No. 15-1182

In The
Supreme Court of the United States

SEQUENOM, INC.,

Petitioner,

v.

ARIOSA DIAGNOSTICS, INC., NATERA, INC., AND DNA DIAGNOSTICS CENTER, INC.,

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

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INTERESTS OF *AMICI*[1]

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[1] The parties have consented to the filing of this brief through blanket consent letters filed with the Clerk's Office.

Counsel of record for all parties received more than 10 days advance notice of *amici*'s intention to file this brief.

Pursuant to Sup. Ct. R. 37.6, *amici* note that no counsel, party, or any other person authored any part of this brief or made any monetary contribution to its preparation or submission.

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.*, 132 S. Ct. 1289 (2012), the Court triggered the most radical redefinition of patent-eligible subject matter in U.S. history by engrafting onto § 101 an inventive application requirement for patenting practical applications of scientific discoveries.

Unfortunately, the *Mayo* Court lacked adequate input on the fundamental question of whether applications of scientific discoveries are patent-eligible. As our brief explains, the Nation's patent statutes, stretching back to the founding era, unmistakably afford patent protection to technological innovations *and scientific discoveries*. The legislative record contains no hint of a second, "inventive application" hurdle for patent-eligibility of scientific discoveries. To the contrary, statutory text and legislative history reflect the transparent, sensible, and intuitive intention to encourage "inventors and *discoverers*" to reveal the "mysteries of nature," whether or not they are inventively applied.

The discovery and application of a novel, nonobvious, and adequately disclosed scientific principle is all that the Patent Act requires, and for good reason. 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."

Furthermore, the *Mayo* briefs failed to address critical context and meaning of key cases bearing on patent eligibility of applications of scientific discoveries. *Neilson v. Harford*, 1 Webster's Patent Cases 295 (1841), on which both *Parker v. Flook*, 437 U.S. 584 (1978), and *Mayo* rely, does not support an "inventive application" requirement. *O'Reilly v. Morse*, 56 U.S (15 How.) 62 (1854), fully understood this. Unfortunately, *Flook* and *Mayo* misconstrue precedent as a result of a profound misinterpretation of *Neilson*.

The *Mayo* decision has left the lower courts adrift in a sea of confusing currents. This case is part of the *Mayo* fallout. It provides a timely and appropriate vehicle for realigning jurisprudence with statutory text, legislative intent, and foundational jurisprudential principles.

Part I explicates the Constitutional and statutory basis for patent protection for applications of *scientific discoveries*. Part II explains the proper interpretation of *Neilson*, as reflected in *Le Roy v. Tatham*, 55 U.S. (14 How.) 156 (1853), *Morse*, and the jurisprudence that followed. Part III highlights the problems that the *Mayo* "inventive application" requirement has wrought in the inventive community, the Patent Office, and the lower federal courts.

I. The Constitutional and Statutory Basis for Patenting Applications of Scientific Discoveries

The inventors in this case sought to patent the application of an important scientific discovery – the presence of cell-free fetal DNA in maternal serum. Their patent claimed "[a] method for detecting a paternally inherited nucleic acid of fetal origin performed on a maternal serum or plasma sample from a pregnant female. . . ." Claim 1, U.S. Patent No. 6,258,540 (Jul, 10, 2001). The lower courts read this Court's *Mayo* decision to bar this claim (and others) on the ground that the application of the scientific discovery, as opposed to the scientific discovery itself, was not sufficiently inventive.

This section fills in the critical gap in the briefing of the *Mayo* case. It shows that every Patent Act dating back to the Nation's founding has provided patent protection for applications of both technological innovations and scientific discoveries. Nowhere in this unbroken chain can one find any indication that applications of scientific discoveries are subject to an additional requirement of "inventive application."

