No. 22-1066

In the Supreme Court of the United States

CAREDX, INC., ET AL.

Petitioners,

v.

NATERA, ET AL.,

Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF OF THE HONORABLE PAUL R. MICHEL (RET.) AND PROFESSOR JOHN F. DUFFY AS *AMICI CURIAE* IN SUPPORT OF PETITIONERS

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INTEREST OF *AMICI CURIAE*[1]

Amicus curiae the Honorable Paul R. Michel (ret.) is a former Circuit Judge of the U.S. Court of Appeals for the Federal Circuit. He served from 1988 until 2010, retiring as Chief Judge. *Amicus* has since remained active in patent-policy activities, working to advance U.S. patent laws and policy that achieve the proper balance between incentivizing innovation and enabling free-market competition.

Amicus curiae John F. Duffy is the Samuel H. McCoy II Professor of Law and the Paul G. Mahoney Research Professor of Law at the University of Virginia School of Law. He teaches and writes in the field of intellectual property generally and has also written specifically on patentable subject matter.

This case concerns *Amici* because it represents a continuing trend of uncertainty and inconsistency in patent-eligibility jurisprudence, now reaching the point that judge-made law in the lower courts directly contradicts statutory commands in the 1952 Patent Act designed to overrule prior 19th-century judge-made law on patentable subject matter that Congress found too restrictive. The outcome undermines the innovation-promoting goals of U.S. patent law.

SUMMARY OF THE ARGUMENT

The Court should grant the petition for several reasons. First, the case comes at a zenith of pleas from

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[1] Pursuant to Supreme Court Rule 37.2, counsel of record for all parties received the required notice of *amici curiae's* intent to file this brief. Pursuant to Supreme Court Rule 37.6, no counsel for any party authored this brief in whole or in part, and no entity or person, aside from *amici curiae* and its counsel, made any monetary contribution toward the brief's preparation or submission.

the Solicitor General, the Federal Circuit, the U.S. Patent and Trademark Office ("PTO"), and the business and legal communities. This Court should resolve the specific legal issue that has sharply split the Executive and Judicial Branches on patentable subject matter. That split produces intolerable uncertainty for businesses, with the Executive Branch issuing meritorious patents like the three patents at issue here, only to have the courts invalidate them.

Second, the decision directly conflicts with the Patent Statute. A "process," as statutorily defined, "includes a new use of a known process." 35 U.S.C. § 100(b). Congress added that language to overrule 19th-century judge-made law forbidding patents on new uses for known technologies. With its explicit authorization for patenting new uses for existing technologies, § 100(b) represents the one "clear example in which the judicial gloss on patentable subject matter has been legislatively rejected." *See* John F. Duffy, *Rules and Standards on the Forefront of Patentability*, 51 Wm. & Mary L. Rev. 609, 632 (2009).

Yet, in contrast to that clearly expressed congressional view, the appeals court held the patents here completely outside of patentable subject matter because the steps in the patented processes—none of which are found in nature (and many of which were not even possible within living memory)—have become "conventional." That "conventionality" point is irrelevant to the patent-eligible inquiry when the process is directed to statutorily defined patent-eligible (rather than patent-ineligible) subject matter. In this case, the patent eligibility of the claimed processes is directly established by the language of § 100(b), for the patents disclose and claim new and innovative uses of existing processes.

Third, this case can resolve the intra-circuit split (as well as the inter-branch split between the Federal Circuit and the Solicitor General) about how to apply patent eligibility to life-saving medical diagnostic inventions. Providing clarity on § 101 is critical for biotechnology and diagnostic industries.

ARGUMENT

I. Patent-Eligibility Law Needs Clarification

The present petition reaches the Court at a unique time. There is almost uniform agreement that clarification of 35 U.S.C. § 101 is needed, particularly as applied to biomedical and diagnostic patents.

