Nos. 2022-1027, -1028

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

CAREDX, INC., THE BOARD OF TRUSTEES OF THE LELAND STANFORD JUNIOR UNIVERSITY,
Plaintiffs-Appellants,
v.
NATERA, INC.,
Defendant-Appellee.

Appeal from the U.S. District Court for the District of Delaware
Case Nos. 1:19-cv-00567-CFC-CJB, 1:20-cv-00038-CFC-CJB,
Judge Colm F. Connolly

CAREDX, INC., THE BOARD OF TRUSTEES OF THE LELAND STANFORD JUNIOR UNIVERSITY,
Plaintiffs-Appellants,
v.
EUROFINS VIRACOR, INC.,
Defendant-Appellee.

Appeal from the U.S. District Court for the District of Delaware,
Case No. 1:19-cv-01804-CFC-CJB, Judge Colm F. Connolly

BRIEF OF *AMICUS CURIAE* PAUL R. MICHEL IN SUPPORT OF APPELLANTS' COMBINED PETITION FOR PANEL REHEARING AND REHEARING EN BANC

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CERTIFICATE OF INTEREST

Counsel for Amicus Curiae Hon. Paul R. Michel (ret.) states the following:

1. **Represented Entities.** Provide the full names of all entities represented by undersigned counsel in this case. Fed. Cir. R. 47.4(a)(1).

Honorable Paul R. Michel (ret.)

2. **Real Party in Interest.** Provide the full names of all real parties in interest for the entities. Do not list the real parties if they are the same as the entities. Fed. Cir. R. 47.4(a)(2).

N/A

3. **Parent Corporations and Stockholders.** Provide the full names of all parent corporations for the entities and all publicly held companies that own 10% or more stock in the entities. Fed. Cir. R. 47.4(a)(3).

None.

4. **Legal Representatives.** List all law firms, partners, and associates that (a) appeared for the entities in the originating court or agency or (b) are expected to appear in this court for the entities. Do not include those who have already entered an appearance in this court. Fed. Cir. R. 47.4(a)(4).

Dowd Scheffel PLLC: Matthew J. Dowd, Robert J. Scheffel

5. **Related Cases.** Provide the case titles and numbers of any case known to be pending in this court or any other court or agency that will directly affect or be directly affected by this court's decision in the pending appeal. Do not include the originating case number(s) for this case. Fed. Cir. R. 47.4(a)(5). See also Fed. Cir. R. 47.5(b).

None.

6. **Organizational Victims and Bankruptcy Cases.** Provide any information required under Fed. R. App. P. 26.1(b) (organizational

victims in criminal cases) and 26.1(c) (bankruptcy case debtors and trustees). Fed. Cir. R. 47.4(a)(6).

None.

I certify the preceding information is accurate and complete to the best of my knowledge.

Date: September 30, 2022

/s/ Matthew J. Dowd
Signature of counsel
Matthew J. Dowd
Counsel for Amicus Curiae

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INTEREST OF *AMICUS CURIAE*[1]

Amicus Curiae Paul R. Michel is a former judge of the U.S. Court of Appeals for the Federal Circuit, appointed in 1988 and serving until 2010, when he retired from the bench as Chief Judge. Since his retirement, *Amicus* has remained active in patent policy discussions, working to help ensure that U.S. patent laws and policy are geared to achieving the proper balance between incentivizing innovation and allowing free-market competition.

The present case is of concern to *Amicus* because the Court's ruling continues a troubling trend of denying even the possibility of patent protection for medical diagnostic inventions. Patent protection is critical to incentivizing innovation in the field of medical diagnostics, and life-saving diagnostics are precisely the type of innovation that the U.S. patent system should be encouraging. The outcome in this case wrongfully shuts the door before any evaluation of the merits of the claimed invention even occurred.

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[1] No party's counsel authored this brief in whole or in part, and no party, party's counsel, or any other person has contributed money intended to fund the preparation or submission of this brief. All parties consented to the filing of this brief.

ARGUMENT

The importance of clarifying patent-eligibility law cannot be overstated. Section 101 is now the de facto, critical barrier to reliable patent protection for critical 21st-century technologies, including medical diagnostics, clean and sustainable energy, artificial intelligence, cutting-edge medical and biotechnology innovation, such as gene therapy. To support and foster the necessary innovation and investment, U.S. patent laws need to provide reliable and predictable protections for innovation. Unfortunately, though, there is wide consensus that patent-eligibility law remains confused and internally inconsistent. It needs to be fixed.

