

In the
Supreme Court of the United States

ATHENA DIAGNOSTICS, INC., OXFORD UNIVERSITY
INNOVATION LTD., AND MAX-PLANCK-GESELLSCHAFT ZUR
FORDERUNG DER WISSENSCHAFTEN E.V.,

Petitioners,

v.

MAYO COLLABORATIVE SERVICES, LLC,
DBA MAYO MEDICAL LABORATORIES, AND MAYO CLINIC,

Respondents.

**On Petition for a Writ of Certiorari to the
United States Court of Appeals for the Federal Circuit**

**BRIEF OF OF THE HONORABLE PAUL R. MICHEL (RET.)
AS AMICUS CURIAE IN SUPPORT OF PETITIONERS**

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INTEREST OF *AMICUS CURIAE*¹

Amicus Curiae the Honorable Paul R. Michel (ret.) served on the U.S. Court of Appeals for the Federal Circuit for over twenty-two years. From 2004 until his retirement in May 2010, he was the chief judge of the court. During his twenty-two years of judicial service, he heard thousands of appeals and authored over 800 opinions, touching on all aspects of the court's jurisdiction, including patent law.

Since he retired from the Federal Circuit, Judge Michel has maintained an active role in the public dialogue about optimal policies governing intellectual property and U.S. innovation. *See, e.g.*, David Kappos & Hon. Paul R. Michel, *The Smallest Salable Patent-Practicing Unit: Observations on Its Origins, Development, and Future*, 32 Berkeley Tech. L.J. 1433 (2018); Paul R. Michel & Matthew J. Dowd, *The Need for "Innovation Certainty" at the Crossroads of Patent and Antitrust Law*, CPI Antitrust Chronicle (Apr. 2017); Hon. Paul R. Michel, *Judicial Litigation Reforms Make Comprehensive Patent Legislation Unnecessary as Well as Counterproductive*, 14 Nw. J. Tech. & Intell. Prop. 131 (2016).

¹ Pursuant to Supreme Court Rule 37.2(a), all parties received timely notice of the intent to file this brief, and consent was granted by all parties. Pursuant to Supreme Court Rule 37.6, no counsel for a party authored this brief in whole or in part, and no such counsel or a party made a monetary contribution intended to fund the preparation or submission of the brief. No person other than the *amicus curiae*, its members, or its counsel made any monetary contribution to the preparation or submission of the brief.

Judge Michel has also been invited to testify before Congress on substantive patent law issues that are critical to the Nation's economic and innovative health. He testified at patent reform hearings in July 2017 before the Subcommittee on Courts, Intellectual Property, and the Internet of the House Committee of the Judiciary.² More recently, in June 2019, he testified before the Subcommittee on Intellectual Property of the U.S. Senate Committee on the Judiciary.³

Judge Michel is one of the nation's leading patent law experts, having a unique combination of judicial experience and legal expertise. Importantly, he has a total absence of any financial conflicts of interest. He does not advocate on behalf of parties, does not own stocks or bonds, does not serve as an employee of any entity, and does not belong to any lawyer's association or trade group. The only exception is his unpaid service on the Board of the Intellectual Property Owners Education Foundation, which seeks to educate the public about intellectual property. His sole objective is to respectfully share his perspective as a true friend of the Court to ensure that the U.S. patent system creates the optimal incentives for inventors, innovators, and investors—as it has traditionally done.

In view of Judge Michel's unique experience and perspective, he offers his arguments as *amicus curiae* directly in his own words.

² Judge Michel's supplemental testimony is available here: <https://www.scribd.com/document/381649917/Supplemental-Statement-of-Paul-R-Michel-Sept-12-2017>.

³ Judge Michel's testimony is available here: <https://www.judiciary.senate.gov/imo/media/doc/Michel%20Testimony.pdf>.

