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 OF PROFESSORS JEFFREY A. LEFSTIN AND PETER S. MENELL AS *AMICI CURIAE* IN SUPPORT OF PETITION FOR A WRIT OF CERTIORARI

JEFFREY A. LEFSTIN
Professor of Law
UNIVERSITY OF CALIFORNIA, HASTINGS COLLEGE OF LAW
200 McAllister Street
San Francisco, CA 94102
(415) 565-4658
lefstinj@uchastings.edu

PETER S. MENELL
Koret Professor of Law
Counsel of Record
UNIVERSITY OF CALIFORNIA, BERKELEY SCHOOL OF LAW
225 Bancroft Way
Berkeley, CA 94720-7200
(510) 642-5489
pmenell@law.berkeley.edu

COCKLE LEGAL BRIEFS (800) 225-6964
WWW.COCKLELEGALBRIEFS.COM

TABLE OF CONTENTS

TABLE OF CONTENTS—Continued

TABLE OF AUTHORITIES

Page

CASES

TABLE OF AUTHORITIES—Continued

TABLE OF AUTHORITIES—Continued

TABLE OF AUTHORITIES—Continued

OTHER AUTHORITIES

H.R. REP. NO. 71-1129 (1930).....8, 9, 10

H.R. REP. NO. 82-1923 (1952).....10, 11

H.R. REP. NO. 83-1455 (1954).....10

Jeffrey A. Lefstin, *Inventive Application: A History*, 67 FLA. L. REV. 565 (2015).....15, 18, 21

Jeffrey A. Lefstin, Peter S. Menell, and David O. Taylor, *Final Report of the Berkeley Center for Law & Technology Section 101 Workshop: Addressing Patent Eligibility Challenges*, 33 BERKELEY TECH. L.J. 551 (2018).....22

Mark A. Lemley, Michael Risch, Ted Sichelman, & R. Polk Wagner, *Life After* Bilski, 63 STAN. L. REV. 1315 (2011).....19

P.J. Federico, *Commentary on the New Patent Act*, reprinted in 75 J. PAT. & TRADEMARK OFF. SOC'Y 161 (1993).....12

TABLE OF AUTHORITIES—Continued

Page

INTERESTS OF *AMICI CURIAE*[1]

The authors of this brief are professors of law at the University of California who study and teach intellectual property law. *Amici* have both explored the patent eligibility doctrine in their scholarship, and submit this brief to assist the Court in interpreting the law of patent-eligible subject matter.

Professor Jeffrey Lefstin holds a law degree and a doctorate degree in biochemistry. His scientific papers on molecular biology and genetics appeared in *Nature*, *Genes & Development* and the *Journal of Molecular Biology*. Much of his research has focused on the historical development of patent law and its institutions.

Professor Peter Menell holds a law degree and a doctorate degree in economics. He co-founded the Berkeley Center for Law & Technology in 1995. He has written and lectured widely on intellectual property law and policy. Since 1998, he has organized more than 60 judicial education programs in conjunction with the Federal Judicial Center, circuit courts, and district courts on intellectual property law and is lead author of a widely used treatise on patent case management.

[1] Pursuant to Sup. Ct. R. 37.6, *amici* note that no counsel for a party authored this brief in whole or in part, and no counsel or party made a monetary contribution intended to fund the preparation or submission of this brief. No person other than *amici curiae* made a monetary contribution to its preparation or submission. Petitioners and Respondents have received timely notice and consented to the filing of this brief through direct correspondence.

SUMMARY OF ARGUMENT

In *Bilski v. Kappos*, 561 U.S. 593, 601 (2010), this Court explained that its interpretation of 35 U.S.C. § 101 has been guided by over 150 years of historical practice. Yet two years later in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 566 U.S. 66 (2012), the Court triggered the most radical redefinition of patent-eligible subject matter in U.S. history by engrafting an *inventive application* requirement for patenting practical applications of scientific discoveries.

Mayo based this requirement on three critical assumptions: (1) Congress has never addressed the question of the patentability of scientific discoveries; (2) foundational precedent of the English courts and of this Court excluded scientific discoveries and demanded inventive application as a condition of patent eligibility; and (3) a new extra-textual limitation on patentability was necessary to address the undue preemption of laws of nature and other scientific discoveries. Unfortunately, inadequate briefing in *Mayo* led the Court astray.

The Nation's patent statutes, stretching back to the founding era, unmistakably afford patent protection to technological innovations *and scientific discoveries*. Congress has expressly sought to encourage *both* technological inventions and scientific discoveries. The legislative concern has not been with preemption of inventive fields, which the durational limits and disclosure constraints of the Patent Act address, but rather

with "min[ing]" the "exhaustless" "treasures" and "unlimited reach of science." Specific legislative enactments in 1930, 1952, and 1954 refute any requirement of inventive application for patent eligibility.