The present case represents an ideal opportunity for the full Court to ensure that patent protection remains available for life-saving diagnostic inventions. The panel decision held that the invention was not patent eligible, in part because "[t]his is not a case involving a method of preparation or a new measurement technique." That conclusion, if upheld, will unnecessarily foreclose patent protection for diagnostic techniques that use a novel and nonobvious combination of techniques that yield a novel and nonobvious result.

The full Court can and should fix the current situation with § 101. The best way to do so is to accurately assess the legal underpinnings of the now-prevalent *Mayo-Alice* test and its application of the so-called "inventive concept" requirement. *See Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66 (2012); *Alice Corp. v. CLS Bank Int'l*, 573 U.S. 208 (2014). *Amicus* respectfully suggests that the current case can be used to revisit the overly broad application of *Mayo* and *Alice*—an application that, in this case, led to the erroneous conclusion that an entirely new method of diagnosing potential organ-donor failure is not eligible for patent protection.

I. A Novel Method For More Accurately Detecting Potential Organ Failure Surely Must Be Eligible For Patent Protection

The question advanced in the rehearing petition is whether an invention that is directed to a new and improved diagnostic measurement method is patent-eligible at step one. *Amicus* submits that, under a proper § 101 analysis, there should be little question that the advance captured by the claimed invention is, at a minimum, patent eligible. *See, e.g.*, *CosmoKey Solutions GmbH & Co. v. Duo Sec. LLC*, 15 F.4th 1091,

1097 (Fed. Cir. 2021) ("Under *Alice* step one, we consider what the patent asserts to be the focus of the claimed advance over the prior art.").

It seems indisputable that, in this case, the "focus of the claimed advance over the prior art" is a novel combination of scientific/experimental techniques that allows one to detect whether transplant rejection, graft dysfunction, or organ failure will occur. One asserted claim, for instance, involves physical transformation steps, including genotyping an organ transplant donor or recipient, extracting cell-free DNA, amplifying DNA, and quantifying a subset of DNA. The claims at issue are thus "directed to" a novel combination of physical transformation methods that enable a medical practitioner to perform a potentially life-saving diagnosis—one that could not be performed as accurately and efficiently before the Stanford University scientists developed their invention.

The claimed invention solves a technical problem that could not be solved before the invention. The claimed invention does not preempt all uses of the underlying natural phenomenon. Thus, even accepting the current analytical § 101 framework, the claimed invention is not trying to claim the natural phenomenon itself and thus is not "directed to a

patent-ineligible concept." *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371, 1375 (Fed. Cir. 2015) (citing *Mayo*, 566 U.S. at 77–78).

II. This Case Represents Another In A Line of Detrimental Cases Involving Life-Saving And Innovative Medical Diagnostic Inventions

The present case represents yet another unfortunate instance in which a seemingly novel and nonobvious medical diagnostic invention is denied patent protection. This outcome runs counter the purpose of the patent system.

For instance, in implementing these judicial exceptions, the Federal Circuit has struck down claims to diagnostic inventions while simultaneously acknowledging the groundbreaking and valuable societal contribution of each invention. *See, e.g.*, *Genetic Veterinary Scis., Inc. v. LABOKLIN GmbH & Co. KG*, 933 F.3d 1302, 1319–20 (Fed. Cir. 2019) (invalidating claims for detecting hereditary nasal parakeratosis in Labrador retrievers); *Roche Molecular Sys., Inc. v. CEPHEID*, 905 F.3d 1363, 1381 (Fed. Cir. 2018) (invalidating a patent directed to novel methods for detecting the pathogenic bacterium *Mycobacterium tuberculosis*); *Genetic Techs. Ltd. v. Merial L.L.C.*, 818 F.3d 1369, 1380 (Fed. Cir. 2016) (invalidating a patent claiming a novel method of using

noncoding sequences of DNA to detect mutations associated with various diseases); *Ariosa*, 788 F.3d at 1381 (invalidating an award-winning, groundbreaking, noninvasive method for detecting Down's Syndrome and other fetal abnormalities without having to use invasive and potentially dangerous amniocentesis); *In re BRCA1- & BRCA2-Based Hereditary Cancer Test Pat. Litig.*, 774 F.3d 755, 765 (Fed. Cir. 2014) (invalidating method claims for screening for genes linked to inherited breast and ovarian cancer).