SUMMARY OF ARGUMENT

To borrow Malcolm Gladwell's phrase, we have reached a "tipping point" in patent law. Perhaps more apropos is an analogy to the fantastical land of Lewis Carroll's "Through the Looking-Glass." Whatever the most apt literary reference or analogy, one thing is absolutely certain: The Federal Circuit's menagerie of patent-eligibility decisions over the past decade are devoid of any semblance of consistency. They have created an unbounded and detrimental uncertainty in biotechnology innovation, and the law needs clarification and correction.

The outcome here is the ultimate manifestation of the palpable legal confusion. The majority of the en banc Federal Circuit believes patent protection should be available for the novel diagnostic method for detecting a life-altering autoimmune disease. Yet the court denied patent protection at the threshold stage of eligibility because, as Judge Lourie put it, they felt "bound by the Supreme Court's decision" in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 566 U.S. 66 (2012).

During my years on the bench and the near-decade since I left judicial service, I know of no remotely similar outcome where the majority of the Federal Circuit believed that a life-saving medical invention was at least eligible for patent protection but nevertheless shut the door at the threshold stage before even considering the merits of the underlying invention. In Judge Moore's view, the majority thought its "hands are tied," even though she and several other judges believed that the outcome was not preordained by *Mayo*.

This fundamental rift within the Federal Circuit is all the more concerning because, on all accounts, the invention in this case is a lifesaving, innovative medical advance—precisely the type the U.S. patent system should and must protect. Patent protection is supposed to be the economic incentive that promotes the progress of the Useful Arts. But the utter doctrinal confusion has created a legal quagmire that impedes technological progress and the societal benefits that flow from groundbreaking innovation.

ARGUMENT

I. NEVER BEFORE HAS THE FEDERAL CIRCUIT BEEN SO SPLINTERED ON A FUNDAMENTAL DOCTRINE OF PATENT LAW

During my twenty-two years on the bench, I do not recall any other legal issue—in patent law or any other issue within the Federal Circuit’s jurisdiction—that created such disharmony, disagreement, and inconsistency. The appeals court has reached a point in its decisionmaking where it produces opinions on patent eligibility that cannot satisfy the needs of inventors, investors, and innovative businesses. One cannot distinguish eligible subject matter from ineligible, with any reasonable certainty. This is unsustainable and contrary to the very reason Congress established the Federal Circuit in 1982.

A. Eight Separate Opinions Result in Patent Invalidation, Even Though the Majority Thought the Invention was Patent Eligible

On one level, it is nearly impossible to overstate the level of judicial discordance in this case, with the Federal Circuit producing multiple opinions denying the petition for rehearing en banc. The appellate process yielded eight separate opinions, with overlapping authorship and reasoning. Never before have I witnessed such an outcome when there is majority agreement about the beneficial value of the underlying invention.

This result is easily the most fractured patent case to reach this Court since it took a renewed interest in patent law decisions almost twenty years ago. *See generally* John F. Duffy, *The Festo Decision and the Return of the Supreme Court to the Bar of Patents*, 6 S. Ct. Rev. 273 (2002). In fact, the judicial disagreements in prior patent-eligibility cases before this Court seem tame compared to the eight opinions here. *Cf. Alice Corp. v. CLS Bank Int'l*, 573 U.S. 208 (2014); *Mayo*, 566 U.S. at 66; *Bilski v. Kappos*, 561 U.S. 208 (2010). This unprecedented intra-circuit split is reason enough to grant review. Indeed, in *Bilski*, the Court granted review, noting that the Federal Circuit “produced five different opinions.” *Bilski*, 561 U.S. at 600. But even with those five opinions, all but one judge thought that the claimed method of commodities hedging was not patent eligible.