Furthermore, the *Mayo* briefs failed to address critical context and meaning of key cases bearing on patent eligibility of applications of scientific discoveries. Both *Parker v. Flook*, 437 U.S. 584 (1978), and *Mayo* relied on a mistaken reading of *Neilson v. Harford*, 1 Webster's Patent Cases 295 (1841), to conclude that English and American courts restricted patents to *inventive applications* of new discoveries. To the contrary, *Neilson* became the primary authority in England and the United States for the position that *practical applications* of discoveries were patentable without any invention in the means of application.

Finally, contrary to *Mayo*'s supposition that a new extra-statutory doctrine was necessary to limit undue preemption of scientific discoveries, this Court has long held that this role was served by patent law's express *disclosure* requirements. *See O'Reilly v. Morse*, 56 U.S. (15 How.) 62 (1854) and subsequent cases.

As reflected in the eight opinions in *Athena Diagnostics, Inc. v. Mayo Collaborative Services*, as well as clear signals in numerous other cases,[2] the Patent

[2] *See, e.g.*, *American Axle & Manufacturing, Inc. v. Neapco Holdings LLC*, 939 F.3d 1355 (Fed. Cir. 2019) (Moore, J., dissenting); *Berkheimer v. HP Inc.*, 890 F.3d 1369 (Fed. Cir. 2018) (denial of rehearing en banc) (Lourie, J., concurring); *Vanda Pharmaceuticals Inc. v. West-Ward Pharmaceuticals International Limited*, 887 F.3d 1117 (Fed. Cir. 2018) (Prost, J., dissenting); *Ariosa*

Office's frequent revision of examiner guidance documents,[3] and legislative hearings, the Federal Circuit, district courts, Patent Office, and inventors have struggled unsuccessfully to apply the *Mayo/Alice*[4] decisions coherently and predictably. These decisions have imposed massive costs upon all of these institutions and the public, thereby undermining the patent system.

This case provides an ideal vehicle for the Supreme Court to revisit the standards for patent eligibility on the basis of thorough briefing of the proper statutory and jurisprudential considerations.

ARGUMENT

I. Congress Has Consistently Expressed its Intent to Provide Patents Based on Practical Applications of Scientific Discoveries

This section fills the critical gap in the *Mayo* briefing and opinions. It shows that every Patent Act has provided patent protection for *practical applications* of

Diagnostics, Inc. v. Sequenom, Inc., 809 F.3d 1282 (Fed. Cir. 2015) (denial of rehearing en banc) (Lourie, J., concurring; Dyk, J., concurring; Newman, J., dissenting).

[3] *See, e.g.*, Ryan Davis, *4 Takeaways From the USPTO's Patent Eligibility Update*, LAW360 (Oct. 23, 2019) (quoting patent practitioner lamenting "[t]here's only so much the patent office can do, since its guidance is based on eligibility decisions from the Federal Circuit and the U.S. Supreme Court that are often contradictory and difficult to reconcile"), available at https://www.law360.com/ip/articles/1212629/4-takeaways-from-the-uspto-s-patent-eligibility-update.

[4] *Alice Corp. v. CLS Bank Int'l*, 573 U.S. 208 (2014).

both technological innovations and scientific discoveries.

A. The Constitution and Early History of the Patent System

Article I, Section 8, Clause 8 of the U.S. Constitution authorizes Congress "To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries." The Founders recognized the importance of encouraging *discoveries* as a means for promoting progress of useful arts, i.e., technology.

The Nation's first Patent Act, the Act of 1790, Ch. 7, 1 Stat. 109-112 (Apr. 10, 1790), authorized any two of the "Patent Board" (the Secretary of State, the Secretary for the Department of War, and the Attorney General) to grant patents to any person who "invented or *discovered* any useful art, manufacture, engine, machine, or device, or any improvement therein not before known or used . . . if they shall deem the invention or *discovery* sufficiently useful and important . . . " Patent Act of 1790, § 1 (emphasis added). This dual "invention or discovery" thread runs through the fabric of U.S. patent law.

The 1790 Act was short-lived due to the administrative burden placed on the Patent Board commissioners. Congress replaced the 1790 Act three years later with another "act to promote the progress of useful arts." Patent Act of February 21, 1793, 1 Stat. 318.