Each invention noted above represented a genuine and important advance in medical diagnostics. But each invention was denied patent protection—not because of novelty or obviousness issues. Despite years of work and untold financial resources devoted to developing those inventions, the inventors (and those who supported the inventors) are essentially told, "Your invention can be used by anyone else for free."

That message is the entirely wrong one to send to the American innovation community, particularly at a time when our country's innovation policy should be encouraging investment in high-tech and complex scientific endeavors, including medical diagnostics. Rewarding innovation with the exclusive right of a patent has been a fundamentally

important element of the United States' success since its founding. Now, however, with a warped patent-eligibility jurisprudence, innovators of medical diagnostics are left blowing in the wind.

III. All Agree: Patent Eligibility Is A Mess

One law professor has noted that "[t]he law of patentable subject matter is a mess."[2] That view is widely held. Members of this Court have expressed similar views:

> Chief Judge Moore: "The majority's blended 101/112 analysis expands § 101, converts factual issues into legal ones and is certain to cause confusion for future cases."[3]
>
> Judge Dyk: "I share the concerns of some of my colleagues that a too restrictive test for patent eligibility under 35 U.S.C. § 101 with respect to laws of nature (reflected in some of the language in *Mayo*) may discourage development and disclosure of new diagnostic and therapeutic methods in the life sciences, which are often driven by discovery of new natural laws and phenomena."[4]

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[2] Prof. Mark A. Lemley, *Patentable Subject Matter Reform Hearings Before the Senate Judiciary Committee*, at 1 (June 4, 2019), https://www.judiciary.senate.gov/imo/media/doc/Lemley%20Testimony.pdf.

[3] *American Axle & Mfg., Inc. v. Neapco Holdings, LLC*, 967 F.3d 1285, 1305 (Fed. Cir. 2020) (Moore, J., dissenting).

[4] *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 809 F.3d 1282, 1287 (Fed. Cir. 2015) (Dyk, J., concurring in the denial of the petition for rehearing en banc).

> Judge Hughes: "I, for one, would welcome further explication of eligibility standards in the area of diagnostics patents. Such standards could permit patenting of essential life-saving inventions based on natural laws while providing a reasonable and measured way to differentiate between overly broad patents claiming natural laws and truly worthy specific applications."[5]

In short, there is broad consensus about the detrimental confusion surrounding the law under § 101.

The confusion is exacerbated when this Court invalidates patents covering innovative diagnostic methods while, at the same time, ruling that very similar inventions are patent eligible, even though the upheld inventions undoubtedly use a "law of nature." *See, e.g.*, *Illumina, Inc. v. Ariosa Diagnostics, Inc.*, 952 F.3d 1367, *opinion modified by* 967 F.3d 1319, 1327 (Fed. Cir. 2020); *INO Therapeutics LLC v. Praxair Distribution Inc.*, No. 18-1019, 2019 WL 4023576 (Fed. Cir. Aug. 27, 2019) (upholding claims for non-invasive methods and devices for accurately determining a person's deep body temperature); *Rapid Litig. Mgmt. Ltd. v. CellzDirect, Inc.*, 827 F.3d 1042 (Fed. Cir. 2016) (holding,

[5] *Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC*, 927 F.3d 1333, 1337 (Fed. Cir. 2019) (Hughes, J., concurring).

as patent eligible, a method of producing a preparation of multi-cryopreserved hepatocytes).

Ultimately, § 101 caselaw has become a stew of inconsistency, with the outcome never certain, whether it be at the district court or on appeal. The U.S. biotech and medical diagnostics industries deserve better from the U.S. intellectual property system, and this Court's en banc review in this case would help in providing some assurance to those research-intensive industries that the fruits of their years-long research will be adequately protected.

If patent-eligibility law is not rationalized, the consequences will continue to worsen for the U.S. innovation community. Inventions ineligible for patenting under current U.S. law are eligible in Europe and Asia, including America's arch-rival China. Moreover, China threatens to overtake U.S. leadership in all the advanced technologies of the 21st century and is massively investing, while U.S. investments in patent-dependent technologies are stalled.

IV. Refining The *Alice/Mayo* Test Would Be Consistent With The Objective Of Protecting And Incentivizing Innovation

Because the Supreme Court has denied all § 101 petitions (except one) since *Mayo* upended the law in 2012, and Congress has failed to act,

this Court continues to have an opportunity to rationalize the law of patent eligibility to ensure that innovation is being properly rewarded. One step forward would be a refinement of the *Alice/Mayo* test and its invocation of the so-called "inventive concept" requirement.

