2017-2508

**UNITED STATES COURT OF APPEALS**
**FOR THE FEDERAL CIRCUIT**

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ATHENA DIAGNOSTICS, INC., OXFORD UNIVERSITY INNOVATION LTD, and MAX-PLANCK-GESELLSCHAFT ZUR FORDERUNG DER WISSENSCHAFTEN E.V.,
*Plaintiffs-Appellants,*

v.

MAYO COLLABORATIVE SERVICES, LLC
(d/b/a Mayo Medical Laboratories), and MAYO CLINIC,
*Defendants-Appellees.*

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Appeal from the United States District Court for the District of Massachusetts in Case No. 1:15-cv-40075-IT,
Indira Talwani, District Judge

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# BRIEF OF AMICI CURIAE SEVEN LAW PROFESSORS IN SUPPORT OF THE PETITION FOR REHEARING EN BANC

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# CERTIFICATE OF INTEREST

Counsel for Amici Curiae certifies the following:

1. The full name of every party or amicus represented by me is:

Richard A. Epstein; Chris Holman; Adam Mossoff; Kristen Osenga; Michael Risch; Ted Sichelman; Brenda M. Simon

2. The name of the real party in interest:

*Not Applicable*

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3. Parent corporations and publicly held companies that own 10% or more of stock in the party:

*Not Applicable*

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4. The names of all law firms and the partners or associates that appeared for the party or amicus now represented by me in the trial court or agency or are expected to appear in this court are:

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5. The title and number of any case known to counsel to be pending in this or any other court or agency that will directly affect or be directly affected by this court's decision in the pending appeal: NONE

Date: April 22, 2019

*/s/ Matthew J. Dowd*
Signature of counsel

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## INTEREST OF *AMICI CURIAE*

The *amici curiae* are scholars who teach and write on patent law and policy. Although *amici* may differ amongst themselves on other aspects of modern patent law and policy, they are concerned that the law properly promotes and protects inventions in the twenty-first-century innovation economy. They have no stake in the parties or in the outcome of the case.[1] The names and affiliations of the *amici* are listed in Appendix A below.

## SUMMARY OF ARGUMENT

This Court should grant the petition for rehearing *en banc* and reverse the panel decision below because it misapplies the two-step "*Mayo-Alice* inquiry" under § 101 set forth by the U.S. Supreme Court. *See Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 566 U.S. 66 (2014); *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289 (2012). Unfortunately, the panel majority and the district court below misapplied the *Mayo-Alice* inquiry in assessing the patent eligibility of

[1] No party's counsel authored this brief in whole or part; no party or party's counsel contributed money intended to fund preparing or submitting the brief; and no person other than members of *amicus* or its counsel contributed money intended to fund preparing or submitting the brief. Fed. R. App. P. 29(a)(4)(E). Pursuant to Federal Rule of Appellate Procedure 29(a) and Federal Circuit Rule 29(c), all parties have consented to the filing of this brief.

breakthrough inventions and discoveries in the twenty-first-century biopharmaceutical sector. This contravenes the function of the patent system to "promote the Progress of . . . useful Arts . . . by securing for Limited Times to . . . Inventors the exclusive Right to their . . . Discoveries." U.S. Const. art. 1, § 8, cl. 8. The *discoveries* of new diagnostic tests that result from multi-million-dollar R&D investments by biopharmaceutical companies are patent eligible under § 101.

The panel, in affirming the district court that a biotechnological method for diagnosing neurological disorders is patent ineligible under § 101, continues a pattern of court decisions that have made patent eligibility doctrine overly restrictive. *See Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC,* 915 F.3d 743, 746 (Fed. Cir. 2019). Courts are now routinely excluding from the patent system cutting-edge discoveries in diagnostic treatments that benefit patients in the healthcare market and thus promote a flourishing society. *See, e.g., Cleveland Clinic Found. v. True Health Diagnostics LLC*, 859 F.3d 1352, 1355 (Fed. Cir. 2017); *Ariosa Diagnostics v. Sequenom, Inc.*, 788 F.3d 1371, 1373 (Fed. Cir. 2015).

Appellants detail the legal failings and technological facts in the panel decision. *Amici* here focus on a separate, key insight about the panel's misapplication of the *Mayo-Alice* inquiry: The majority's analysis of patent eligibility doctrine contradicts Supreme Court decisions in famous and oft-cited cases in which the Court affirmed the patentability of cutting-edge inventions and discoveries. This Court has the decisional authority within the Supreme Court's *Mayo-Alice* framework to reestablish reliable and effective patent rights in new and useful diagnostic methods made possible by the biotech revolution. Thus, this Court should grant the petition for rehearing *en banc* and reverse the panel decision.

