No. 19-430

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 FOR THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA AS *AMICUS CURIAE* IN SUPPORT OF PETITION FOR A WRIT OF CERTIORARI

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INTEREST OF *AMICUS CURIAE*[1]

The Pharmaceutical Research and Manufacturers of America (PhRMA) represents the country's leading innovative biopharmaceutical research companies, which are devoted to discovering and developing medicines that enable patients to live longer, healthier, and more productive lives.[2] Over the past decade, hundreds of new medicines have been approved by the Food and Drug Administration (FDA). In view of the risky biopharmaceutical research and development process, which has a significant failure rate, and the substantial requirements of the FDA to demonstrate safety and efficacy of new products, those results come at a significant cost. Since 2000, PhRMA member companies have invested more than $900 billion in the search for new treatments and cures, including an estimated $79.6 billion in 2018 alone.

PhRMA members depend heavily on a robust system of patent rights and fair procedures for adjudicating their validity. PhRMA aims to advance public policies that foster medical innovation, including by ensuring adequate patent protection to enable and incentivize its members' substantial investments

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[1] Pursuant to Rule 37.6, *amicus curiae* affirms that no counsel for a party authored this brief in whole or in part, and that no person other than *amicus curiae* or its counsel made any monetary contributions intended to fund the preparation or submission of this brief. Petitioners' counsel has filed a blanket consent to the filing of all timely amicus briefs. Respondents' counsel was timely notified of PhRMA's intent to file this brief and consented to its filing.

[2] A complete list of PhRMA members is available at http://www.phrma.org/about/members (last visited October 31, 2019).

in research and development. To those ends, PhRMA seeks to prevent inappropriate barriers from arising that undermine intellectual property protections, including as *amicus curiae* before this Court.

INTRODUCTION AND SUMMARY OF ARGUMENT

The Federal Circuit's decisions applying this Court's decision in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 566 U.S. 66 (2012), have all but precluded innovators' ability to patent any medical diagnostic, no matter how novel or groundbreaking. Indeed, the Federal Circuit acknowledged in this case that it has not upheld a *single patent* on a medical diagnostic since this Court's *Mayo* decision. That cannot be the result this Court intended in 2012 when it issued its narrow holding regarding "the *particular* claims before us." *Id.* at 72 (emphasis added). This case provides an ideal opportunity for the Court to clarify its precedent and lift a cloud of uncertainty that is stifling investment and innovation in life-saving technologies at the forefront of modern medicine.

As the decision below shows, the judges of the Federal Circuit unanimously agree that novel diagnostics generally *should* be patent eligible, but a slight majority believes its hands are tied by this Court's *Mayo* decision. The resulting confusion and uncertainty regarding the patent eligibility of diagnostics and related treatments pervades the U.S. Patent and Trademark Office ("Patent Office") and the biopharmaceutical industry.

This Court's intervention is urgently needed to resolve the confusion. Diagnostics play a crucial role in

promoting public health. Although diagnostics represent only a small fraction of total healthcare expenses, they guide a majority of all clinical decisions. Diagnostics are also key to unlocking the promise of "precision medicine" by enabling physicians to tailor treatments to the individual molecular profiles of patients. As medicine becomes more personalized, innovative "companion diagnostics" increasingly are being paired and co-developed with therapeutic products.

These life-saving advances require significant investments, and thus depend on robust patent protection. Patents provide an essential economic incentive for companies to pursue lengthy research and development projects characterized by high costs and failure rates.

The confusion surrounding the patent eligibility of diagnostics is already chilling innovation in the diagnostics field. The adverse effects extend to universities, smaller companies, and individual inventors who rely on patents to secure the partnerships needed to convert their discoveries into marketable medical products. Unless and until the patent eligibility of diagnostics is clarified and confidence in the U.S. patent system is restored, innovation in this life-saving field will remain hampered, with potentially far-reaching consequences for public health.