The 1793 Act relieved the administrative burden of patent examination by shifting to a registration system, leaving issues of patent validity to subsequent judicial enforcement. The 1793 Act retained the dual eligibility structure, referring to "said invention or discovery." *Id*. at § 1. Section 3 of the 1793 Act reinforces the dual focus—requiring that "every inventor . . . shall swear . . . he is the true inventor or *discoverer* of the art, machine, or improvement . . . " (emphasis added). *See also* § 10 (referring to the patentee as the "inventor or discoverer").

The Patent Act of 1836, Ch. 357, 5 Stat. 117, confirms Congress's intention to provide patent protection for inventions and *discoveries*. Section 1 establishes a Patent Office "to superintend, execute, and perform, all such acts and things touching and respecting the granting and issuing of patents for new and useful *discoveries*, inventions, and improvements." (emphasis added). Section 6 states:

> That any person or persons having *discovered* or invented any new and useful art, machine, manufacture, or composition of matter . . . not known or used by others before his or their *discovery* or invention thereof, . . . may make application in writing to the Commissioner of Patents, expressing such desire, and the Commissioner, on due proceedings had, may grant a patent therefor.

Id. at § 6 (emphasis added). The dual eligibility framework appears throughout the 1836 Act more than a dozen times.

The Senate Report leaves no doubt that Congress fully intended patent protection for *practical applications* of *scientific discoveries*:

> Whoever imagines that, because so many inventions and so many improvements in machinery have been made, there remains little else to be discovered, has but a feeble conception of the infinitude and vastness of mechanical powers, or of the unlimited reach of science. *Much as has been discovered, infinitely more remains unrevealed.* The ingenuity of man is exploring a region without limits, and delving in a mine whose treasures are exhaustless. 'Neither are all the mysteries of nature unfolded, nor the mind tired in the pursuit of them.'
>
> The first conceptions of ingenuity, like the first suggestions of science, are theories which require something of experiment and *practical* exemplification to perfect. . . .

SENATE REPORT ACCOMPANYING SENATE BILL NO. 239, 24th Cong., 1st Sess. (Apr. 28, 1836) (emphasis added). Congress believed and intended that by granting inventors time-limited exclusive rights to practical applications of scientific discoveries, the patent system would promote revelation and unfolding of the "mysteries of nature."

Congress made modest amendments to the 1836 Act over the ensuing years, but retained the Act's protection of both technological inventions and scientific discoveries.

B. The 1870 Act

The next general revision of the patent laws took place in 1870. *See* Patent Act of 1870, Ch. 230, 16 Stat. 198 (Jul. 8, 1870). The updated statute perpetuated the dual structure of the prior acts, referring to "invention or discovery" and "inventor or discoverer" throughout the statute. *See* R.S. §§ 4884, 4886, 4887, 4888, 4890, 4891, 4892, 4893, 4895, 4896, 4897, 4899, 4902, 4908, 4916, 4917, 4920, 4922, 4923, 4924, 4926, 4927.

C. The Plant Patent Act of 1930 and 1954 Amendment

Congress's next major revision of the patent statutes was the Plant Patent Act of 1930 (PPA), 46 Stat. 703. The PPA amended the existing patentability statute, R.S. § 4886, to include new varieties of asexually reproduced plants among the categories of inventions eligible for patents. The proposed legislation would provide patents for naturally occurring bud variants or naturally occurring mutants in cultivated plants, which a plant breeder might discover and then asexually reproduce by routine and conventional means. *See* H.R. REP. NO. 71-1129, at 4 (1930); S. REP. NO. 71-315, at 3 (1930). Congress therefore had to confront directly the question of whether the Constitution and the patent statutes sanctioned patents based on a discovery applied by routine and conventional means, or whether further invention was necessary to transform a discovery into a patent-eligible invention.

Congress concluded that discovery alone sufficed. The House and Senate Committee Reports[5] on the bills (H.R. 11372 and S. 4015) that became the PPA state:

> Present patent laws apply to "any person who has invented or discovered any new and useful art, machine, manufacture, or composition of matter, or any new and useful improvement thereof. . . ." *It will be noted that the laws apply both to the acts of inventing and discovery* and this alternative application has been true of the patent laws from their beginning. See, for instance, the Patent Act of 1790 (1 Stat. 109).

H.R. REP. NO. 71-1129, at 7 (1930); S. REP. NO. 71-315, at 6 (1930) (quoting R.S. § 4886) (emphasis added). As the Committee Reports explained further, according to linguistic convention when the Constitution was written, the term "Inventors" in Article I, Section 8, Clause 8 encompassed those who discovered as well as those who created. H.R. REP. at 8-9; S. REP. at 8.