To begin, the Court has called for the Solicitor General's views in five recent cases. In each of those five cases, the Solicitor General has recommended that the Court grant review in an appropriate case. *See* U.S. Br. 10, *Tropp v. Travel Sentry, Inc.*, 143 S. Ct. 361 (2022) (No. 22-22), *Interactive Wearables, LLC v. Polar Electro Oy*, 143 S. Ct. 78 (2022) (No. 21-1281) 2023 WL 2817859 ("*Tropp*"); U.S. Br. 9-10, *Am. Axle & Mfg., Inc. v. Neapco Holdings LLC*, 142 S. Ct. 2902 (2022) (No. 20-891), 2022 WL 1670811; U.S. Br. 8, *Hikma Pharm. v. Vanda Pharm., Inc.*, 140 S. Ct. 911 (2020) (No. 18-817), 2019 WL 6699397; U.S. Br. 10-11, *HP Inc. v. Berkheimer*, 140 S. Ct. 911 (2020) (No. 18-415), 2019 WL 6715368. In the Government's unequivocal view, across several terms, the Court should take a case to resolve the jurisprudential confusion.

Beyond the Solicitor General, numerous Federal Circuit judges have repeatedly expressed their need for guidance and clarification on patent eligibility.

> 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."[2]
>
> 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."[3]
>
> 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."[4]

Rarely do multiple judges on a single appeals court repeatedly and explicitly request further guidance on a fundamental legal issue. *See CareDx, Inc. v. Natera, Inc.*, No. CV 19-0567-CFC-CJB, 2021 WL 4439600, at *5 (D. Del. Sept. 28, 2021) (collecting quotes from current and former Federal Circuit judges describing the uncertainty infecting § 101 law). These judicial requests for clarification are all the more important because the Federal Circuit is the only appeals court (with limited

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

[3] *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).

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

exceptions) that decides patent-law issues, and its views on patentable subject matter plainly conflict with the views of the Executive Branch, which continues to issue patents only to see them invalidated in the Federal Circuit. The conflicting rulings also demonstrate an intra-circuit split, *see infra*, which, for purposes of patent law and this Court's consideration, is the relevant split.

Just as importantly, the PTO, responsible for granting (and also for revoking) patents, has expressed its own concerns about the existing status of patent-eligibility law. According to the PTO, it is "difficult" to apply the *Alice/Mayo* test "in a consistent manner," and that difficulty "has caused uncertainty." 2019 Revised Patent Subject Matter Eligibility Guidance, 84 Fed. Reg. 50, 50 (Jan. 7, 2019).

Finally, the business, legal, and academic communities have repeatedly expressed the need for clarifying § 101 law. In testimony to the Senate, Professor Mark Lemley observed that "[t]he law of patentable subject matter is a mess."[5] Numerous others in the business and legal communities have detailed the problems with § 101 uncertainty. *E.g.*, Peter O'Neill, *State of Patent Eligibility in America, Part III Before the Senate Judiciary Subcommittee on Intellectual Property*, at 3 (June 11, 2019) (explaining that "decisions from the federal courts have cast a cloud of uncertainty over our work in the field of diagnostic tests and life sciences");[6] PTO, *Report to Congress, Patent Eligible Subject Matter: Public Views on the Current*

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[5] 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.

[6] https://www.judiciary.senate.gov/imo/media/doc/O%27Neill%20Testimony.pdf.

Jurisprudence in the United States, at 16-20 (June 2022) ("*PTO Report*") (describing the continuing split in the innovation community).[7]

II. The Decision is Wrong

The Court should grant certiorari because the decision of the Federal Circuit is erroneous. The decision below overlooks the Patent Act's text and conflicts with this Court's precedent. The Federal Circuit's decision also disregarded the specific, technologically advanced steps of the claimed processes. The decision invokes a troubling reliance on "conventionality," which led to conflating patent eligibility (under § 101) with the requirements for patentability (in §§ 102, 103, and 112).