On another level, this case is remarkable for its nearly uniform request for help. I do not repeat all the salient points from the Federal Circuit’s eight opinions

here, as Petitioners have ably summarized those opinions and explained why review is warranted. But a limited examination of the eight opinions reveals sincere requests for this Court’s assistance. The consistent message running throughout the opinions—whether expressly or implicitly—is that this Court needs to clarify when lifesaving medical diagnostic inventions are eligible for patent protection. Pet. App. 62a (“The multiple concurring and dissenting opinions regarding the denial of en banc rehearing in this case are illustrative of how fraught the issue of § 101 eligibility, especially as applied to medical diagnostics patents, is.”).

In the first opinion, Judge Lourie, joined by Judges Reyna and Chen, lamented that the Federal Circuit “can accomplish little in [rehearing the case en banc], as we are bound by the Supreme Court’s decision in *Mayo*.” *Id.* at 58a. Next, Judge Hughes, joined by Chief Judge Prost and Judge Taranto, echoed this assessment:

I, for one, would welcome further explication of eligibility standards in the area of diagnostics patents. Such standards could permit patenting of essential lifesaving 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.

Id. at 63a. Following that, Judge Dyk, with Judges Hughes, and Chen, explicitly stated that “[i]t would be desirable for the Supreme Court to refine the *Mayo* framework to allow for sufficiently specific diagnostic patent claims with proven utility.” *Id.* at 71a. In his own

concurrency, Judge Chen reiterated his belief that the Federal Circuit “would benefit from the Supreme Court’s guidance as to whether it intended to override central tenets of” *Diamond v. Diehr*, 450 U.S. 175 (1981), when it issued *Mayo*. *Id.* at 79a.

The four dissenting opinions also implicitly recognize the need for this Court’s intervention. In the first dissent, Judge Moore, joined by Judges O’Malley, Wallach, and Stoll, concluded with the following statement: “Your only hope lies with the Supreme Court or Congress.” *Id.* at 119a. While penned in disagreement with the majority, that sentiment acknowledges the reality in view of the majority’s denial of rehearing.

Judge Newman, joined by Judge Wallach, argued that “[t]he majority’s position is a flawed interpretation of the Court’s decision in *Mayo*.” *Id.* at 121a. Judge Stoll, joined also by Judge Wallach, asserted that the Federal Circuit’s “bright-line rule is based on an overreaching and flawed test for eligibility, a test that undermines the constitutional rationale for having a patent system—promoting the progress of science and useful arts.” *Id.* at 136a.

Last was Judge O’Malley, who deemed the doctrinal confusion as stemming directly from this Court’s precedent itself: “[T]he Supreme Court has instructed federal courts to read into Section 101 an ‘inventive concept’ requirement—a baffling standard that Congress removed when it amended the Patent Act in 1952.” *Id.* at 139a. Accepting Judge O’Malley’s view, the Federal Circuit has its hands tied, as Judge Hughes said, and only this Court can correct what she sees as a fundamentally flawed interpretation of 35 U.S.C. § 101.

In the end, taking all eight opinions together, my former colleagues on the appeals court need this Court to clarify and correct the law. The current situation, with the degree of legal uncertainty, is administratively unsustainable. And the *status quo* fundamentally impedes the basic purpose of the Federal Circuit—to bring uniformity to patent law. *See Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 162 (1989) (“Congress conferred exclusive jurisdiction of all patent appeals on the Court of Appeals for the Federal Circuit, in order to ‘provide nationwide uniformity in patent law.’” (quoting H.R. Rep. No. 97-312, at 20 (1981))).

B. A More Recent Federal Circuit Decision Confirms the Doctrinal Confusion

Although touching on a different technology, one recent Federal Circuit decision confirms my view that the appeals court needs clarification of the law. This more recent case illustrates how far astray the appeals court has been led by the rote application of the two-step “*Mayo/Alice* analysis.”

In *American Axle & Manufacturing, Inc. v. Neapco Holdings LLC*, 939 F.3d 1355 (Fed. Cir. 2019), a majority held as not patent eligible a “method for manufacturing a shaft assembly of a driveline system.” The majority seemed to think that because a law of nature was utilized in making the shaft assembly—an actual physical object—the claim was not patent eligible.