## ARGUMENT

### I. The Panel Decision Misapplied the *Mayo-Alice* Inquiry by Creating Overly Restrictive Patent Eligibility Doctrine Under § 101 As Evidenced By Its Contradiction With Supreme Court Decisions Affirming Patents As Valid

This case exemplifies a fundamental error in the ongoing misapplication of the *Mayo-Alice* inquiry, which has produced overly restrictive patent eligibility doctrine under § 101. Courts have applied the *Mayo-Alice* inquiry in a manner that calls into legal question famous nineteenth-century patents that the Supreme Court expressly validated.

*Amici* identify only a few examples to illustrate the legal conflicts that now exist in patent law between the Supreme Court's patentable subject matter analysis and the panel majority decision's misapplication of the *Mayo-Alice* inquiry. *See* Michael Risch, *Nothing is Patentable*, 67 Fla. L. Rev. 46, 51–53 (2015) (identifying numerous historical patents which the Supreme Court affirmed as patent eligible but are now likely unpatentable under the overly restrictive application of the *Mayo-Alice* inquiry).

One prominent example is Samuel F.B. Morse's patent on the electro-magnetic telegraph, which was affirmed as valid and infringed by the Supreme Court. *See O'Reilly v. Morse*, 56 U.S. 62 (1853). Today, courts typically cite *Morse* for the proposition that the Supreme Court invalidated Claim 8 of the patent as an abstract idea. *See, e.g.*, *Alice*, 573 U.S. 208, 216 (2014). More importantly, though, the Supreme Court explicitly affirmed the validity of the first seven claims in Morse's patent. *See Morse*, 56 U.S. at 112 ("We perceive no well-founded objection . . . to his right to a patent for the first seven inventions set forth in the specification of his claims."). Morse's Claim 1 recites a method of operating an electro-magnetic telegraph that would almost certainly be

invalid under the panel's misapplication of the *Mayo-Alice* inquiry. This is compelling evidence of the panel's misunderstanding of the *Mayo-Alice* inquiry.

Claim 1 of Morse's patent reads as follows:

> 1. Making use of the motive power of magnetism, when developed by the action of such current or currents substantially as set forth in the foregoing description of the first principal part of my invention, as means of operating or giving motion to machinery which may be used to imprint signals upon paper or other suitable material, or to produce sounds in any desired manner, for the purpose of telegraphic communication at any distances. . . .

U.S. Reissue Patent No. 117 (issued June 13, 1848).

Under step one of the *Mayo-Alice* inquiry, applying the majority's approach here to the specific elements of Morse's invention, Claim 1 begins with a natural law ("the motive power of magnetism") and ends with an abstract idea ("telegraphic communication at any distances"). The majority's approach to applying the *Mayo-Alice* inquiry leads to the conclusion that Claim 1 is directed to ineligible subject matter.

The second step in the *Mayo-Alice* inquiry requires assessing whether Morse's Claim 1 recites "well-understood, routine, and conventional activity." *Mayo,* 566 U.S. at 73. Again, under the majority's approach, Morse's Claim 1 recites entirely conventional activity for the

art in his time. First, looking at Morse's specification, just as the panel did with the patent in this case, Morse admits that prior to his invention "it had been essayed to use the currents of electricity or galvanism for telegraphic purposes," and he even acknowledges in a lengthy parenthetical at the end of Claim 1 that there already "are various known methods of producing motion by electro-magnetism." U.S. Reissue Patent No. 117. Second, the steps in Claim 1 of "operating or giving motion to machinery," "imprinting signals upon paper or other suitable material," and "produc[ing] sounds" were undeniably routine and conventional in the 1830s when Morse invented his electro-magnetic telegraph. The depositions and testimonial evidence in the case confirm this fact. *See* Adam Mossoff, *O'Reilly v. Morse* (Aug. 18, 2014), http://ssrn.com/abstract=2448363.

While Morse could argue that the natural law and abstract idea recited in Claim 1 are applied to a useful machine ("giving motion to machinery"), the panel in this case would easily conclude that this is merely "conventional [post]-solution activity" that is "not sufficient to transform an unpatentable law of nature into a patent-eligible application of such a law." *Athena Diagnostics*, 915 F.3d at 753 (quoting

*Mayo*, 566 U.S. at 79). The majority's approach in applying the *Mayo-Alice* inquiry to each individual claim element leads to the conclusion that Morse's Claim 1 is unpatentable subject matter, which contradicts the Supreme Court's decision in *Morse*. *See* 56 U.S. at 112.