A. The Federal Circuit's Reasoning Overlooks the Text of the Patent Statute and Conflicts with This Court's Precedent

The Patent Act mandates that "[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title." 35 U.S.C. § 101. An invention falling within a category of "patent-eligible" subject matter must still satisfy other statutory requirements for patentability, specifically 35 U.S.C. §§ 102, 103, 112. *See Bilski v. Kappos*, 561 U.S. 593, 602 (2010). In view of the statute's plain text, this Court has instructed that "courts should not read into the patent laws limitations and conditions which the legislature has not expressed." *Diamond v. Chakrabarty*, 447 U.S. 303, 308 (1980) (quoting *United States v. Dubilier Condenser Corp.*, 289 U.S. 178, 199 (1933)).

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[7] https://www.uspto.gov/sites/default/files/documents/USPTO-SubjectMatterEligibility-PublicViews.pdf.

Notwithstanding that instruction, the Court has adopted implicit exceptions to the text of § 101, including to the meaning of "process" by considering the traditional usage of that term. For instance, the Court has concluded that, with respect to mathematical equations, not "every discovery" of a process is "embraced within the statutory terms." *Diamond v. Diehr*, 450 U.S. 175, 182-85 (1981); *see also Corning v. Burden*, 56 U.S. (15 How.) 252, 267-68 (1854) (explaining that "[o]ne may discover a new and useful improvement in the process of tanning . . . irrespective of any particular form of machinery or mechanical device . . . and [he] may be entitled to his patent"). This Court has further clarified that "laws of nature, natural phenomena, and abstract ideas" are not patent-eligible. *Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 573 U.S. 208, 217 (2014); *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66 (2012); *Bilski*, 561 U.S. at 601.

In assessing whether a new process is patentable subject matter, the text of the statute must be the starting point, with two provisions having primary importance. First, 35 U.S.C. § 101 authorizes a patent on "any new and useful improvement" of a "process." Second, 35 U.S.C. § 100(b) defines "process" to mean "process, art or method, and includes a new use of a known process, machine, manufacture, composition of matter, or material." Taken together, a new process that is presented as an improvement on a known useful process is presumptively patent eligible.

In other words, when defining "process" to "include[] a new use of a known process," Congress recognized that the mere fact that the process was known or "conventional" should not necessarily prevent an improvement of that process from consideration for patent protection. The "new process" is an improvement

on a conventional process. Applying the plain language of the statute, the fact that a claimed invention is an improvement to a "conventional" process ought not to play a dispositive role in the question of whether the new, improved process is patent-eligible.

"Conventionality" of a newly developed process may inform other inquiries, such as whether the new process advances the public store of technical knowledge enough to warrant patent protection. But answers to those inquiries lie in other sections of the Patent Act. *See* 35 U.S.C. §§ 102, 103, 112. To interpret § 101 as imposing a strict "non-conventionality" standard for patentable subject matter—while not respecting the definition of § 100(b) and the explicit roles of § 102 and § 103—is to wander so far from the words of the Patent Act as to end up in the wilderness of atextualism.

The Court's approach in *Diehr* is an instructive example of how a court can stay true to the statutory text for process inventions while acknowledging the implicit judicial exceptions. The claim in *Diehr* was directed to a process for "molding raw, uncured synthetic rubber into cured precision products." *Diehr*, 450 U.S. at 177. That description, by itself, should eliminate any doubt about patent eligibility. A process for making rubber-molded products is patent-eligible, even if that process is conventional. It is a typical process of manufacturing articles of commerce. Rubber molding is still an important process in modern manufacturing, and there have been countless improvements on the process, with many protected by patent. And if a process engineer devised an improvement on that old process based on new, scientific insight about the rubber-curing process, that new process again would be patent eligible, with novelty and nonobviousness to be assessed separately, per the statute.

The only wrinkle in *Diehr* was that the rubber-curing process incorporated data measurements that were then used in the Arrhenius equation, which informed a user when the rubber press should be opened. *Id.* at 188. But that incorporation of a scientific principle did not change that the claim protected a tangible process, and the Court correctly ruled that the claimed process satisfied § 101.