This conclusion, in my view, represents a gross misapplication of § 101 and undermines the very purpose of the Patent Act. The decision takes the seemingly unprecedented step of declaring a physical

process, *i.e.*, a method of making a tangible article of manufacture that has real-world uses and benefits, to be not even eligible for patent protection. The denial of patent protection would perhaps be defensible if it were premised on a lack of novelty under § 102 or obviousness under § 103. But the result, as Judge Moore aptly explained in dissent, “expands § 101 well beyond its statutory gate-keeping function and the role of th[e] appellate court well beyond its authority.” 939 F.3d at 1369 (Moore, J., dissenting).

It may be that the decision in *American Axle* is corrected on rehearing or later by this Court. The important point, for purposes of the present petition, is that *American Axle* is a symptom of existing doctrinal confusion over § 101. Without this Court’s intervention here (or Congress’s intervention with a legislative fix), I expect to see more troubling decisions by the courts that will adversely affect innovators in the medical diagnostics field.

II. THE CONFUSION IN PATENT ELIGIBILITY EXTENDS WELL BEYOND THIS CASE, WITH THE THREE BRANCHES OF GOVERNMENT ADOPTING INCONSISTENT POSITIONS

The Federal Circuit’s hopelessly fractured outcome epitomizes the existing disagreement on patent eligibility among the branches of the Federal Government. Congress through statute has authorized broad patent eligibility, but the courts have imposed non-statutory restrictions. The Executive Branch, through the U.S. Patent and Trademark Office (“PTO”), is left adopting its own interpretation as it tries to grant patents on important biomedical advances. This disharmony among the three branches of the Federal Government

is all the more reason to grant the petition—particularly when the strong consensus is that the underlying invention in this case is a groundbreaking advance in medical diagnostics.

A. Congress Has Statutorily Authorized Broad Patent Protection, Which Should Include Groundbreaking Biomedical Technologies

What Congress intended with patent eligibility should have been clear. In 1952, Congress codified the four broad independent categories of invention that are eligible for patent protection: “any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof.” 35 U.S.C. § 101.

Appellate and district courts are instructed, as they should be, to focus on the statute’s express language. The text of § 101 recites four broad categories, without any narrowing qualifiers. In fact, Congress used the expansive modifier “any” when setting forth the four categories of invention. And that broad modifier should have been sufficient for the word “any” to mean “any.” *E.g.*, *SAS Inst. Inc. v. Iancu*, 138 S. Ct. 1348, 1351 (2018) (“[T]he word ‘any’ ordinarily implies every member of a group.”); *see also Diamond v. Chakrabarty*, 447 U.S. 303, 308 (1980) (“In choosing such expansive terms . . . modified by the comprehensive ‘any,’ Congress contemplated that the patent laws should be given wide scope.”).

In the four explicit categories of inventions, there is no language which would suggest that innovative diagnostic methods, such as the one at issue in this

case, would not be patent eligible. Indeed, the claims in Athena Diagnostic’s patent (as set forth in the petition) describe a quintessential “process,” or method. Pet. 6–8.

Looking at the statute, there should be no question that Athena Diagnostic’s innovative method of diagnosing myasthenia gravis patients would be at least eligible of patent protection (recognizing that novelty and nonobviousness are separate requirements the invention must satisfy after the threshold inquiry on patent eligibility). But not so fast, as Congress’s statutory language is no longer the controlling language in patent-eligibility determinations.