By extending R.S. § 4886 to newly discovered plant varieties subsequently propagated by conventional means,[6] Congress made clear that it intended discovery plus *practical* application, not discovery plus *inventive* application, to be the standard for patent eligibility. Even though the plant breeder's efforts might be "less creative in character than those of the chemist

---

[5] This Court has relied upon these Reports in construing § 101. *See Diamond v. Chakrabarty*, 447 U.S. 303, 312-13 (1980).

[6] Only new varieties discovered in plants under cultivation were protectable, not new varieties discovered in the wild.

in aiding nature to develop a composition of matter," Congress nonetheless regarded such efforts as invention or discovery within the meaning of the Constitution and patent statutes. H.R. REP. at 8; S. REP. at 7-8.

Indeed, when the Patent Office denied a claim to a newly discovered plant variety on the grounds that the applicant had not "invented or discovered" anything within the meaning of R.S. § 4886 by merely discovering and propagating the plant, *see Ex Parte Foster*, 90 U.S.P.Q. 16 (Pat. & Tr. Office Bd. App. 1951), Congress promptly amended the plant patent statutes to reverse the Office's decision. *See* H.R. REP. NO. 83-1455, at 2 (1954); S. REP. NO. 83-1937, at 2 (1954).[7] Taken just two years after the 1952 Act, Congress's action belies the notion that it intended to exclude conventional applications of new discoveries from the patent system.

D. The 1952 Codification

The impetus for the Patent Act of 1952 was the need to consolidate and codify the patent statutes into Title 35 of the United States Code. *See* H.R. REP. No. 82-1923, at 1-2 (1952). The Committee called upon P.J. Federico, Examiner-in-Chief of the U.S. Patent Office, as well as other government officers, representatives of patent law associations, and members of the Bar. While characterizing codification as the "principal purpose" of the 1952 Act, Congress made two "major" substantive

---

[7] The 1952 Act separated the provisions for plant and utility patents into § 101 and § 161, but both maintained the language of "invents or discovers." H.R. REP. NO. 82-1923, at 17 (1952).

changes: "incorporating a requirement for invention in § 103 and the judicial doctrine of contributory infringement in § 271." *Id.*

Congress crafted § 101 based on the wording of R.S. § 4886, with two non-substantive alterations: (1) it replaced the term "art" with "process"; and (2) it transferred the provision on plant patents to a new section. *See* H. REP. NO. 82-1923, at 17 (1952). As this Court has explained, the latter was merely a housekeeping measure, and did not change the substantive requirements for either plant or utility patents. *J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc.*, 534 U.S. 124, 133, 138 (2001). Section 100(a) of the 1952 Act expressly restated the traditional definition of "invention" as "invention or discovery," making clear that Congress intended to continue the historical practice of providing patents based on discoveries.

Congress made one change that bears directly on whether conventional applications of new discoveries constitute patent-eligible subject matter. Section 100(b) defined "process" to include "a new use of a known process, machine, manufacture, composition of matter, or material." The purpose of this language was to clarify that "processes or methods which involve merely the new use of a known process, machine, manufacture, composition of matter, or material" are patent-eligible subject matter. H. REP. NO. 82-1923, at 17 (1952).

Thus, § 100(b) expressly defines a use of a new material in a known process to be patent-eligible subject matter. Yet under the Federal Circuit's application

of *Mayo* in this case, this new use cannot be patent-eligible because the claimed methods would recite only known and conventional process steps. But as P.J. Federico, the chief drafter of the 1952 Act, explained, § 100(b) was intended to remove any doubt that such claims were patent-eligible subject matter under § 101:

> It is believed that the primary significance of the definition of method above referred to is merely that a method claim *is not vulnerable to attack, on the ground of not being within the field of patentable subject matter, merely because it may recite steps conventional from a procedural standpoint* and the novelty resides in the recitation of a particular substance, which is old as such, used in the process. . . . [T]he statute, as has been said, recognizes a process or method which involves only a new use of an old material, as within the field of subject matter capable of being patented.

P.J. Federico, *Commentary on the New Patent Act*, reprinted in 75 J. PAT. & TRADEMARK OFF. SOC'Y 161, 177-78 (1993) (emphasis added).[8] Such new uses arise when "a discovery has been made that a known substance or thing has some hitherto unknown property, or can be used to obtain a particular result for which is [sic, it] had not been used before." *Id.* at 177.

---

[8] This Court has previously relied on Federico's commentary to interpret the 1952 Act. *See Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 39 (1997); *Aro Mfg. Co. v. Convertible Top Replacement Co.*, 365 U.S. 342 n.8 (1961); *see also Chakrabarty*, 447 U.S. at 303 n.6 (describing Federico as a principal draftsman of the 1952 Act).