At its base, the general rubber-curing process in *Diehr* was "conventional," but that did not matter for eligibility purposes. The claimed process was new, an improvement of what was already known, and the improvement stemmed from the recognition that certain temperature measurements (when used with the Arrhenius equation) could identify a better way to operate the rubber-curing press. Utilizing a scientific principle to improve a known process is—and should be—patent eligible. As the Court has explained, "it is equally clear that a process is not unpatentable simply because it contains a law of nature or a mathematical algorithm." *Parker v. Flook*, 437 U.S. 584, 590 (1978) (citing *Eibel Process Co. v. Minn. & Ontario Paper Co.*, 261 U.S. 45 (1923); *Tilghman v. Proctor*, 102 U.S. 707 (1880)).

Also instructive is this Court's decision in *Cochrane v. Deener*, 94 U.S. 780 (1876). There, the Court affirmed the validity of a patent directed to an improved method for bolting flour. In doing so, the Court recognized, in broad terms, "[t]hat a process may be patentable, irrespective of the particular form of the instrumentalities used, cannot be disputed." *Id.* at 787.

> A process is a mode of treatment of certain materials to produce a given result. It is an act, or a series of acts, performed upon the subject-matter to be transformed and reduced to a different state or thing. If new and useful, it is just as

> patentable as is a piece of machinery. In the language of the patent law, it is an art.

Id. at 788. *Cochrane* reinforces the text of the Patent Act and teaches that the focus for patent eligibility of a process is not whether the claimed process is "conventional" but whether the claimed invention satisfies the statutory meaning of "process."

Unfortunately, the Federal Circuit's decision in the present case does not address the statutory text and does not adequately consider *Diehr* and its reasoning. The appeals court's opinion does not cite § 100(b), and it cites *Diehr* only twice, both in sentences offering general background on patent-eligibility law. *See* Pet. App. 11a. The court did not once attempt to reconcile how its overreliance on "conventionality" was in any way consistent with *Diehr*'s guidance. As explained *infra*, it is difficult to see—from an eligibility perspective—any meaningful difference between the process invention in *Diehr* and the process invention at issue here. Both processes involve complex chemical transformations, not performed in nature, and they both utilize scientific principles to create "new and useful improvement[s]" of known processes. They both incorporate data analysis to yield a useful result. They both offer specific technological solutions to a problem that remained unsolved for many years. When viewed this way, the present case offers the best opportunity for this Court to delineate when improvements of technological processes are patent eligible and to correct a decision that conflicts with the statutory text and this Court's precedent.

B. The Claimed Method is the Type That is Traditionally Eligible for Patent Protection

The Federal Circuit's ruling also overlooks the undisputed facts that Petitioners' claimed methods involve specific, transformative chemical reactions—none

of which attempt to "monopolize" a law of nature or a natural phenomenon. They involve biochemical transformations that, as claimed, do not occur in nature but exist only as the product of human invention. The panel decision purported to summarize the detailed process limitations into a condensed version of the claim, *see* Pet. App. 8a, but the court's high-level abstraction of the claimed processes added to the error by overlooking the true nature of the invention.

First, several steps in the claimed processes involve specific, complex biochemical reactions that do not occur in nature and occur only through the provision of human ingenuity. The claims do not preempt any fundamental natural phenomenon. Nor are they an abstract idea, simply because they build on and improve a known process. As this Court has explained, a claim to otherwise eligible statutory subject matter does not become ineligible by its use of a law of nature or natural phenomenon. *See Diehr*, 450 U.S. at 187; *Flook*, 437 U.S. at 590.

Take claim 1 of Petitioners' '607 patent. One step in the claimed process involves a complex series of chemical transformations known as a "sequencing-by-synthesis reaction." Sequencing by synthesis is a widely adopted next-generation sequencing method that allows for rapid analysis of genetic biomolecules. It involves chemical reactions that, taken as a whole, are not naturally occurring in any living organism. "Sequencing by synthesis" has transformed the biomedical science and medical diagnostic fields. The general process and the numerous "new and useful improvement[s] thereof" have, not surprisingly, been the subject of scores of patents.