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 first Patent Act, the Act of 1790, Ch. 7, 1 Stat. 109-112, 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 . . . 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 Patent Board commissioners. Congress replaced the 1790 Act three years later with another "act to promote the progress of useful arts." 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 lack of an examination system led to the proliferation of "unrestrained and promiscuous grants of patent privileges," John Ruggles, SELECT COMMITTEE REPORT ON THE STATE AND CONDITION OF THE PATENT OFFICE, S. DOC. NO. 24-338, at 4 (1836), eroding faith in the patent system and ultimately leading to the Act of 1836 which instituted examination in a newly constituted Patent Office. See SENATE REPORT ACCOMPANYING SENATE BILL NO. 239, 24th Cong., 1st Sess. (Apr. 28, 1836).

The Patent Act of 1836, Ch. 357, 5 Stat. 117, reinforces 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 authorized "any person . . . having *discovered* or invented any new and useful art, machine, manufacture, or composition of matter" to seek patent protection. (emphasis added). The dual eligibility framework appears more than a dozen times throughout the 1836 Act.

The Senate Report leaves no doubt that Congress fully intended patent protection for applications of *scientific discoveries* – including revealing and unfolding the "mysteries of nature":

> 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, *supra*. 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

Congress's next major revision of the patent statutes was the Plant Patent Act of 1930 (PPA), 46 Stat. 703. The PPA extended patent protection to the discovery and cultivation of new, asexually reproduced, distinct varieties of plants. The legislative history of the PPA shows that Congress fully intended *conventional* applications of new discoveries to be patent-eligible subject matter.

1. Congress Expressly Declared that the Patent Statutes Embrace the Act of Discovery

The House and Senate Committee Reports[2] 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).

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

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.

2. Congress Regarded Conventional Applications of Discoveries as Patent-Eligible

Under the PPA, routine and conventional techniques sufficed to transform discoveries into patent-eligible inventions. While plants found in the wild were not themselves eligible,[3] the plant breeder might discover and propagate a new "sport," a naturally occurring bud variation on a cultivated plant. Or the plant breeder might discover and propagate a naturally occurring mutant from a cultivated plant. In either case, Congress intended that discovery of the variety plus conventional propagation would qualify as an invention or discovery under the Act. H.R. REP. at 4; S. REP. at 3. Congress also made new hybrids patentable. Hybridization might require nothing more than growing two plants next to each other to

[3] A new *application* employing a plant or substance found in nature would, of course, be eligible for a utility patent. *See Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107, 2120 (2013).

promote natural cross-pollination, or transferring pollen between them with a brush. H.R. REP. at 8; S. REP. at 7. Thus, Congress made clear that the application of routine and conventional techniques to discoveries yielded patent-eligible subject matter. Even though the plant breeder's efforts might be "less creative in character than those of the chemist 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.

3. The PPA Amendments Applied to the Utility Patent Statute

The 1930 legislation directly incorporated Congress's views on discovery into the utility patent statute. The PPA amended the basic patentability statute, R.S. § 4886, to include asexually reproduced plants. Act of May 23, 1930, § 1, 46 Stat. 376. After the amendment, R.S. § 4886 made patents available to one "who has *invented or discovered* and asexually reproduced any distinct and new variety of plant," as well as one "who has *invented or discovered* any new and useful art, machine, manufacture, or composition of matter." In enacting the PPA, Congress plainly intended the phrase "invented or discovered" in R.S. § 4886 to have the same meaning for both plant and utility patents. If discovery plus conventional application would suffice for a plant patent, then it must suffice for a utility patent as well.

The PPA further reinforces that Congress understood and intended the words "invented or discovered" in amended R.S. § 4886 to encompass the act of discovery. And Congress unquestionably regarded the discovery of a new sport or mutant, coupled with conventional cultivation techniques, as a patent-eligible invention under that language.[4] It necessarily follows that patent-eligible subject matter under R.S. § 4886 encompassed applications of scientific discoveries by routine and conventional means.

D. The 1952 Codification

The impetus for the Patent Act of 1952 was the need to consolidate and codify the numerous sections of the patent law into Title 35 of the United States Code. See H.R. REP. No. 82-1923, at 1-2 (1952). The Committee held hearings and 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.

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[4] Congress enacted the PPA not because discoveries were previously thought unpatentable, but because plants were not thought capable of being described in writing as required for utility patents. *See J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc.*, 534 U.S. 124, 134 (2001). Conventional applications of discoveries were commonly understood to be patent-eligible at the time. *See* Jeffrey A. Lefstin, *Inventive Application: A History*, 67 FLA. L. REV. 565, 609-23 (2015).