B. Medical Diagnostic Inventions Have Experienced Mixed Treatment by the Judicial Branch

Despite the focused language of § 101, this Court has “long held that this provision contains an important implicit exception[:] Laws of nature, natural phenomena, and abstract ideas are not patentable.” *Mayo*, 566 U.S. at 70 (internal quotation marks and brackets omitted). Those judicially created exceptions conflict with Congress’s statutory mandate. But even accepting the validity of those judicial exceptions for the sake of argument, there is little debate that those non-statutory exceptions have been the primary gremlins causing havoc in § 101 law. Michel & Dowd, *supra*, at 2 (noting that *Mayo*, *Alice*, and *Bilski* “created enormous uncertainty about the patentability of medical

diagnostics, software, computers, and business methods”).⁴

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 Genetic Veterinary Scis., Inc. v. LABOKLIN GmbH & Co. KG*, 933 F.3d 1302 (Fed. Cir. 2019) (invalidating claims for detecting hereditary nasal parakeratosis in Labrador retrievers); *Roche Molecular Sys., Inc. v. CEPHEID*, 905 F.3d 1363 (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 (Fed. Cir. 2016) (invalidating a patent claiming a novel method of using noncoding sequences of DNA to detect mutations associated with various diseases); *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371 (Fed. Cir. 2015) (invalidating an award-winning, groundbreaking, noninvasive method for detecting Down Syndrome and other fetal abnormalities without having to use invasive and potentially dangerous amniocentesis); *In re BRCA1- & BRCA2-Based Hereditary Cancer Test Patent Litig.*, 774 F.3d 755 (Fed. Cir. 2014) (invalidating method claims for screening for genes linked to inherited breast and ovarian cancer).

At the same time, the Federal Circuit has affirmed the patent eligibility of inventions even though they undoubtedly use a “law of nature.” *See, e.g., INO*

⁴ <https://www.competitionpolicyinternational.com/wp-content/uploads/2017/04/CPI-Michel-Dowd.pdf>

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); *Endo Pharms. Inc. v. Teva Pharms. USA, Inc.*, 919 F.3d 1347 (Fed. Cir. 2019) (upholding method of using oxymorphone to treat pain in patients with impaired kidney function); *Natural Alternatives Int’l, Inc. v. Creative Compounds, LLC*, 918 F.3d 1338 (Fed. Cir. 2019) (upholding claims for method of treatment using natural product beta-alanine); *Vanda Pharms. Inc. v. West-Ward Pharms. Int’l Ltd.*, 887 F.3d 1117 (Fed. Cir. 2018) (validating a patent related to a method of treating schizophrenia patients with iloperidone); *Rapid Litig. Mgmt. Ltd. v. CellzDirect, Inc.*, 827 F.3d 1042 (Fed. Cir. 2016) (holding, as patent eligible, a method of producing a preparation of multi-cryopreserved hepatocytes).

Whether invalidated or not, each invention in the cited cases seems to be a “process” under the statutory language. But many of those processes fell prey to the judicial exceptions attack, as either an “abstract idea” or a “product of nature.” Unfortunately, with the current state of the law, it is difficult to know, with any reasonable certainty, if method claims covering diagnostics, biotechnology, or medical treatments will survive a § 101 validity attack.

I told Congress much the same in June 2019:

In my view, recent cases are unclear, inconsistent with one another and confusing. I myself cannot reconcile the cases. That applies equally to Supreme Court and Federal Circuit cases. Nor can I predict outcomes in indiv-

idual cases with any confidence since the law keeps changing year after year. If I, as a judge with 22 years of experience deciding patent cases on the Federal Circuit's bench, cannot predict outcomes based on case law, how can we expect patent examiners, trial judges, inventors and investors to do so?

The State of Patent Eligibility in America, Part I: Hearing Before the Subcomm. on Intellectual Property of the S. Comm. on the Judiciary, 116th Cong. 2 (2019) (Testimony of Hon. Paul R. Michel).

Ultimately, § 101 caselaw has become a menagerie of inconsistency, with the outcome never certain, even after knowing which Federal Circuit judges are deciding the appeal. The U.S. biotech and medical diagnostics industries deserve better, and this Court's review is necessary.