The invention of the '607 patent also includes a step of "performing a selective amplification of target sequences . . . wherein said selective amplification . . .

amplifies a plurality of genomic regions comprising at least 1,000 [SNPs]." Pet. App. 6a-7a. Selective amplification, at its base, is a chemical manufacturing process. Selective amplification involves specific biochemical reactions that, when applied as claimed, are chemical transformations that do not occur in nature. This selective amplification step traces its roots to the original "polymerase chain reaction," the discovery of which earned the Nobel Prize in 1993 and which was protected by patents. *See, e.g.*, Rex Dalton, *Promega and Roche Take Up Battle Over PCR Patents*, 404 Nature, Mar. 2, 2000, at 7, 7.[8] Notably, the specific cell-free DNA that is being chemically manufactured in the invention is not the type that is amplified in an organ patient's body. Additionally, single nucleotide polymorphisms ("SNPs") that are quantified by selective amplification are unique to the organ donor and recipient. Those quantified SNPs are then used to diagnose organ rejection.

These complex processes are all types of biological and chemical processes that can be patented, if novel and nonobvious. Too many examples of such patents exist to list here, as the pioneering inventions opened the field to innumerable improvements, such as PCR making it possible to later develop next-generation DNA sequencing. These later process improvements are now, not surprisingly, the subject of disputes among innovators, but these disputes are typically trained on the merits of the patented invention. *See, e.g.*, *Intelligent Bio-Systems, Inc. v. Illumina Cambridge Ltd.*, 821 F.3d 1359, 1370 (Fed. Cir. 2016) (affirming, as patentable, a method of labeling DNA nucleotides in a deoxyribonucleic acid, without any patent-eligibility dispute).

[8] https://www.nature.com/articles/35003722.

The claimed processes do also include conventional steps, such as "genotyping a sold organ transfer donor" and obtaining a blood plasma sample. But including some "conventional" steps in an otherwise novel and nonobvious technological process cannot render the claimed processes as a whole to be entirely excludable from patent consideration. As the Solicitor General explained in an earlier case, "[g]enerally speaking, technologies and industrial processes are not abstract ideas." U.S. Tropp Br. 14. Of course, all this readily flows from *Diehr*. *See supra*.

Petitioners' claimed processes also include a step for analyzing certain physical characteristics of the new composition that is produced from the selective amplification and sequence-by-synthesis steps. The analysis step is recited as "quantifying" the amount of a certain type of circulating cell-free DNA. Pet. App. 9a. Including an analysis step as part of a technological process claim cannot be a total bar to possible patent protection, without any consideration of the invention's merits. After all, the claim as a whole is directed to an extraordinarily complex technological process, and the "quantifying" limitation is doing much more than trying to preempt or simply state a law of nature. *Cf. Alice*, 573 U.S. at 221 ("[T]o transform an unpatentable law of nature into a patent-eligible application of such a law, one must do more than simply state the law of nature while adding the words 'apply it.'" (citing *Gottschalk v. Benson*, 409 U.S. 63, 71-72 (1972))).

Here, the appeals court created an overly simplistic "summary" of the claimed processes. *See* Pet. App. 16a-17a. But that high-level summary erroneously presents the invention at a level of abstraction that eviscerates key features of the claimed processes. A better way to view the claimed processes is to analogize

them to more traditional yet equally important processes for which there is no reasonable dispute about patent eligibility—specifically, processes of refining and analyzing precious metals.

Numerous processes have been developed for preparing, purifying, and analyzing metals, such as gold, bronze, and others. At a high level, the general process steps can be seen as "conventional" because they are well-known: obtaining a sample of metal ore or raw material, treating the sample with heat and other conditions to purify the desired metal, and then analyzing the purified metal. These general steps date to thousands of years ago, when humans first purified copper and later made bronze and so forth, yet innovators continue to develop refinements and improvements of the basic steps, and the technological advances continue to warrant patent protection. *See* U.S. Patent No. 8,186,607 (an improved leaching method for purifying gold, copper, and other metals); U.S. Patent No. 4,895,626 (1990) (electrolytic process for purifying gold to "a purity of at least 98.5%"); U.S. Patent No. 3,663,388 (1972) (using the principle of electrolysis in a claimed process for removing gold plating); U.S. Patent No. 961,924 (1910) (process for purifying gold). Some process advances may be "obvious" and thus fail the patentability requirement of § 103, but metallurgical processes are all "patent eligible" as being a process or an "improvement thereof," despite employing fundamental scientific principles, such as heating and electrolysis, to purify a naturally occurring substance.