Mayo's requirement for an inventive application is impossible to square with Congress's enactment of § 100(b). As Federico explained, Congress intended new processes consisting only of *conventional* steps applied to known materials to be patent-eligible under § 101, although many might be unpatentable under § 103. *Id.* at 178. Yet under *Mayo*, all such processes are ineligible under § 101 because apart from the discovery of the new property itself, the steps of the process "involve well-understood, routine, conventional activity previously engaged in by researchers in the field." *Mayo*, 566 U.S. at 73. *Mayo*'s requirement for *inventive application* thus contravenes not only Congress's long-standing insistence that "discoveries" stand on equal footing with "inventions" in the patent laws, but Congress's specific definition of patent-eligible subject matter in the 1952 Act.

II. A Requirement for Inventive Application Fundamentally Misreads the Sole Precedential Basis for the Inventive Application Concept

If Congress so clearly and consistently recognized discovery as a foundation of the patent statutes since the time of the Framers, how could *Flook* and *Mayo* conclude that applications of scientific discoveries were ineligible unless inventively applied?[9] *Flook* and *Mayo* based their engrafting of a requirement of *inventive*

[9] The patents at issue in *Flook* and *Mayo* were likely unpatentable on other grounds—notably non-obviousness in *Flook* and non-obviousness, inadequate disclosure, and overbroad claiming in *Mayo*.

application on a profound misunderstanding of a single, key historical precedent—the 1841 English *Neilson* case. *Diamond v. Diehr*, 450 U.S. 175 (1981), corrected *Flook*—although *Diehr* sidestepped *Flook*'s error by basing its decision on the text of the Patent Act rather than addressing *Flook*'s misreading of *Neilson*. Now that *Mayo* has revived and amplified *Flook*'s misinterpretation of *Neilson*, it is imperative for the Court to correct this error.

Scientific discoveries, like other fundamental principles, have never been patentable *in the abstract*. "A principle, *in the abstract*, is a fundamental truth; an original cause; a motive; these cannot be patented, as no one can claim in either of them an exclusive right." *Le Roy v. Tatham*, 55 U.S. (14 How.) 156, 175 (1853) (emphasis added). But as this Court recognized in *Diehr*, the test of patent eligibility focuses not on whether the inventor claims an *inventive* application of a scientific principle, but whether the inventor claims a *practical* application of a scientific principle. *Diehr*, 450 U.S. at 191.

A. *Neilson* Did Not Treat Discoveries as "Being Well Known"

Flook and *Mayo* drew a contrary conclusion from *Neilson v. Harford*, a landmark 1841 English case addressing James Neilson's patent for the hot-blast smelting process, discussed at length in several of this Court's seminal decisions. *See Le Roy*; *Morse*; and *Tilghman v. Proctor*, 102 U.S. 707 (1880). *Flook* based

its requirement for *inventive application* on the Exchequer's statement that "[w]e think the case must be considered as if the principle being well known." *Neilson v. Harford*, 1 Webster's Patent Cases 295, 371 (1841), believing that the Exchequer was proclaiming that scientific discoveries should be treated as though they were known (i.e., in the prior art) and therefore could not contribute to patent eligibility. *See Flook*, 437 U.S. at 592-93. Close examination of *Neilson*, however, shows that the Exchequer intended nothing of the sort.

That statement was instead a declaration that Neilson's patent claimed a machine, rather than an abstract scientific principle. It referred to *Minter v. Wells*, 1 Carpmael's Pat. Cases 622 (1834), a case decided by the Exchequer seven years earlier, in which the defendants had attacked the patent on the grounds that it merely claimed a well-known principle of mechanics in the abstract. Because Neilson had argued that his patent was not limited to the form of heating apparatus he had disclosed in his specification, his patent was questioned on the same grounds. But as it had for Minter's patent, the Exchequer construed Neilson's patent to be the *application* of a principle—a patentable machine—except that in *Neilson*, the principle was newly discovered rather than well-known. *See* Jeffrey A. Lefstin, *Inventive Application: A History*, 67 FLA. L. REV. 565, 581-87 (2015).

Contrary to *Flook*, *Neilson* provides no support for engrafting a requirement of *inventive application* of scientific discoveries onto U.S. patent law. Read in proper context, the fateful phrase addresses whether

Neilson's claim was to a *machine* rather than an abstract scientific principle. The case did not turn on whether the application of the scientific principle was inventively applied. As the next section demonstrates, any such suggestion is directly contradicted by the main ground of attack in the *Neilson* case.