ARGUMENT

I. THE FEDERAL CIRCUIT'S APPLICATION OF *MAYO* HAS THROWN INTO DOUBT THE PATENT ELIGIBILITY OF MEDICAL DIAGNOSTICS

In 2012, this Court's opinion in *Mayo* set forth a two-step inquiry to assess patent eligibility under 35 U.S.C. § 101: (1) is the claim at issue directed to a patent-ineligible concept—that is, an abstract idea, natural phenomenon, or law of nature—and if so, (2) does the claim add an "inventive concept" that transforms it into a patent-eligible application of such a concept? *See Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 573 U.S. 208, 217 (2014) (citing *Mayo*, 566 U.S. at 72–73).

In the wake of *Mayo*, the Federal Circuit has found every medical diagnostic claim it has considered ineligible for patent protection. *See Athena Diagnostics v. Mayo Collaborative Services*, 927 F.3d 1333, 1352 (Fed. Cir. 2019) (Moore, J., dissenting from denial of rehearing en banc) ("Since *Mayo*, we have held every single diagnostic claim in every case before us ineligible.") (collecting cases).[3] The inventions held

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[3] *See Cleveland Clinic Found. v. True Health Diagnostics LLC*, 760 F. App'x 1013 (Fed. Cir. 2019); *Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC*, 915 F.3d 743 (Fed. Cir. 2019); *Roche Molecular Sys., Inc. v. CEPHEID*, 905 F.3d 1363 (Fed. Cir. 2018); *Cleveland Clinic Found. v. True Health Diagnostics LLC*, 859 F.3d 1352 (Fed. Cir. 2017), *cert. denied*, 138 S. Ct. 2621 (2018); *Genetic Techs. Ltd. v. Merial L.L.C.*, 818 F.3d 1369 (Fed. Cir. 2016), *cert. denied*, 137 S. Ct. 242 (2016); *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371 (Fed. Cir. 2015), *cert. denied*, 136 S. Ct. 2511 (2016); *In re BRCA1- and BRCA2-Based*

ineligible in these cases included important medical advances for the diagnosis and treatment of cardiovascular disease, autoimmune disease, cancer, and tuberculosis, and for the prenatal detection of genetic disorders. Yet in each case, the Federal Circuit, based on its understanding of *Mayo*, concluded that the claims at issue were directed to a natural law or phenomenon and that the recited steps did not supply the inventive concept required for patentability. Under the Federal Circuit's understanding of *Mayo*, "groundbreaking," "breakthrough," and "even brilliant" discoveries, narrowly applied to useful ends, may nevertheless be ineligible for patent protection. *Ariosa*, 788 F.3d at 1380; *id.* at 1381 (Linn, J., concurring).

The judges of the Federal Circuit openly acknowledge that their precedent threatens to eliminate patent protection for diagnostics as a class. *See, e.g.*, *Athena*, 927 F.3d at 1337 (Hughes, J., concurring in denial of rehearing en banc) ("[T]he bottom line for diagnostics patents is problematic."); *id.* at 1354 (Moore, J., dissenting from denial of rehearing en banc) ("We have turned *Mayo* into a *per se* rule that diagnostic kits and techniques are ineligible."). Scholars and stakeholders of the patent system share their assessment. In one scholar's view, "*Mayo*'s requirement for inventive application has virtually eliminated patent protection for new diagnostics and other kinds of discovery-based inventions."[4] For the

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Hereditary Cancer Test Patent Litig., 774 F.3d 755 (Fed. Cir. 2014); *PerkinElmer, Inc. v. Intema Ltd.*, 496 F. App'x 65 (Fed. Cir. 2012), *cert. denied*, 134 S. Ct. 102 (2013).

[4] *The State of Patent Eligibility in America, Part I: Hearing Before the Subcomm. on Intellectual Property of the S. Comm. on*

Cleveland Clinic, a medical care provider and research center, the case law has "cast a cloud of uncertainty over [its] work in the field of diagnostic tests and life sciences."[5]