C. The Patent Office Offers Its Own Guidance on the Patent Eligibility of Medical Diagnostic Inventions

Added to Congress's and the courts' competing views on patent eligibility are the views of the PTO. The PTO's Director Andrei Iancu has made impressive progress on providing clearer guidance to the innovation community. The PTO's efforts are, in my view, very positive steps forward, but they present yet another interpretation of patent eligibility within the Federal Government.

Specifically, the PTO has issued new guidelines aimed to "improve certainty and reliability in how examiners apply § 101." *See, e.g., United States Patent and Trademark Office, 2019 Revised Patent Subject*

Matter Eligibility Guidance, 84 Fed. Reg. 50, 52 (Jan. 7, 2019). For instance, the guidance tries to contextualize and explain the “abstract idea” judicial exception by categorizing different “abstract ideas.” *Id.* This is supposed to help patent examiners “to more readily determine whether a claim recites subject matter that is an abstract idea.” *Id.* Whether it accomplishes its objectives is up for debate, and I question whether the “abstract idea” exception will ever be amenable to a consistent application, particularly for biotech and medical diagnostic inventions.

More recently, in October 2019, the PTO issued an update to its Patent Eligibility Guidance. *See* United States Patent and Trademark Office, *October 2019 Update: Subject Matter Eligibility* (Oct. 17, 2019).⁵ Included with the Updated Guidance were additional examples of hypothetical claims that the PTO considers to be either eligible or ineligible. Again, this additional agency guidance can be helpful, but only if consistent with controlling law. Many have argued that it is not.

While the guidance of an expert agency is helpful, ultimately it does not bind the federal courts, as the Federal Circuit recently explained when it declined to consider the PTO’s Patent Eligibility Guidance. *See Cleveland Clinic Found. v. True Health Diagnostics LLC*, 760 Fed. App’x 1013, 1020 (Fed. Cir. 2019) (non-precedential). The end result is yet another competing application of 35 U.S.C. § 101. In the long term, this creates more confusion and uncertainty, as the PTO continues to issue medical diagnostic patents under

⁵ https://www.uspto.gov/sites/default/files/documents/peg_oct_2019_update.pdf

its internal guidance which may not adhere to binding precedent of this Court.

Ultimately, the status quo leaves the innovation community wondering which branch of the Federal Government will ultimately have the final word. But as we know, until Congress steps in with a legislative fix, “[i]t is emphatically the province and duty of the Judicial Department to say what the law is.” *Marbury v. Madison*, 5 U.S. (1 Cranch) 137, 177 (1803).

III. THE UNCERTAINTY AND CONFUSION WITH PATENT ELIGIBILITY UNDERMINE INVESTMENT IN THE U.S. BIOTECH AND MEDICAL DIAGNOSTICS INDUSTRIES

In my years off the bench, I have had the invaluable opportunity to interact with all sectors of the U.S. innovation community. I speak to various industry and interest groups. I learn which patent law issues most affect these companies and inventors. Based on these myriad conversations, I can say confidently that the one sector most adversely impacted by current patent-eligibility law is the medical diagnostic sector.

The medical diagnostic sector is immensely important. A 2005 industry report estimated that diagnostic tests formed the basis of 60%–70% of all medical treatment decisions. See The Lewin Group, *The Value of Diagnostics Innovation, Adoption and Diffusion into Health Care* (July 2005).⁶ That number has likely risen since then with the increasing importance of genetic-based testing. The development of diagnostic

⁶ <https://dx.advamed.org/sites/dx.advamed.org/files/resource/Lewin%20Value%20of%20Diagnostics%20Report.pdf>

tests is expensive and time-consuming. One survey concluded that the average R&D and commercialization costs for a diagnostic test is between \$50–\$75 million and can exceed \$100 million for developing and commercializing novel diagnostic technologies. Diaceutics Group, *Mystery Solved! What Is the Cost to Develop and Launch a Diagnostic?* (Jan. 15, 2013).⁷

In short, developing diagnostic tests and methods requires a substantial expenditure of capital, in addition to the human and time resources necessary. Rational market participants will make that investment only if they are reasonably likely to get a return on their investment. And in the medical diagnostics space, patent protection is necessary to ensure a reasonable return on the investment. Without patent protection, free-riding competitors will copy the innovator's product and commercialize it without having to make the financial investment.