1. 35 U.S.C. § 101 Incorporated Congress's Inclusion of Scientific Discovery in R.S. § 4886

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*, 534 U.S. at 133, 138.

As described above, the act of discovery, applied by conventional means, yielded patent-eligible subject matter under R.S. § 4886. Congress intended "invents or discovers" in § 101 to perpetuate that meaning. "[I]t will not be inferred that Congress, in revising and consolidating the laws, intended to change their effect unless such intention is clearly expressed." *Finley v. United States*, 490 U.S. 545, 554 (1989) (quoting *Anderson v. Pacific Coast S.S. Co.*, 225 U.S. 187, 199 (1912)). See also *Kappos v. Hyatt*, 243 S. Ct. 1690, 1698 (2012) (relying on predecessor statute to interpret § 145 of the 1952 Act).

2. Section 100(b) Declared New Processes Employing Conventional Steps Patent-Eligible

The 1952 Act expressly defines some processes, representing conventional applications of new discoveries, as patent-eligible subject matter. Section 100(a)

expressly restates the traditional definition of "invention" as "invention or discovery." Furthermore, Congress defines "process" to include "a new use of a known process, machine, manufacture, composition of matter, or material." § 100(b). 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).

Section 100(b) directly applies to Sequenom's claim for a new use (fetal diagnostic testing) of a known composition of matter (maternal serum). Yet under the Federal Circuit's application of *Mayo*, the new use of a known composition of matter *cannot* be patent-eligible, unless the individual steps of the method are new and inventive as well. This conclusion contradicts § 100(b). As P.J. Federico, the chief drafter of the 1952 Act, explained:

> 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).[5] 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] had not been used before." *Id.* at 177.

It is difficult to imagine language more clearly fitting the claims in this case. The claimed processes recite conventional steps (amplifying and detecting DNA) in conjunction with a known substance (maternal serum). The new process arose when the inventors discovered a hitherto unknown property in the known substance (the presence of cell-free fetal DNA). Section 100(b) was intended to remove any doubt that such a process recites patent-eligible subject matter.

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[5] This Court has 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).

II. A Requirement for Inventive Application Fundamentally Misreads the 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?[6] *Flook* and *Mayo* based their engrafting of a requirement of *inventive* application onto § 101 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 correcting *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*. This Court explained long ago that "[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*, 14 How. 156, 175 (1853) (emphasis added). But as this Court recognized in *Diehr*, the

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

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 historic 1841 English case that was discussed at length in several of this Court's seminal decisions. See *Le Roy; Morse;* and *Tilghman v. Proctor*, 102 U.S. 707 (1880). Referring to James Beaumont Neilson's patent for the hot-blast smelting process, Baron Parke's opinion for the Exchequer stated:

> It is very difficult to distinguish [this patent] from the specification of a patent for a principle, and this at first created in the minds of some of the court much difficulty; but after full consideration, we think that the plaintiff does not merely claim a principle, but a machine embodying a principle, and a very valuable one. *We think the case must be considered as if the principle being well known*, the plaintiff had first invented a mode of applying it by a mechanical apparatus to furnaces; and his invention then consists in this – by interposing a receptacle for heated air between the blowing apparatus and the furnace.

Neilson v. Harford, 1 Web. P. C. 295, 371 (1841) (emphasis added).

Flook based its requirement for inventive application on the italicized phrase, 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. Examination of *Neilson* shows that the Exchequer intended nothing of the sort. Rather, the Exchequer was merely postulating, in classic common law parlance, a counter-factual scenario: Even under the assumption that Neilson's discovery was well known, the Exchequer's prior decision in *Minter v. Wells*, 1 Carpmael's Patent Cases 622 (1834), required the court to treat Neilson's claim as a *machine*, not an abstract scientific principle. Further background about the *Minter* and *Neilson* cases brings these points home.