Patent eligibility for medical innovations outside the diagnostics realm may also be at risk. Heeding the Supreme Court's guidance that "a new way of using an existing drug" should be patent eligible, *Mayo*, 566 U.S. at 87, the Federal Circuit had on several occasions confirmed the eligibility of method-of-treatment claims that utilize natural phenomena, *see Endo Pharm. Inc. v. Teva Pharm. USA, Inc.*, 919 F.3d 1347 (Fed. Cir. 2019); *Vanda Pharm., Inc. v. West-Ward Pharm. Int'l Ltd.*, 887 F.3d 1117 (Fed. Cir. 2018), *petition for cert. pending* (No. 18-817). However, the court recently distinguished this precedent in a split decision deeming a different method-of-treatment claim "directed to [a] natural phenomenon" and thus patent ineligible. *INO Therapeutics LLC v. Praxair Distrib. Inc.*, No. 2018-1019, 2019 WL 4023576, at *4 (Fed. Cir. Aug. 27, 2019). It is thus unclear how courts will evaluate the patent eligibility of methods that contain a mix of diagnostic and treatment elements. While *Mayo* provides "certain guideposts," "there are wide gaps . . . and little guidance as to where the line between them lies."[6] As a

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the Judiciary, 116th Cong. (2019) (testimony of Jeffrey A. Lefstin, Professor of Law and Associate Academic Dean, University of California, Hastings College of Law) at 1.

[5] *Id., Part III* (testimony of Peter O'Neill, Executive Director, Cleveland Clinic Innovations) at 1.

[6] *Id.* (testimony of Corey Salsberg, Vice President and Global Head Intellectual Property Affairs, Novartis) at 3.

result, the case law not only casts a shadow over such hybrid patent claims that straddle the boundary between diagnosis and treatment,[7] but threatens to unsettle the patentability of "a wide range of important medicines, diagnostics, [and] treatments."[8]

Confusion regarding the conditions for patent eligibility of diagnostic methods and related innovations in medical treatment pervades the government, industry, and academia.[9] According to Paul Michel, the retired Chief Judge of the Federal Circuit, "[t]he current state of eligibility must be characterized as chaotic. Massive uncertainty pervades all determinations, whether by 8,300 patent examiners, 1,000

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[7] *Id.* (reporting that Novartis "lost several cancer-related 'method of treatment' claims that involve first checking to ensure that the patient has a specific genetic mutation before administering the novel drug that targets the mutation").

[8] *Id.* (testimony of Laurie Hill, Vice President, Intellectual Property, Genentech, Inc.) at 16 ("The present uncertainty surrounding Section 101 threatens to disrupt the development of a wide range of important medicines, diagnostics, [and] treatments."); *id.* (testimony of Corey Salsberg) at 4 ("[W]e face regular rejections on everything from medically promising isolated and purified proteins, to important biomarkers, primers, and vectors.").

[9] *See, e.g.*, *id.* (testimony of Natalie Derzko, Covington & Burling LLP, on behalf of the Pharmaceutical Research and Manufacturers of America) at 7–11 (describing the state of uncertainty in the patent landscape, "particularly for diagnostic patents"); *id.* (testimony of Rick Brandon, Associate General Counsel, University of Michigan, on behalf of the Association of American Universities and the Association of University Technology Managers) at 2.

federal trial judges, or 18 Federal Circuit judges."[10] Furthermore, "industry and scholars alike" deem it "unclear whether diagnostic methods are patentable in any meaningful way."[11] Even those opposed to broad reform of the *Mayo* framework readily acknowledge the "very real and valid concerns related to Section 101" in the "medical diagnostics" sector.[12]

Puzzlement regarding the state of patent eligibility law has led stakeholders to call upon this Court to clarify and potentially refine the *Mayo* framework, particularly as it pertains to the patent eligibility of diagnostic innovations. In *Sequenom, Inc. v. Ariosa Diagnostics, Inc.*, *twenty-two* amicus briefs urged the Court to provide guidance regarding the standard for patent eligibility of diagnostics.[13]

Although the Court did not grant review in *Sequenom*, the need for this Court's intervention is increasingly urgent, as is evident from the Federal Circuit's opinions concerning the denial of rehearing en banc in this case. *See Athena*, 927 F.3d at 1337 (Hughes, J., concurring in denial of rehearing en banc)

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[10] *Id., Part I* (testimony of Hon. Paul R. Michel (Ret.), United States Court of Appeals for the Federal Circuit) at 6.

[11] *Id., Part II* (testimony of Hans Sauer, Deputy General Counsel and Vice President for Intellectual Property, Biotechnology Innovation Organization) at 7.