Under the Federal Circuit's approach, however, any refinement to such a known process—including analyzing the final composition—is seemingly excluded from patent protection because the over-generalized steps (as rewritten by the appeals court) are all "conventional." That is a troubling approach to statutory analysis because

it allows judge-made "conventionality" to usurp the traditional, statutory roles of novelty and nonobviousness. Indeed, with the Federal Circuit's approach, almost any claim to a diagnostic invention could be rewritten at a level of abstraction that renders it ineligible for patent consideration, even though the specific claim limitations establish that the invention is novel and nonobvious. *See, e.g.*, *Ariosa Diagnostics*, 809 F.3d at 1294 (Newman, J., dissenting) (noting that the patent invalidated under § 101 was directed to a "new diagnostic method [that] is novel and unforeseen, and is of profound public benefit—'a significant contribution to the medical field'").

C. The Federal Circuit's Reliance on "Conventionality" is Misplaced

The appeals court's reasoning also erroneously imposes its rigid non-textual "conventionality" standard on the plain text of § 101 and its categories of patent-eligible inventions. The appeals court's repeated invocation of "conventionality" underscores how its analysis is a troubling conflation of the distinct concepts of patent eligibility (§ 101) and patentability (primarily §§ 102, 103, 112).

Through the statutory text, Congress made clear that issues of novelty and nonobviousness reside in 35 U.S.C. § 102 and § 103, respectively. Novelty and non-obviousness are perhaps the most important issues for patentability, but as the Solicitor General explained in *Tropp*, while "those considerations may sometimes overlap with the abstract-idea inquiry, they are the purview of different statutory provisions and perform different functions." U.S. Tropp Br. 11.

As the Solicitor General similarly explained: "An automobile is not an abstract idea. A remote control is not an abstract idea. A camera is not an abstract idea." U.S. Tropp Br. 14. But under the Federal Circuit's reasoning

in this case, all those inventions would be deemed "conventional," and thus "abstract," and therefore not even eligible for patent protection. That approach, of course, would be wrong. If someone were to broadly claim an automobile as his or her invention, such a claim should be rejected, as being not novel and therefore anticipated under § 102. Importantly, the lack of novelty does not mean that the claim is directed to non-patentable subject matter. An automobile is a "composition," after all, made only through human ingenuity, and cannot in any sense fall into one of the judicial exceptions to patentable subject matter.

The same holds true for biological and chemical processes that are designed to provide life-saving diagnostic results. The diagnostic processes are not products of nature, and they are not claiming the fundamental, scientific principle. Instead, they are a type of process that solves a technological problem. *See Alice*, 573 U.S. at 223 (explaining that § 101 does not exclude patents for an invention "designed to solve a technological problem in 'conventional industry practice'").

The appeals court's extensive reliance on "conventionality" not only conflates the various requirements for patentability but also rests on a misreading of this Court's precedent. Upon closer review, the appeals court's broad application of the *Alice/Mayo* test lacks foundation in the precedent, 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 need not overrule the *Alice/Mayo* test, but it would allow a more faithful application of this Court's precedent to achieve the objective of the Constitution's Patent Clause and would respect the text of the Patent Act.

The *Mayo* and *Alice* opinions rely in part on pre-1952 cases, but those earlier cases seemed to be analyzing patentability, not eligibility. The earlier decisions employ the word "patentable" throughout. They contain no reference to "eligibility."

