly construed as a vanishing portal that shrinks in scope with every step of the "Progress of Science and the useful Arts." U.S. Const. art. I, § 8.

Yet, the panel's decision leads to each of these results, all stemming from a fundamental misreading of the *Mayo* eligibility framework. Tragically, the decision goes well beyond merely finding that a particular invention that applies "man-made tools of biotechnology" in a "revolution[ary]" way is ineligible for patenting. Op. 15. Indeed, because, as Judge Linn concludes, the invention in this case "is nothing like" the invention in *Mayo*, Linn Op. 4, the decision threatens to signal to other courts and the USPTO to expand its flawed reasoning to untold numbers of other inventions. For Novartis, that threat begins with our own inventions related to personalized medicine, biomarkers and point-of-care testing, as well as the inventions of third parties upon which we now or may in the future depend to help meet our goal of providing the right medicine to the right patient at the right time. If these inventions are no longer patent-eligible, the incentives to develop them may well disappear, or move overseas, or push us and others to rely on trade secrets, marking the death of a system in which the "public good fully coincides . . . with the claims of the individuals." The Federalist No. 43 (James Madison).

But the threat does not end there. If the same flawed reasoning were to be expanded further to methods of treatment, medical therapies—or to any claim that in some way incorporates a natural phenomenon—the results for drug discovery and development, and for the future of medicine, could be nothing short of devastating. With so much riding on the panel's decision, the beneficiaries of innovation—from inventors, to industry, to patients and society—deserve another look.

ARGUMENT

I. The Panel Decision Impermissibly Narrows the Eligibility Test for Method Claims by Failing to Consider the "Claims as a Whole"

The panel in this case fundamentally erred by misinterpreting the second step of the Supreme Court's test for method claim patent-eligibility. That test, properly applied, does *not* compel the result in this case, but in fact leads readily to the opposite result. The two-part test, set forth in *Mayo*, instructs the courts to first determine whether the claims are directed to a patent-ineligible concept, and second, if they are, to consider whether "other elements *or a combination of elements*, sometimes referred to as an 'inventive concept'" transform the claim into a patent-eligible application. *Mayo*, 132 S. Ct. at 1294 (emphasis added). The panel here correctly determined that cffDNA and its presence in maternal blood are natural phenomena. It erred, however, in the second step by completely excising these natural phenomena from the claim, asking only whether what remained (e.g. PCR) was "inventive" on its own. PCR, of course, was not inventive on its own in 1997—*but* performing PCR on a blood sample in order to amplify cffDNA surely was. This latter conclusion is precisely what the *Mayo* court held *can* satisfy § 101 under the "combination of elements" or "claim as a whole" test, a second layer of analysis that is clearly required beyond the initial "additional elements" analysis at which the panel here wrongly stopped.

Both *Mayo* and *Diehr* (which *Mayo* identified as "directly on point," *id.* at 1298) further explain that under this second level of analysis, the "claims must be

considered as a whole," such that "a new combination of steps in a process may be patentable even though all the constituents . . . were well known and in common use before the combination was made." *Diehr*, 450 U.S. at 188. Leaving no doubt as to the meaning of this test, *Diehr* expressly rejected the rigid "additional elements" approach that the panel applied here:

> [It is argued that] if everything other than the [patent-ineligible concept] is determined to be old in the art, then the claim cannot recite statutory subject matter. The fallacy in this argument is that we did not hold in *Flook* that the [patent-ineligible concept] could not be considered at all when making the §101 determination. To accept [that] analysis . . . would, if carried to its extreme, make all inventions unpatentable because all inventions can be reduced to underlying principles of nature which, once known, make their implementation obvious.

Id. at 189, n12.

In *Mayo*, the Court not only reaffirmed *Diehr*, but *applied* it as a secondary check on Step 2 patent-eligibility. Specifically, after first considering the three claim steps individually and concluding that none gave rise to an inventive concept on its own, the Court considered the claim as a whole, inquiring whether "the three steps as an ordered combination adds [something more] to the laws of nature that is not already present when the steps are considered separately." *Mayo*, 132 S. Ct. at 1298. In so doing, the Court did not excise the natural phenomenon—there, the precise levels of metabolites that signify toxicity and efficacy—from the claims, as these levels were "already present when the steps are considered separately." Instead, in line with *Diehr*, the Court's secondary analysis indicates that it was searching for an inventive concept in the way that the inventor arranged the known

elements in the claim as a whole, including the natural phenomenon. *See also Diehr*, 450 U.S. at 188 ("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.")

Mayo's conclusion that there was not an inventive concept present in those particular claims does not of course negate the validity of the "claim as a whole" analysis, or excuse the panel in this or future cases from adhering to that analysis. As the *Mayo* Court was careful to state, "[o]ur conclusion rests upon an examination of the particular claims before us." *Id.* at 1289. And as Judge Linn correctly concluded in this case, "Sequenom's invention is nothing like" those claims. Linn Op. 4. The panel in this case was required to put the particular claims before it through the *Diehr* analysis upheld in *Mayo*. Had it done so, it could not have reached the erroneous result that it did.