[12] *Id.*, *Part III* (testimony of Sean Reilly, Senior Vice President and Associate General Counsel, The Clearing House Payments Company) at 4; *see also id.* (testimony of Mark A. Lemley, Professor, Stanford Law School) at 2 (favoring a "conservative approach" that would solve the "identified problems in the medical diagnostics business").

[13] *See Sequenom, Inc. v. Ariosa Diagnostics, Inc.*, https://www.supremecourt.gov/search.aspx?filename=/docketfiles/15-1182.htm.

("The multiple concurring and dissenting opinions . . . are illustrative of how fraught the issue of § 101 eligibility, especially as applied to medical diagnostic patents, is."). The Federal Circuit split seven-to-five on whether to grant rehearing, and issued eight separate concurring and dissenting opinions expressing a range of views on the proper application of *Mayo* to diagnostic claims. *Compare, e.g.*, *id.* at 1337 (Hughes, J., concurring in denial of rehearing en banc) ("[T]he language in *Mayo* . . . forecloses this court from adopting an approach or reaching a result different from the panel majority's."), *with, e.g., id.* at 1364 (Newman, J., dissenting from denial of rehearing en banc) ("We have mistakenly enlarged the Court's holding [in *Mayo*], in substance and in application.").

Notably, however, the judges of the Federal Circuit unanimously agree on one essential point: medical diagnostic innovations generally *should* be patent eligible. *See id.* at 1352 (Moore, J., dissenting from denial of rehearing en banc) ("None of my colleagues defend the conclusion that claims to diagnostic kits and diagnostic techniques, like those at issue, should be ineligible."). Thus, even judges who voted against rehearing called upon this Court to clarify how *Mayo* applies in the diagnostics context. *See id.* at 1337 (Hughes, J., concurring in denial of rehearing en banc) ("I, for one, would welcome further explication of eligibility standards in the area of diagnostics patents."); *id.* at 1339 (Dyk, J., concurring in denial of rehearing en banc) ("[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 1349 (Chen, J., concurring in denial of rehearing en banc) ("Resolution of the present confusion is important . . . .").

This case provides an ideal opportunity for the Court to clarify its precedent concerning the patent eligibility of diagnostics. As described in the petition for certiorari, the claims at issue recite a method of diagnosing neurological disorders using man-made molecules to detect previously unused biomarkers through a series of precise chemical steps never before employed in this manner. *See* Pet. at 7–8. The discovery of the association between the biomarkers and neurological disorders was undisputedly groundbreaking, and the narrow sequence of steps claimed by the inventors leaves open other ways to detect the same disorders and thus does not raise significant preemption concerns. *See id.* at 33. The Federal Circuit's ruling that such a specific, inventive, and non-preempting diagnostic method is nevertheless patent ineligible cannot be reconciled with the mandate of Section 101, which broadly provides patent eligibility for "[w]hoever invents or discovers any new and useful process . . . or any new and useful improvement thereof." 35 U.S.C. § 101.

The Court should grant review to bring the Federal Circuit's errant Section 101 jurisprudence back on track and clarify the patent eligibility standard for diagnostics.

II. THE MEDICAL DIAGNOSTICS FIELD DEPENDS ON RELIABLE PATENT INCENTIVES

A. Diagnostics Play A Crucial Role in Promoting Public Health

Physicians rely on diagnostic tests to treat patients in a safe, effective, and cost-efficient manner. Diagnostics have become an "indispensable" tool for assessing patients' risk of developing diseases, diagnosing and monitoring diseases, generating prognoses and predicting treatment responses, and guiding patient management.[14] They also have an outsized impact on medical care: while accounting for only 2.3% of healthcare expenses, diagnostic testing "guides approximately 66% of clinical decisions" in the United States.[15]

Diagnostics are also central to ongoing efforts to overcome some of the most intractable healthcare challenges. In the case of Alzheimer's, for example, "[n]ew diagnostic tests, that measure biomarkers . . . will be critically important . . . because they will eventually allow for proactive disease management at a very early stage."[16] Because the Alzheimer's disease

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[14] Ulrich-Peter Rohr et al., *The Value of In Vitro Diagnostic Testing in Medical Practice: A Status Report*, PLoS ONE 11(3) (2016) at 2.