Minter's patent had claimed a reclining chair embodying the principle of the self-adjusting leverage. *Id.* at 624. Because Minter had declared that his claim was not limited to any precise shape or form of chair, the defendants sought to invalidate the patent on the ground that Minter had merely claimed a well-known principle of mechanics in the abstract. *Id*. at 644. The Exchequer rejected the ineligibility argument, finding that Minter's claim sufficiently applied a well-known mechanical principle in the construction of a chair. *Id.* at 646. Thus, Minter's claim was not to a well-known principle, but rather applied a

well-known principle to a chair to produce a patent-eligible *machine*. The critical passage in *Neilson* refers to this doctrine – relating to what constitutes a *machine* – not to whether scientific discoveries are to be treated as well known or prior art for purposes of patent-eligibility. This is plain to see by reading the sentence *preceding* the critical passage.

Prior to Neilson's discovery, it was believed that the best way to stoke a blast furnace was to inject cold air. Neilson claimed that preheating the air would increase the efficiency of the blast furnace. His specification provided few details about how to preheat the air, and declared that the shape, size, and form of the heating vessel were immaterial to improved efficiency of the blast. All methods of preheating injected air worked, and Neilson claimed them all.

The defendants attacked Neilson's patent on the ground that he merely claimed a scientific principle in the abstract – the superiority of hot air to cold. *Neilson*, 1 Web. P.C. at 335.[7] The Exchequer recognized that the defendants' attack paralleled the invalidity argument in *Minter*. In the critical passage in *Neilson* – stating that "the case must be considered as if the principle being well known" – the Exchequer drew upon *Minter* to show that Neilson's broad claim to furnaces embodying the preheating principle, like

[7] Some judges of the court were initially concerned about this point as well. *See Neilson*, 1 Web. P.C. at 342.

Minter's broad claim to chairs embodying the self-adjusting leverage, was drawn to a *machine* and was not merely claiming an abstract scientific principle.

As Baron Parke fully recognized, Neilson's scientific discovery, unlike Minter's, was theretofor unknown. Parke engaged in the counter-factual postulation simply to show that Neilson's patent was for a *machine*.

The same comparison to *Minter* was drawn in *Household v. Neilson*, a proceeding under Neilson's Scottish patent. The Court of Session used *Minter* to explain that Neilson had claimed an application, not a principle:

> [I]t was the application of a well-known principle, but for the first time applied to a chair. . . . Lord Lyndhurst and the rest of the court held, that this was not a claim to a principle, but to the construction of a chair on this principle, in whatever shape or form it may be constructed. *Just so as to the hot blast, only the principle is also new*.

Household Coal & Iron Co. v. Neilson, 1 Web. P.C. 673, 686 (1843) (emphasis added).

Thus, the critical *Neilson* passage cited by *Flook* and *Mayo* in no way supported engrafting a requirement of inventive application of scientific discoveries onto U.S. patent law. Read in proper context, the fateful passage addresses whether Neilson's claim was to a *machine* rather than a pure scientific principle. It did not turn at all on whether the application

of the scientific principle was inventively applied. As the next section demonstrates, any such suggestion is directly contradicted by a second ground of attack in the *Neilson* case.

B. Foundational Precedent Required Only Conventional 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*, 132 S. Ct. at 1300. 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, the Exchequer expressly recognized that Neilson's means of preheating were routine and well-known in the art. As Baron Parke's opinion fully

acknowledged and accepted, the patentee argued that:

> [t]he mode of heating air was perfectly well known; it was no discovery of Mr. Neilson's, every body knew it. Air had been heated, and there had been different shaped vessels employed for heating the air; for heating the air economically, and for heating it to a higher or lesser degree of temperature; all that was perfectly well known.

Id. at 344; see also *id.* at 337 (Alderson, B.) (stating that Neilson's means were "perfectly well known").

Opinions in the other hot-blast cases were to the same effect. See Lefstin, *supra*, 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. 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*, [1989] R.P.C. 147; *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. *Id.* 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*, 1 Web. P.C. at 683). 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, *supra*, at 599-623.