B. Foundational Precedent Required Only Practical Application, Not Inventive Application

Mayo's misreading of this passage was even more profoundly mistaken than *Flook*'s. The *Mayo* Court baldly asserts that Neilson's patent was upheld *because* Neilson implemented the preheating principle in an inventive and unconventional way. *Mayo*, 566 U.S. at 83-84. Examination of the case shows that nothing could be further from the truth. Neilson's patent was sustained precisely because he employed *well-understood, routine, and conventional means* in the application of a new scientific discovery.

The primary argument leveled against the validity of the patent in *Neilson* was inadequate disclosure. Neilson had disclosed little about the preheating apparatus and said nothing about the need to increase the surface area of the heating vessel when scaling up the process. *Neilson*, 1 Web. P.C. at 339. (In modern terminology, the defendants challenged the patent for lack of enablement.) In rejecting that attack, both the patentee and the court emphasized that *all* of Neilson's means were routine, conventional, and "perfectly well

known." *See id.* at 337 (Alderson, B.); *id.* at 344 (patentee's argument).

Opinions in the other hot-blast cases were to the same effect, explaining that a patentee's means of applying his discovery might well be simple and obvious. *See* Lefstin, *Inventive Application*, at 588-91. Indeed, in English law, *Neilson* became the primary authority for the proposition that new scientific discoveries were patentable without any invention whatsoever in the means of application, provided that the patent supplied an enabling disclosure. *See id.* at 591-93. Thus, in *Otto v. Linford*, which became one of the canonical cases on patentable subject matter in English law, the Court of Appeal put forth Neilson's invention as the paradigm case for the patentability of discoveries applied by old and conventional means:

> One of the strongest illustrations that I know of is the patent for the hot blast in the iron manufacture, where there was nothing new at all except the idea that the application of hot air instead of cold air to the mixture of iron ore and fuel would produce the most remarkable results in the shape of economy in the manufacture of iron. . . . In the case of the hot blast the man did not pretend to invent anything; he said a machine of any shape in which you can heat air is sufficient.

Otto v. Linford, [1882] 46 L.T. (N.S.) 35, 39-40 (Jessel, M.R.).

The English courts have never wavered from that position. It remains the law today that even obvious

applications of new discoveries constitute patent-eligible subject matter. *See, e.g.*, *Genentech, Inc.'s Patent*, [1987] R.P.C. 553; *Genentech, Inc.'s Patent*, [1989] R.P.C. 147; *Gale's Application*, [1991] R.P.C. 305; *Kirin-Amgen Inc. v. Hoechst Marion Roussel Ltd.*, [2004] UKHL 46.

This Court correctly read and fully embraced the rationale of the hot-blast cases in *Le Roy v. Tatham*, 55 U.S. (14 How.) 156 (1853), which this Court has often cited as the fountainhead of its subject-matter jurisprudence. *Le Roy* explained that "[a] principle in the abstract" was not patentable. *Id.* at 175. But the Court drew from the hot-blast cases the lesson that "[a] new property *discovered* in matter, when practically applied" was patentable so long as the patent provided an enabling disclosure. *Le Roy*, 55 U.S. at 175 (emphasis added). This Court further explained, quoting from the hot-blast cases, that a patent might be founded "*on the discovery of a great, general, and most comprehensive principle in science or law of nature*," if the patent applied that discovery to a practical end. *Id*. (quoting *Househill v. Neilson*, 1 Webster's Patent Cases 673, 683 (1843). And detailed examination of the historical record has shown that for at least one hundred years after the hot-blast cases, this Court, the lower courts, and the authors of learned treatises adhered to the principle that patents based on discoveries required neither novelty nor "invention" in the means of application. *See* Lefstin, *Inventive Application*, at 599-23.

III. Patent Law's Disclosure Requirements Have Long Addressed Concerns Over Undue Preemption

Mayo's final justification for imposing a new extra-textual limitation on discovery-based inventions was that other requirements of the 1952 Act, such as the enablement and written description requirements of 35 U.S.C. § 112, were incapable of addressing undue preemption of natural laws. However, this Court recognized long ago that patent law's *disclosure* doctrines, not its subject-matter categories, police the patent bargain against undue preemption. Disclosure, not subject-matter, was the basis of this Court's seminal decision in *Morse*. This Court denied Morse's infamous eighth claim not because Morse sought to monopolize electromagnetism, but because Morse had not enabled any way to use electromagnetism for writing at a distance beyond the specific machinery he disclosed.