Mayo also relied on *Flook* and its invocation of the "inventive concept." A close reading of *Flook*, however, shows the term being used only twice and without quoting or even citing any precedent. The Court's opinion, written by Justice 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." *Flook*, 437 U.S. at 594. "Conversely, the discovery of such a phenomenon cannot support a patent unless there is some other inventive concept in its application." *Id.*

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 *Benson*, which states that "one may not patent an idea," but the Court's holding there did not employ an "inventive concept" test. 409 U.S. at 71. The relevant precedent thus comprises a line of cases offering almost no support for *Flook*'s invocation of "inventive concept" as the touchstone for patent eligibility. And as noted, there is no basis for imposing a rigid "inventive concept" standard on the categories of § 100(b) and § 101.

Chakrabarty came next and seemed to refocus the patent-eligibility analysis to the statutory text. The Court's analysis started with "the language of the statute" and explained that "words will be interpreted as taking their ordinary, contemporary, common meaning." 447

U.S. at 308. "In choosing such expansive terms as 'manufacture' and 'composition of matter,' modified by the comprehensive 'any,' Congress plainly contemplated that the patent laws would be given wide scope." *Id.* It seemed, for a time, that the statutory text would regain its importance in the patent-eligibility analysis.

The Court's next § 101 decision was *Diehr*, decided one year after *Chakrabarty* and three years after *Flook*. In *Diehr*, the Court held that the concept of "inventiveness" has no place in the eligibility analysis. 450 U.S. at 192-93. In fact, Justice Stevens—the author of a 6-3 *Flook* majority—observes in his 4-5 *Diehr* dissent that the majority was "trivializing" *Flook*'s inventive concept. *Id.* at 205. 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.

"Inventive concept" seemingly re-entered the § 101 vernacular with the Court's decision in *Mayo*, however. *Mayo* repeatedly relied on the idea of "conventional" as a synonym for "inventive concept." 566 U.S. at 1292-94. "Inventive concept" was thus pulled from its resting place, taken from *Flook* after its burial in *Diehr*. This continued tension and seeming conflict, though, flows from *Mayo* purporting to follow *Diehr* as well as *Flook*, which were expressly recognized as the closest precedents. *Id.* at 1298. The conclusion seems inescapable: "[I]nventive concept" as a key requirement for patent eligibility finds little support in this Court's historical precedent. This tension makes it challenging for the Federal Circuit, district courts, and the PTO to apply § 101 in a consistent manner.

In the present case, the Federal Circuit applied the "inventive concept" paradigm in a way that conflicts with the statute and *Diehr*. *See* Pet. App. 18a ("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 non-obviousness and other aspects of patentability, which does not comport with the statutory text of § 101. *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.").

III. This Case is an Excellent Vehicle

The present case is an excellent vehicle. The legal issue is clean for review, and the patented invention is lifesaving. The case fits the bill as the ideal opportunity for the Court to clarify § 101 and § 100(b) jurisprudence and to correct the appeals court's decision.

A. Patent Protection for Diagnostic and Biomedical Inventions is Critically Important

The objective of the patent laws, as authorized by the Constitution's Patent Clause, is to promote the progress of "useful arts," *i.e.*, technological innovation. To do so, the eligibility requirement of 35 U.S.C. § 101 must be interpreted and applied in a manner that accomplishes that objective by striking the proper balance between rewarding inventors for their innovative efforts and ensuring that patent exclusivity does not unduly restrict the use of natural phenomenon or abstract ideas. An unduly burdensome narrow view of patent eligibility harms innovation by precluding important technological innovation from the benefits of patent protection. It also harms society because the lack of patent protection disincentivizes public disclosure of the invention, which forms the basis of the *quid pro quo*.

In exchange, the patent accomplishes its innovation-incentivizing role primarily through the force of the exclusive right contemplated by the Founders and specified in the Constitution. *See* 35 U.S.C. § 154. This Court has recognized the same. *E.g.*, *Horne v. Dep't of Agric.*, 576 U.S. 350, 359 (2015) (stating that a patent "confers upon the patentee an exclusive property in the patented invention" (quoting *James v. Campbell*, 104 U.S. 356, 358 (1882))). The exclusive right is what ultimately enables a patentee to reap the full reward of his or her innovative efforts and to prevent free riders from adopting the technology without incurring the expense of research and development. Indeed, the original Patent Act embodied Thomas Jefferson's philosophy that "ingenuity should receive a liberal encouragement." *Chakrabarty*, 447 U.S. at 308-09 (quoting 5 Writings of Thomas Jefferson 75-76 (Washington ed. 1871)).