II. The Panel Decision Conflicts with the Broader Patent Law by Construing Patent-*Eligibility* More Restrictively Than Patentability

The panel's error in misconstruing *Mayo*'s eligibility framework is further evident from the problematic implications that such a reading would have for the broader patent system if allowed to stand. Specifically, were the panel's interpretation correct, it would mean that claims that contain an "inventive *step*" for purposes of 35 U.S.C. § 103 (i.e. are non-obvious) may nevertheless lack an "inventive concept" for purposes of § 101. To be sure, the existing § 101 case law has yet to fully develop the confines of what constitutes an "inventive concept." But whatever such a test requires, it most certainly cannot be more than the level of in-

ventiveness required to satisfy Section 103. This is clear from the language of Section 101 itself, which provides that "Whoever invents or discovers any new and useful process [etc.]. . . may obtain a patent therefor, *subject to the conditions and requirements of this title*." 35 U.S.C. § 101 (emphasis added). It is also clear from Congress's mandate that this Section be construed as liberally as possible. And it is clear from the Supreme Court's reminder that Section 101 is a "threshold," a "general statement" of the categories of only "*possibly* patentable subject matter." *Id.* at 189 (emphasis added). *Diehr* in fact stressed this very point, leaving no room for an interpretation of Section 101 that requires more than Section 103:

> [I]t may later be determined that the [claimed] process . . . fails to satisfy . . . novelty § 102 or nonobviousness under § 103. A rejection on either of these grounds does not affect the determination that [the] claims recited subject matter . . . eligible for patent protection under § 101.

Id. at 191.

Yet, the panel's reading of the *Mayo* eligibility test leads to precisely this result by denying the existence of an "inventive concept" in a claim that undoubtedly contains an "inventive step" (is non-obvious). Indeed, the panel in this case expressly "agree[d]" that the invention represents "a significant human contribution" that "combined and utilized man-made tools of biotechnology in a new way that revolutionized prenatal care." Op. 15. In his concurring opinion, Judge Linn further concluded that prior to the invention "*no one* was amplifying and detecting paternally-inherited cffDNA using the plasma or serum of pregnant mothers," and called it a "truly meritorious" and "groundbreaking invention," an acknowledged

"paradigm shift" in the field. Linn Op. 4, 5. On this record, there is little doubt that the claims in this case are sufficiently inventive to satisfy Section 103. That being the case, it cannot be that they lack the "threshold" inventiveness to satisfy the "inventive concept" requirement of Section 101.

III. The Panel Decision Improperly Converts the Judicial Exceptions into "Moving Targets," Creating Needless Uncertainty and Undermining the Objectives of the Patent System

The panel's reading of *Mayo* must also be wrong because it converts the necessarily static concept of "judicial exceptions" into a set of moving targets that depend entirely on the constantly-changing state of the art, a result which conflicts with the nature of the exceptions, and undermines the predictability that the patent system is designed to provide. There are and have always been only three judicial exceptions to eligibility—"laws of nature, natural phenomena, and abstract ideas," *Mayo*, 132 S. Ct. at 1289. These exceptions are exceptions precisely because they are universal constants or "manifestations of nature" that are outside the reach of human intervention, and thus, do *not* readily change over time. *See id.* (citing minerals, gravity, and $E=mc^2$ as archetypal examples). Logically, then, what amounts to a "natural phenomenon" at a given time cannot become an invention later, nor can a human invention become a "natural phenomenon" with the passage of time.

Yet, that is another incongruous result of the panel's misreading of *Mayo*, which transforms the "natural phenomenon" exception into a variable that evolves with every advance in the art. In the panel's view, the use of polymerase chain re-

action (PCR) to amplify cffDNA in maternal plasma or serum was not patent-eligible in 1997, because the PCR technique in general was well-known by that time. Op. 11. But implicit in this reasoning is that the use of PCR *would* be patent-eligible if the technique were new, as it was when Kary Mullis invented (and indeed patented) the process in 1983. *See e.g.* U.S. Patent No. 4,683,195. While these opposite results may be reconcilable through principles of novelty and obviousness, they should not be reconciled—and logically *cannot* be—under Section 101 or through the judicial exceptions that define its bounds. If the broad application of PCR to *any* form of DNA was not an ineligible "natural phenomenon" in 1983, it cannot have become one 14 years later when applied to a more specific form of DNA in an admittedly "revolution[ary]" way. Op. 15. This illogical and unnecessary result can be avoided by adopting the correct *Mayo/Diehr* analysis.

CONCLUSION

The panel's decision, if not corrected, will significantly narrow the gates to the patent system in a way that conflicts with Supreme Court precedent and the unmistakable will of Congress. With an error of this magnitude, the stakes are too high to let the decision stand. The Court should grant Rehearing *En Banc*.

Date: August 27, 2015

Respectfully submitted,
/s/ Corey A. Salsberg

Corey A. Salsberg
NOVARTIS INTERNATIONAL AG
Novartis Campus, CH-4002 Basel, CH
+41 61 324-4320
corey.salsberg@novartis.com
Counsel for Amicus Novartis AG

CERTIFICATE OF SERVICE

I, Corey A. Salsberg, hereby certify that on August 27, 2015, I electronically filed the foregoing BRIEF OF NOVARTIS AG AS AMICUS CURIAE IN SUPPORT OF REHEARING EN BANC with the Clerk of the Court for the United States Court of Appeals for the Federal Circuit by using the Court's CM/ECF system. Participants in the case who are registered CM/ECF users will be served by the CM/ECF system.

/s/ Corey A. Salsberg

Counsel for Amicus Novartis AG