Unfortunately, this Court was misled in the *Mayo* briefing by commentary asserting that something beyond enablement was necessary to explain *Morse*, because Morse taught the only way known at the time to use electromagnetism for writing at a distance. *See* Mark A. Lemley, Michael Risch, Ted Sichelman, & R. Polk Wagner, *Life After* Bilski, 63 STAN. L. REV. 1315, 1332-33 (2011). But neither the 1836 Act nor § 112 would have permitted Morse to claim all future applications of electromagnetism simply because he disclosed the telegraph. This Court based *Morse* expressly on Morse's failure to satisfy the disclosure provisions of the 1836 Act, which, like current § 112, required the

inventor to provide a written description sufficient to enable one of ordinary skill in the art to make and use the claimed invention. *See Morse*, 56 U.S. at 118-20. Since *Morse*, this Court's precedent and the precedent of the Federal Circuit have consistently held that § 112 and its predecessors do not permit an inventor to claim all ways to use a discovery merely because the inventor has taught one way to do so. *See Holland Furniture Co. v. Perkins Glue Co.*, 277 U.S. 245, 256-57 (1928) (citing *Morse*); *Béné v. Jeantet*, 129 U.S. 683, 685-86 (1889); *In re Hyatt*, 708 F.2d 712, 714 (Fed. Cir. 1983) (citing *Morse*).

Moreover, the Federal Circuit has employed the § 112 written description requirement to address precisely the concern raised in *Mayo*: overly broad preemption of laws of nature and other discoveries. The Federal Circuit's decision in *Ariad Pharmaceuticals, Inc. v. Eli Lilly & Co.*, 598 F.3d 1336 (Fed. Cir. 2010) (en banc), holds that an inventor cannot claim a new discovery without disclosing a specific and practical means of application. Furthermore, in *Williamson v. Citrix Online, LLC*, 792 F.3d 1339 (Fed. Cir. 2015) (en banc in relevant part), the Federal Circuit tightened the standards for functional claiming under § 112(f), ensuring that patents employing broad functional claiming without corresponding disclosure of structure are indefinite under § 112(b).

In some cases, § 112 allows an inventor to claim broadly. But prior to *Mayo*, the patent system recognized that limited preemption of new discoveries and inventions is the quid pro quo that motivates inventors.

That an inventor's claim might practically preempt all use of a discovery will, as this Court explained in *Dolbear v. Am. Bell Tel. Co.*, 126 U.S. 1, 535 (1888), "show more clearly the great importance of his discovery, but it will not invalidate his patent." Unlike patents on business methods, patents on diagnostics or other applications of new discoveries are not some novelty that arose because the Federal Circuit or the USPTO relaxed historical standards of patentability. With few exceptions, the patent system prior to *Mayo* embraced inventions that represented merely conventional applications of new discoveries. *See* Lefstin, *Inventive Application*, at 593-40.

Mayo's exclusion of such inventions thus represents nothing more than an intuitive judgment that some otherwise patentable inventions should now be removed from the patent system because they may preempt more progress than they will promote. Such an intervention in the patent system, if warranted, "is a matter of high policy for resolution within the legislative process after the kind of investigation, examination, and study that legislative bodies can provide and courts cannot." *Diamond v. Chakrabarty*, 447 U.S. 303, 317 (1980).

IV. Engrafting "Inventiveness" or "Undue Preemption" onto § 101 Short-Circuits the 1952 Act Patentability Framework

The most important structural change brought about by the 1952 Act was to provide distinct statutory

requirements to test the validity of patents, including an express non-obviousness requirement. Out of the amorphous concepts of "invention" and "undue breadth" that prevailed before the 1952 Act came a clear structural delineation of patent law's requirements: § 101's eligibility standard; § 102's novelty standards; § 103's non-obviousness requirement; and § 112's disclosure requirements. *Mayo* contradicts Congress's careful design. By importing inventiveness and preemption into the § 101 eligibility determination, *Mayo* collapses Congress's careful, logical, and sensible structured framework into a subjective amorphous standard. In a nutshell, *Mayo* overrides the legislative mandate to weigh inventiveness and preemption concerns under § 103 and § 112, respectively.

The confusion generated by *Mayo* has produced an arbitrary, standardless patent regime. Inventors and technologists cannot determine with any predictability what is patent-eligible. *See generally* Jeffrey A. Lefstin, Peter S. Menell, and David O. Taylor, *Final Report of the Berkeley Center for Law & Technology Section 101 Workshop: Addressing Patent Eligibility Challenges*, 33 BERKELEY TECH. L.J. 551, 581-92 (2018) (describing the fallout of the *Mayo* decision). In another recent controversy, the Federal Circuit, applying *Mayo*, held over a vigorous dissent that a claim to an improved automobile driveshaft that reduces vibration is not patent-eligible. *See American Axle & Manufacturing, Inc. v. Neapco Holdings LLC*, 939 F.3d 1355 (Fed. Cir. 2019); *cf. id*. (Moore, J., dissenting) (expressing concern about the manipulability of the *Mayo* standard and its

subsumption of § 112). Is it possible that the drafters of the 1952 Patent Act or, for that matter, the drafters of the 1793 Patent Act, would consider a claim to an improved vehicle driveshaft to be ineligible for patent protection before any assessment of novelty or disclosure is made?