This *quid pro quo* falls apart when the patent-eligibility requirement strays too far from the text of § 101 (and § 100(b)). When that happens, it creates situations where technological advances are disclosed in a patent, only to have the patent later invalidated—without even considering if the invention is novel and nonobvious. Innovators will continue to lose confidence in the bargained-for exchange if this trend is not corrected.

Confidence in the U.S. patent system is critically important, as the PTO recognizes: "[C]urrent eligibility jurisprudence has a direct impact on investment, research, and innovation." *PTO Report* at 2; *see also* A. Sasha Hoyt, *The Impact of Uncertainty Regarding Patent Eligible Subject Matter for Investment in U.S. Medical Diagnostic Technologies*, 79 Wash. & L. Rev. 397, 398 (2022) ("[Uncertainty with patent eligibility] has rippled through the medical diagnostic and venture

capital industries, sparking concerns about under-investment in diagnostic R&D.").

B. This Case Addresses an Intra-Circuit Split in Patent Eligibility for Life-Saving Medical Diagnostics

The current law has reached a point where the Federal Circuit is applying § 101 to invalidate some diagnostic patents while maintaining others, without a clear, uniform rationale. This uncertainty harms innovation in medical diagnostics, and the confusion for innovative businesses imposes disadvantages in the competitive marketplace.

The confusion lies when courts invalidate patents covering innovative diagnostic methods while, at the same time, ruling that similar inventions are patent eligible, even though the upheld inventions undoubtedly use a "law of nature." *See, e.g.*, *CardioNet, LLC v. InfoBionic, Inc.*, 955 F.3d 1358, 1367 (Fed. Cir. 2020); *Exergen Corp. v. Kaz USA, Inc.*, 725 Fed. App'x 959, 966 (Fed. Cir. 2019) (upholding claims for non-invasive methods and devices for accurately determining a person's body temperature); *Rapid Litig. Mgmt. Ltd. v. CellzDirect, Inc.*, 827 F.3d 1042, 1044 (Fed. Cir. 2016) (holding, as patent eligible, a method of preparing multi-cryopreserved liver cells).

Other times, the Federal Circuit strikes down claims to diagnostic inventions, despite them being ground-breaking and valuable societal contributions. *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 for novel methods of detecting *Mycobacterium tuberculosis*); *Cleveland Clinic Found. v. True Health Diagnostics LLC*, 859 F.3d 1352, 1363 (Fed.

Cir. 2017); *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371, 1381 (Fed. Cir. 2015) (invalidating a groundbreaking method for detecting fetal abnormalities without using invasive, risky amniocentesis).

Ultimately, the varied cases applying § 101 have become a collection of inconsistency, with the outcome rarely predictable. *See, e.g.*, *CardioNet*, 955 F.3d at 1379 (Dyk, J., concurring in part and dissenting in part) ("[T]he language of the panel opinion is likely to sow confusion for both the district court and the bar."); *Mirror Imaging, LLC v. PNC Bank, N.A.*, No. W-21-CV-00518-ADA, 2022 WL 229363, at *3 (W.D. Tex. Jan. 26, 2022) ("[D]ivining the bounds of these judicial exceptions has proved increasingly challenging, thanks in large part to the Supreme Court's 2014 decision in *Alice*[.]"). The medical diagnostics industry needs to maintain its innovative edge. This Court's review would aid in assuring research-intensive industries that the fruits of their years-long investments will be protected so that they can develop more life-saving innovation.

CONCLUSION

Amici respectfully submit that this Court should grant the petition or, alternatively, call for a response and call for the Solicitor General's views.

Respectfully submitted.

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