[15] *Id.* at 10; *see also* Lewin Group, *The Value of Diagnostics Innovation, Adoption and Diffusion into Health Care* (July 2005) at 1 ("While diagnostics comprise less than 5% of hospital costs and about 1.6% of all Medicare costs, their findings influence as much as 60–70% of health care decision-making.").

[16] *The State of Patent Eligibility in America, Part III* (testimony of Robert Deberardine, Chief Intellectual Property Counsel, Johnson & Johnson) at 4.

process starts "10 to 20 years prior to actual symptoms," diagnostics could "ultimately enable the prevention of symptom development with early treatment." *Id.*

In addition to prolonging and saving lives, diagnostic tools reduce medical treatment costs. By enabling earlier detection of illness and targeted treatment plans, diagnostics can decrease hospitalization rates and prevent resort to unnecessary, unsuccessful, and often expensive treatments.[17] Thus, "[i]nvestment in diagnostics goes to the core of containing spiraling health care costs."[18]

Diagnostics are an integral component of the burgeoning field of personalized (or precision) medicine, which uses a patient's individual characteristics to determine the treatments and procedures best suited for that patient and to develop individually-tailored treatment plans.[19] The benefits of this approach include improved methods of administration and

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[17] *See id.* (testimony of Natalie Derzko) at 2; *Athena*, 927 F.3d at 1355 (Moore, J., dissenting from denial of rehearing en banc); Lewin Group, *The Value of Diagnostics Innovation* at 2.

[18] David J. Kappos & Paul R. Michel, *Supreme Court Patent Decisions Are Stifling Health Care Innovation*, MORNING CONSULT (Oct. 29, 2018), https://morningconsult.com/opinions/supreme-court-patent-decisions-stifling-health-care-innovation/.

[19] *See* Jeffrey A. Lefstin et al., *Addressing Patent Eligibility Challenges*, 33 Berkeley Tech. L.J. 551, 582 (2018); *The State of Patent Eligibility in America, Part III* (responses of Robert Deberardine to questions for the record) at 1.

treatment options as well as a reduction of adverse reactions and side effects.[20]

Diagnostic tests are driving personalized medicine because they enable physicians to tailor treatments to the molecular profiles of patients, targeting specific treatments to the patient subpopulations who will benefit while sparing expenses and side effects for the remainder.[21] Diagnostics increasingly guide the prescription of products for oncology, cardiovascular disease, and infectious diseases, among others. For example, biomarker identification and genomic testing for mutations have been shown to increase survival time and decrease costs for treating multiple types of cancer.[22]

In addition, "companion" diagnostics "provide[] information that is essential for the safe and effective use of a corresponding drug or biological product," and may be co-developed with that drug or product.[23]

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[20] *See The State of Patent Eligibility in America, Part III* (testimony of Natalie Derzko) at 2–3.

[21] *See id.* at 2; Lefstin, 33 Berkeley Tech. L.J. at 582 ("Molecular diagnostics play a central role in driving precision medicine research and development.").

[22] *The State of Patent Eligibility in America, Part III* (responses of Natalie Derzko to questions for the record) at 3.

[23] FDA, *Companion Diagnostics* (Dec. 7, 2018), https://www.fda.gov/medical-devices/vitro-diagnostics/companion-diagnostics. Companion diagnostics are classified as "medical devices," a category that includes, among other things, in vitro diagnostic products such as general purpose lab equipment, reagents, and test kits, and monoclonal antibody technology. *See* FDA, *Is The Product A Medical Device?* (Mar. 22, 2018), https://www.fda.gov/medical-devices/classify-your-medical-device/product-medical-device.

Companion diagnostics are particularly helpful for health care professionals seeking to identify the patients most likely to benefit or suffer serious side effects from particular therapies.[24] Relatedly, new methods of treatment that involve a diagnostic followed by administration of a particular drug "reflect important innovations that in practice help to improve health outcomes and save healthcare costs by ensuring that patients get the right drug tailored to their disease."[25]

B. Patent Eligibility Is Indispensable for Fostering Advancement of Diagnostics and Related Treatments

Patents provide essential economic incentives for the biopharmaceutical industry to take on the substantial costs and risks of developing new medicines as well as new diagnostic methods and tests.