Upon closer review, the *Alice/Mayo* test's foundation must be seen as lacking, and the test should be reassessed to ensure it is applied in a manner that stays true to the Constitution's goal of promoting the progress of the useful arts. This reassessment does not require an overruling of the *Alice/Mayo* test, but it would allow a more faithful application of Supreme Court precedent to respect the objective of the Constitution's Patent Clause.

As explained in more detail in other articles,[6] the *Mayo* and *Alice* opinions rely on pre-1952 cases, but those earlier cases seemed to be

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[6] *See, e.g.*, Paul R. Michel, *Is It Time to Reevaluate 'Inventive Concept' Test for Patent Eligibility?*, Bloomberglaw (May 18, 2020), https://news.bloomberglaw.com/ip-law/insight-is-it-time-to-reevaluate-inventive-concept-test-for-patent-eligibility; Paul R. Michel & John Battaglia, *Flaws in the Supreme Court's §101 Precedent and Available Ways to Correct Them* (Apr. 27, 2020), https://www.ipwatchdog.com/2020/04/27/flaws-supreme-courts-%C2%A7101-precedent/id=121038/.

analyzing patentability, not eligibility. The earlier decisions employ the word "patentable" throughout. They contain no reference to "eligibility."

Mayo also relies on *Parker v. Flook*, 437 U.S. 584 (1978), and its invocation of the "inventive concept." When *Flook* is read carefully, however, it uses the term only twice and without quoting or even citing any precedent. The opinion by Justice John Paul Stevens says simply: "Even though a phenomenon of nature or a mathematical formula may be well known, an inventive application of the principle may be patented. Conversely, the discovery of such a phenomenon cannot support a patent unless there is some other inventive concept in its application." *Id.* at 594.

The Supreme Court precedent cited in *Flook* is similarly silent about the "inventive concept" paradigm. None of the older cases—*Funk Brothers Seed Co. v. Kalo Co.*, 333 U.S. 127, 130 (1948), and *Mackay Radio & Telegraph Co. v. Radio Corp. of America*, 306 U.S. 86, 94 (1939)—mentioned "inventive concept." The same is true for *Gottschalk v. Benson*, 409 U.S. 63, 71 (1972), which states that "one may not patent an idea," but does not employ the "inventive concept" test. Thus, we are

left with a line of cases offering almost no support for *Flook*'s reliance on "inventive concept."

On that shaky ground, we next have the Court's decision in *Diamond v. Diehr*, 450 U.S. 175 (1981), decided three years after *Flook*. The Supreme Court in *Diehr* clearly held that the concept of "inventiveness" has no place in the eligibility analysis. In fact, Justice Stevens—the author of a 6-3 *Flook* majority—complains in his 4-5 *Diehr* dissent that the Court is "trivializing" *Flook*'s inventive concept. Along with *Diehr*'s condemnation of an improper dissecting of claims, one can readily conclude that *Diehr* overruled at least this aspect of *Flook*'s reasoning.

Notwithstanding this shaky foundation, Justice Stephen Breyer (as author of the *Mayo* opinion) repeatedly relied on the idea of "conventional" as a synonym for a lack of "inventive concept." Thus, "inventive concept" was resurrected from *Flook* after its burial in *Diehr*. Yet, the *Mayo* decision purported to follow *Diehr* as well as *Flook*, which it expressly recognized as the closest precedents. The conclusion therefore seems inescapable: "inventive concept" as a key requirement for establishing patent eligibility finds little support in the precedent.

The shaky ground must be considered by courts when applying the *Mayo/Alice* test.

In the present case, the panel applied the "inventive concept" paradigm. *See* Op. 18 ("We have repeatedly held that applying standard techniques in a standard way to observe natural phenomena does not provide an inventive concept."). The problem with the panel's conclusion, however, is that it impermissibly parses the claimed invention into its separate limitations, rather than assessing the claim as a whole. It also conflates patent eligibility with nonobviousness and other aspects of patentability. *Cf. Athena*, 927 F.3d at 1334 (Lourie, J., concurring) ("The laws of anticipation, obviousness, indefiniteness, and written description provide other filters to determine what is patentable.").

V. Conclusion

For the reasons discussed above, *Amicus Curiae* the Honorable Paul R. Michel (ret.) respectfully submits that the Court should grant the petition for rehearing en banc.

Date: September 30, 2022

Respectfully submitted,

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UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

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