I have witnessed this problem personally with many companies, inventors, and investors, including those in the medical diagnostic space. I also have written on the topic with David Kappos, the former Director of the PTO:

This uncertain patent climate has a chilling effect on innovation in biosciences to the detriment of public health. . . . [I]nvestors are less interested in funding costly new biomarker diagnostic research. As a result, diseases will go undiagnosed, and patients will suffer the consequences. . . . Investment in diagnostics

⁷ <http://www.diaceutics.com/?expert-insight=mystery-solved-what-is-the-cost-to-develop-and-launch-a-diagnostic>

goes to the core of containing spiraling health care costs, improving patient outcomes and treating illnesses before they become debilitating to suffering Americans.

David Kappos & Paul R. Michel, *Supreme Court Patent Decisions are Stifling Health Care Innovation*, Morning Consult (Oct. 29, 2018).⁸

Unfortunately, the existing problems in patent-eligibility law are having detrimental effects on those in the medical diagnostics space. They fear a loss on their investments when patents covering groundbreaking and innovative diagnostic methods are being struck down at the threshold stage of § 101. No longer can they argue the merits of the invention or rely on objective evidence to demonstrate how their invention is a true advance in the “useful arts.” Instead, they must grapple with abstract and undefined terms such as “abstract idea.”

More importantly, they do not know which view of the law will prevail. Will it be the PTO’s new guidance on § 101 for patent examiners, or will it be the Federal Circuit’s implementation of the law? They simply do not know, and that is one of the major concerns I hear about when I interact with leaders in the field.

As I have written before, for innovation to thrive, the innovation creators need the proper environment that has sufficient “innovation certainty.” *See Michel & Dowd, supra*, at 1. An innovator needs intellectual capital, an educated workforce, and access to financial

⁸ <https://morningconsult.com/opinions/supreme-court-patent-decisions-stifling-health-care-innovation/>

capital. These resources permit an innovator—whether a small or large company—to conduct the necessary research and development to create the next lifesaving diagnostic test. And the innovation certainty allows those companies to optimize those diagnostic tests and methods so that they become commercially successful, which in turn creates additional capital for the development of the next generation of diagnostic tests.

In short, the current state of the law under § 101 is destroying the innovation certainty needed for medical diagnostic companies to thrive in the United States. Those companies are increasingly turning to other jurisdictions, such as China and Europe, where the foreign patent systems offer the broader protection for medical diagnostic inventions. Rather than narrowing the scope of eligibility, those jurisdictions are expanding what can be patented.

These real-world effects on medical diagnostics innovators are another reason for this Court to accept this case for review. Indeed, this Court faced a similar milestone almost forty years ago when it was asked to determine if non-natural, genetically engineered organisms are patent eligible. *Chakrabarty*, 447 U.S. at 308. By the slimmest of margins (5-4), the Court said “yes” and affirmed the patent eligibility of those inventions. In doing so, the Court helped usher in a scientific and commercial revolution that led to a plethora of technologies in the biotech field.

A similar opportunity lies with the present petition. This case is a chance to ensure that inventors of lifesaving medical diagnostics are rewarded for their efforts and that patent protection enables those innovators to develop the technologies and

obtain capital to develop future technologies—just like what occurred after *Diamond v. Chakrabarty*.

CONCLUSION

For the foregoing reasons, the Honorable Paul R. Michel respectfully submits that the petition for a writ of certiorari should be granted.

Respectfully submitted,

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