The development of new and improved medicines "typically require[s] significant amounts of pioneering research, and both fixed costs and risks of failing to develop a marketable product . . . are very high."[26] A

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[24] FDA, *Companion Diagnostics* (Dec. 7, 2018), https://www.fda.gov/medical-devices/vitro-diagnostics/companion-diagnostics.

[25] *The State of Patent Eligibility in America, Part III* (testimony of Corey Salsberg) at 3 (emphasis omitted).

[26] Fed. Trade Comm'n (FTC), *To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy*, ch. 3, at 5 (Oct. 2003), https://www.ftc.gov/sites/default/files/documents/reports/promote-innovation-proper-balance-competition-and-patent-law-and-policy/innovationrpt.pdf.

reliable system of patent rights drives biopharmaceutical companies to innovate by providing a degree of assurance that they can obtain a return on their otherwise risky and costly R&D investments.[27] As industry representatives make clear, "[i]f an invention can't get intellectual property protection, usually that is a fatal flaw and the invention is abandoned at that point."[28] A "basic adage in the pharmaceutical industry" thus holds that "drugs without strong patent protection are not worth developing,"[29] and "pharmaceutical companies systematically screen their drug candidates to exclude the ones lacking strong patent protection."[30] More generally, when companies cannot rely on the patent system to protect their inventions, they are dis-incentivized from investing the time and resources necessary to innovate.[31] For these reasons, there is "a causal relationship between the strength of patent rights and innovation."[32]

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[27] *See The State of Patent Eligibility in America, Part III* (testimony of Natalie Derzko) at 4.

[28] *Id.* (testimony of Peter O'Neill) at 3.

[29] Benjamin N. Roin, *Unpatentable Drugs and the Standards of Patentability*, 87 Tex. L. Rev. 503, 547 (2009).

[30] *Id.* at 545*; see also The State of Patent Eligibility in America, Part III* (testimony of Sherry M. Knowles, Principal, Knowles Intellectual Property Strategies, LLC) at 28 ("Companies adamantly will not pursue a lengthy and costly product development program without any assurance of a repayment and return on the investment.").

[31] *See id.* at 5.

[32] Stephen Haber, *Patents and the Wealth of Nations*, 23 Geo. Mason L. Rev. 811, 829 (2016).

The promise of robust patent rights also plays a critical role in the research decisions of universities, smaller technology companies, and individual inventors. Such entities often lack the financial resources to themselves develop their inventions into marketable products, and instead use their patents as assets to secure venture capital or partnerships with larger companies.[33]

Diagnostics are "precisely the type of innovation that the patent system exists to promote." *Athena*, 927 F.3d at 1355 (Moore, J., dissenting from denial of rehearing en banc). Like biopharmaceutical products, diagnostic kits and techniques require substantial initial investments in terms of both time and money. As of 2011, development of a new diagnostic test was already estimated to take up to 10 years and cost up to $100 million.[34] Because diagnostics are not only expensive to develop but typically cheap to reproduce, the exclusivity conveyed in patent grants is especially important to render investment in their development

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[33] *The State of Patent Eligibility in America, Part III* (responses of Robert Deberardine to questions for the record) at 2–3; *see also id.* (testimony of Rick Brandon) at 1 (emphasizing that "American research universities have a front row seat to the incentives provided by our patent system").

[34] *See* Iruka N. Okeke et al., *Diagnostics as Essential Tools for Containing Antibacterial Resistance*, 14 Drug Resistance Updates 95, 101 (April 2011); *see also Mystery Solved! What is the Cost to Develop and Launch a Diagnostic*, DIACEUTICS (Jan. 15, 2013), https://www.diaceutics.com/?expert-insight=mystery-solved-what-is-the-cost-to-develop-and-launch-a-diagnostic (estimating the average cost of developing and marketing a diagnostic in the United States at $50–75 million, ranging from $20 million to $106 million).