A possible exception, at least with respect to product claims, was *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127 (1948), decided by this Court four years before the 1952 Act. But whether or not Congress expressly overturned *Funk* with the 1952 Act, see Lefstin, *supra*, at 631-34, *Funk*'s reasoning became untenable after the 1952 Act. *Funk*'s reasoning depended on the non-obviousness and eligibility doctrines both being lodged in the words "invented and discovered" of R.S. § 4886, see *Cuno Eng'g Corp. v. Automatic Devices Corp.*, 314 U.S. 84, 90 (1941), as well as the old doctrine of "aggregation,"

see Lefstin, *supra*, at 626-27. Neither premise remained sound following passage of the 1952 Act, and the articulation of the non-obviousness requirement in § 103. Moreover, as discussed above, the enactment of § 100(b) precluded a requirement for inventive application in process claims.

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

The most important innovation of 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 § 101's eligibility standard, § 102's novelty standards, § 103's non-obviousness requirement, and § 112's disclosure requirements. By shoehorning an extra requirement for inventiveness and a concern over undue preemption into § 101, *Mayo* contradicts Congress's carefully crafted framework and ignores 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 technology companies cannot determine with any predictability what is even patent-eligible. The PTO is rejecting claims with boilerplate explanations. The district courts are awash in § 101 motions at all

stages of litigation. Many of them are being granted without clear explanations. The Federal Circuit is adrift, see *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371, 1380 (Fed. Cir. 2015) (Linn, J. concurring); *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 809 F.3d 1282 (Fed. Cir. 2015) (denial of rehearing en banc) (Lourie, J. (joined by Moore, J.) (concurring), Dyk, J. (concurring), Newman, J. (dissenting)), resolving most § 101 challenges in unexplained, non-precedential rulings.

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*, 333 U.S. at 133 (Frankfurter, J., concurring).

The Court's suggestion in *Mayo* 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 judgment 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 a question reserved to Congress. See *Eldred v. Ashcroft*, 537 U.S. 186, 211-17 (2003).

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 *O'Reilly v. Morse*. This Court denied Morse's infamous eighth claim not because Morse sought to preempt electromagnetism, but because Morse had not enabled any way to use electromagnetism beyond the specific machinery he disclosed. 56 U.S. at 119. The Court drew from and correctly distinguished *Neilson* on this very ground. That an inventor's claim might practically preempt all use of a discovery will, as this Court said 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." Section 112 provides the tools for ensuring that patents do not extend beyond their proper scope.

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 by judicial fiat 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.*, 134 S. Ct. 2120 (2014). Nor has the Federal Circuit been idle. In *Ariad Pharmaceuticals, Inc. v. Eli Lilly & Co.*, 598 F.3d 1336 (Fed. Cir. 2010) (en banc), the court confirmed a separate written description requirement under § 112(a), rendering invalid any patent that attempts to claim a new scientific discovery without disclosing a specific and concrete means of application. And in *Williamson v. Citrix Online, LLC*, 792 F.3d 1339 (Fed. Cir. 2015) (en banc), 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).

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 established under the 1952 Act. The judicial branch may not discard that statutory framework in favor of an "I-know-it-when-I-see-it" standard for patentability under § 101.

CONCLUSION

The Court relies heavily on the information provided by parties and *amici* to resolve important

and vexing legal questions. This is especially true in interpreting statutory regimes that trace back to the founding era.

As we have explained, it is inconceivable that the crafters of the Patent Act would have considered a claim to a non-invasive method for detecting fetal DNA 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 conflicts with clear statutory text, legislative intent, and two centuries of patent jurisprudence.

The Court simply did not have the materials that it needed to address patent-eligibility of scientific principles in the *Mayo* case, resulting in regrettable errors. The *Mayo* and *Sequenom* decisions open up the absurd possibility that the discoverer of a monumental scientific discovery who claims specific and practical applications for curing disease or addressing climate change will be denied patent protection on the ground that he or she did not also apply it inventively. If the inventor has met the other requirements of the Patent Act – novelty, non-obviousness, and adequate disclosure – then all Congress has required is that the discoverer apply his or her discovery for a practical purpose. Section 101's text and meaning, as well as nearly two centuries of jurisprudence, could not be more clear. 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 so as to consider the continued vitality of this long-standing and important institution.

Respectfully submitted,

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