Justice Frankfurter forewarned this very disaster: "Everything that happens may be deemed 'the work of nature,' " and a doctrine that denies the eligibility of specific and practical applications of discoveries "could fairly be employed to challenge almost every patent." *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 133 (1948) (Frankfurter, J., concurring).

The Court's suggestion in *Mayo* and *Alice* that patent eligibility turns on concerns about the extent to which a technological discovery will be preempted misapprehends the inherent logic of the patent system. Congress has repeatedly expressed its view that discoveries embodied in one of the statutory classes of subject matter should be eligible for patents, notwithstanding the costs entailed by the temporary monopoly of a patent. As this Court has recognized, whether a long-standing legislative directive represents the optimal balance to promote innovation is reserved to Congress. *See Eldred v. Ashcroft*, 537 U.S. 186, 211-17 (2003).

Overly broad and abstract claims pose problems for the patent system, particularly if patents are not restricted to the technological arts. *See* Peter S. Menell, *Forty Years of Wondering in the Wilderness and No*

Closer to the Promised Land: Bilski*'s Superficial Textualism and the Missed Opportunity to Return Patent Law to its Technology Mooring*, 63 STAN. L. REV. 1289 (2011). But the proper response is not to rewrite § 101 through unsupported judicial interpretation to include a double requirement of inventive discovery *and* inventive application, but to ensure that the doctrines specified by Congress are implemented with appropriate rigor—as this Court has done for the non-obviousness requirement of § 103 in *KSR International Co. v. Teleflex Inc.*, 550 U.S. 398 (2007), and for the claim definiteness requirement of § 112(b) in *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898 (2014).

These doctrines may require fact-intensive inquiries into such matters as the state of the prior art, the capabilities of skilled artisans, and the claim scope permissible based on the specification. But that is the structure Congress enacted in the 1952 Act and should not be circumvented through judicial amendment.

CONCLUSION

The Court relies heavily on the information provided by parties and *amici* to resolve important and difficult legal questions. This is especially true in applying statutory regimes tracing back to the founding era to cutting edge technologies. The *Mayo* opinion was based on a woefully inadequate set of briefs. It is not surprising, therefore, that the opinion overlooked key

statutory text and legislative history and misread a key 19th century precedent.

This case illustrates the risks of making radical changes to the patent system without thorough consideration. The invention claimed here applied a biological discovery to provide a new diagnostic method offering valuable public health benefits. Future advances in precision medicine will require the development of new diagnostics like the one here, especially for patients with rare or idiosyncratic forms of a disease. Yet under the Federal Circuit's interpretation of *Mayo*'s "inventive application" test, essentially all such diagnostics have been excluded from the patent system.

As this brief highlights, it is inconceivable that the crafters of the Patent Act would have considered claims to a method for diagnosing a medical condition based on a breakthrough scientific discovery ineligible for patent protection on subject matter grounds. The claims in question may well fail for lack of novelty, obviousness, or inadequate disclosure. But the conclusion that the application of a scientific discovery is ineligible unless the implementation is also inventive contradicts the clear statutory text of the Patent Act, abundant legislative history, and two centuries of patent jurisprudence.

The Court simply did not have the background research and analysis that it needed to address patent eligibility of scientific principles in *Mayo*. The *Mayo* decision opens up the likelihood that a scientist who

makes a monumental scientific discovery and claims specific and practical applications for curing disease or addressing climate change will be denied patent protection on the ground that the breakthrough was not also inventively applied. Congress has long sought to address humankind's and the planet's greatest challenges through affording patents for practical applications of scientific discoveries. We urge the Court to grant certiorari in this case to restore the vitality of this long-standing and important institution.

Respectfully submitted,

JEFFREY A. LEFSTIN
Professor of Law
UNIVERSITY OF CALIFORNIA,
HASTINGS COLLEGE OF LAW
200 McAllister Street
San Francisco, CA 94102
(415) 565-4658
lefstinj@uchastings.edu

PETER S. MENELL
Koret Professor of Law
Counsel of Record
UNIVERSITY OF CALIFORNIA,
BERKELEY SCHOOL OF LAW
225 Bancroft Way
Berkeley, CA 94720-7200
(510) 642-5489
pmenell@law.berkeley.edu