financially viable.[35] This is all the more true given the scientific and regulatory uncertainty associated with the development of both new treatments and diagnostic methods.[36] In short, "patent protection of . . . diagnostics is critical to incentivizing their very existence." *Athena*, 927 F.3d at 1359 (Moore, J., dissenting from denial of rehearing en banc).[37]

In sum, diagnostics—and in particular companion diagnostics that enable methods of treatment tailored to the individual patient—are ushering in a new era of personalized medicine, and robust patent protections incentivizing such innovations are critical to realize the full potential of modern medicine.[38]

III. THE STATE OF THE CASE LAW STIFLES VITAL INNOVATION IN MEDICAL DIAGNOSIS

Confusion regarding the patent eligibility of diagnostics is already chilling investment and innovation in future life-saving medicines.

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[35] *See* Anatole Krattiger, *Promoting Access to Medical Innovation, in* World Intellectual Property Organization Magazine (Sept. 2013), *available at* https://www.wipo.int/wipo_magazine/en/2013/05/article_0002.html.

[36] *See The State of Patent Eligibility in America, Part III* (testimony of Natalie Derzko) at 4.

[37] *See also id.*, *Part I* (responses of Hon. Paul R. Michel to questions for the record) at 3 ("Recent breakthroughs in basic science show enormous promise in new areas such as . . . advanced diagnostics . . . . The promise can only be realized if the patent system is restored.").

[38] *See id., Part III* (responses of Laurie Hill to questions for the record) at 5 ("We are at a pivotal juncture in personalized medicine, much of which depends on whether such innovation is

The uncertainty created by Section 101 jurisprudence and the erosion of patent protection for diagnostics hampers the development of new diagnostics and paired treatments in several ways. First, companies and investors are discouraged from funding new research and development, and reduced investment slows the pace of advances in the field.[39] "The math is simple . . . : Without patent protection to recoup the enormous R&D cost, investment in diagnostic medicine will decline." *Athena*, 927 F.3d at 1358 (Moore, J., dissenting from denial of rehearing en banc). According to a former Patent Office director, "[c]urrently, there is too much uncertainty in the United States about whether life altering innovations will receive patent protection . . . to enable American innovation in . . . diagnostics."[40] The same could prove true for methods of treatment consisting of a companion diagnostic test paired with a therapeutic product.[41] Second, firms that do not believe their inventions will obtain patent protections will instead

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considered patent-eligible in the U.S."); *id.* (responses of Robert Deberardine to questions for the record) at 1 ("[T]he pharmaceutical industry is on the cusp of a healthcare revolution - personalized medicine. . . . However, substantial investment by pharmaceutical companies will be required to realize the full potential that these technologies hold.").

[39] *See id.* (testimony of Natalie Derzko) at 5; *see also* Lefstin, 33 Berkeley Tech. L.J. at 583 ("The shift in patent eligibility for diagnostics threatens research and development investment in medical diagnostics.").

[40] *The State of Patent Eligibility in America, Part I* (responses of David J. Kappos, former Patent Office Director, to questions for the record) at 1.

[41] *See id., Part III* (testimony of Corey Salsberg) at 3.

"maintain their discoveries as trade secrets, thereby reducing public disclosure that would support further discovery by others."[42]

These concerns are not speculative. A recent survey of nearly five hundred venture capital and private equity investors revealed that uncertainty about what constitutes patentable subject matter has not only caused an "adverse impact on investments" in the biotechnology and pharmaceutical industries generally but also "reduced investment in diagnostics" in particular.[43] The survey results show that "the funding needed to fuel American innovation in [the life sciences, diagnostics, and artificial intelligence industries] is already being reduced," and that as a result, "American innovation is already falling behind . . . foreign innovation in these critical industries."[44]

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[42] *Id., Part I* (testimony of Jeffrey A. Lefstin) at 2; *see also id.*, *Part III* (responses of Robert Deberardine to questions for the record) at 2 ("[I]n the absence of reliable patent protection, innovative companies may be incentivized to develop products that . . . benefit from other forms of protection—such as trade secrets and regulatory exclusivity.").

[43] David O. Taylor, *Patent Eligibility and Investment*, Card. L. Rev. (forthcoming 2019) at 58, http://ssrn.com/abstract=3340937; Lefstin, 33 Berkeley Tech. L.J. at 583 (noting that while the Section 101 case law has had "negative impacts on all of life science research and development, [it has] been particularly severe for the diagnostics sector").

[44] *The State of Patent Eligibility in America, Part I* (responses of David Kappos to questions for the record) at 1; *see id., Part II* (responses of Scott Partridge, Past Chair of the American Bar Association Section of Intellectual Property Law, to questions for the record) at 5 (noting that Professor Taylor's study "confirms

The impact of decreased investment in the development of new diagnostics is not limited to biopharmaceutical companies. To the contrary, the present climate of legal uncertainty "has a profound impact on the research decisions of universities, smaller technology companies, and individual inventors" with more limited financial resources and whose patents are "the primary business asset[s]" that enable them to partner with companies or secure venture capital.[45] In the past several years, the Association of American Universities has "seen the incentive system break down in the case of medical diagnostic technologies" as uncertainty concerning patent eligibility has "put at risk [universities'] licensees' investments and therefore the availability of some diagnostics."[46] The University of Michigan, for instance, "ha[s] seen several recent examples of the problems caused by this uncertainty, where investment was based on a presumption of patent protection."[47] As a result, medical diagnostics "are not being brought to market in the first place. Patients have no access to these technologies at all."[48]

[the American Bar Association's] anecdotal evidence of the negative impact of the current state of jurisprudence on patent eligibility").

[45] *Id.*, *Part III* (responses of Robert Deberardine to questions for the record) at 2–3.

[46] *Id.* (testimony of Rick Brandon) at 2.

[47] *Id.*

[48] *Id.*

These reports should not be ignored. The effect of uncertainty about patent protection on innovation tends to go "largely unnoticed by the public" as "decisions to discard [drug candidates] are made behind closed doors" and "[p]harmaceutical companies do not announce the drug candidates that they choose not to develop."[49] And as personalized medicines become an increasingly important treatment modality, the lack of patent protection for companion diagnostics could affect companies' R&D decisions for drug and biological products.

Due to lowered expectations regarding patent eligibility, the United States is falling behind other industrialized countries in innovation in diagnostics and the life sciences more generally. A recent study of almost 18,000 patent applications rejected by the Patent Office as patent ineligible found that counterpart applications were "routinely granted in the European Union or China, or both."[50] Although the United States has historically been the leader in terms of providing "expansive patent protection," former Patent Office directors now declare that "under current U.S. law governing patent eligibility, it is easier to secure patent protection for critical life sciences . . . inventions in the People's Republic of China and

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[49] Roin, 87 Tex. L. Rev. at 552.

[50] Kappos & Michel, *supra* note 20, at 3; *see* Kevin Madigan & Adam Mossoff, *Turning Gold into Lead: How Patent Eligibility Doctrine is Undermining U.S. Leadership in Innovation*, 24 Geo. Mason L. Rev. 939, 956 (2017).

in Europe, than in the U.S."[51] As a result, innovation investment is "mov[ing] to other jurisdictions," undermining national competitiveness in critical technologies.[52]

The consequences of diminished innovation in the medical diagnostics field are difficult to overstate. "[A] wholesale bar on patent eligibility for diagnostic claims has far-reaching and long-ranging implications for the development of life-saving diagnostic methods. The eligibility of life-saving inventions is not only one of the most important issues of patent law, but of human health." *Athena*, 927 F.3d at 1370 (Stoll, J., dissenting from denial of rehearing en banc).

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[51] *The State of Patent Eligibility in America, Part I* (testimony of David J. Kappos) at 2; *see also* Ryan Davis, *Kappos Calls for Abolition of Section 101 of Patent Act*, LAW360 (Apr. 12, 2016), https://www.law360.com/articles/783604/kappos-calls-for-abolition-of-section-101-of-patent-act (reporting that former Patent Office Director Kappos "said he has begun telling clients that . . . they are better off seeking patents in [China and Europe] because of the way U.S. courts have interpreted Section 101").

[52] *The State of Patent Eligibility in America, Part I* (testimony of Q. Todd Dickinson, former Patent Office Director) at 27.

CONCLUSION

For the reasons set forth above and in the petition, the Court should grant the petition for a writ of certiorari.

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