Another example of the majority's misunderstanding of the *Mayo-Alice* inquiry under § 101 is that its approach would invalidate Claim 5 of Alexander Graham Bell's patent on the telephone. *See* U.S. Patent No. 174,465 (issued Mar. 7, 1876). The Supreme Court affirmed Bell's Claim 5 as patentable subject matter in *Dolbear v. American Bell Telephone Company*, 126 U.S. 1, 531–35 (1888). Claim 5 states:

> The method of and apparatus for transmitting vocal or other sounds telegraphically, as herein described, by causing electrical undulations, similar in form to the vibrations of the air accompanying the said vocal or other sounds, substantially as set forth.

As it understands the *Mayo-Alice* inquiry, the majority here would first determine if Claim 5 is directed to ineligible subject matter. Claim 5 begins and ends with "vocal and or other sounds" and covers the transmission of sounds by "electrical undulations." These are natural phenomena and laws of nature, under the majority's reasoning, and thus unpatentable. *See Athena Diagnostics*, 915 F.3d at 751.

Following the same approach in applying step two, the majority's reasoning would find that Claim 5 merely recites what was routine, well understood, and conventional at the time. Telegraphic transmission of sounds and electrical undulation had been long known in the art by the time of Bell's invention. *See* Christopher Beauchamp, *Invented by Law: Alexander Graham Bell and the Patent That Changed America* 58–85 (2014) (recounting many prior and existing uses of electrical currents in telegraphic communication prior to Bell's invention that were introduced into evidence in the trial). The majority's § 101 analysis would necessarily lead to the conclusion that Bell's Claim 5 is unpatentable subject matter, contrary to the *Dolbear* Court's decision that this is a patentable discovery. *See Dolbear*, 126 U.S. at 531–35.

Lastly, the first U.S. patent would likely be deemed invalid under the panel's misapplication of the *Mayo-Alice* inquiry. The first U.S. patent issued to Samuel Hopkins in 1790 for his discovery of a new method of making potash. U.S. Patent No. X00001 (granted July 31, 1790). His novel method comprised well-known steps at the time such as burning and dissolving ash. Hopkins' sole discovery was improving the timing and specific order of the steps. *See* Henry M. Payntor, *The First*

*Patent* (rev. 1998).[2] If the majority's approach here were followed, Hopkins' method patent would be deemed to be directed to natural phenomena and laws of nature with nothing more contributed beyond well-known, conventional human activity.

This is significant because Hopkins's patent application was reviewed, approved, and ultimately signed by Thomas Jefferson as Secretary of State, who was a member of the three-person committee created under the 1790 Patent Act to review patent applications. Jefferson was both a drafter of some of the early patent laws and is known today for his belief that patents should be granted rarely and for only truly innovative inventions. *See* Adam Mossoff, *Who Cares What Thomas Jefferson Thought About Patents? Reevaluating the Patent "Privilege" in Historical Context*, 92 Cornell L. Rev. 93, 959–63 (2007).[3] Moreover, Hopkins's patent was issued under the 1790 Patent Act, which was drafted by original Framers of the Constitution who were then

[2] http://www.me.utexas.edu/~longoria/paynter/hmp/The_First_Patent.html.

[3] Hopkins's patent was also signed by President George Washington and Attorney General Edmund Randolph, both of whom were members of the Constitutional Convention.

serving in Congress. *See* Neal Katyal & Paul Clement, *On the Meaning of "Natural Born Citizen,"* 128 Harv. L. Rev. 161, 161 (2015) ("The Supreme Court has long recognized that two particularly useful sources in understanding constitutional terms are British common law and enactments of the First Congress."); *cf. Wisconsin v. Pelican Ins. Co.*, 127 U.S. 265, 297 (1888) (recognizing that actions of the first Congress are "contemporaneous and weighty evidence" of the Constituion's "true meaning"). Thus, when a panel decision's interpretation of patent eligibility doctrine calls into question the validity of a patent issued under the 1790 Patent Act and signed by Jefferson, it is cause to question whether the panel has correctly interpreted and applied the law.

## II. The Overly Restrictive Application of the *Mayo-Alice* Inquiry Undermines Twenty-First-Century Innovation In Diagnostic Tests That The Patent System is Designed to Promote

The panel's overly restrictive application of the *Mayo-Alice* inquiry in patent eligibility doctrine contravenes the Supreme Court's admonition in *Bilski v. Kappos*, 561 U.S. 593, 605 (2010), that § 101 is a "dynamic provision designed to encompass new and unforeseen inventions." Significant research and development ("R&D") in new diagnostic testing methods, like Athena's invention, exemplify the

"Discoveries" that the patent system is intended to promote as the "progress of . . . useful Arts." U.S. Const. art. 1, § 8, cl. 8.

As a result of the biotech revolution born of the Supreme Court's decision in *Diamond v. Chakrabarty*, 447 U.S. 303 (1980), the value of genetic and similar *in vitro* diagnostic tools has increased dramatically. A 2005 industry report estimated that diagnostic tests formed the basis of 60%–70% of all medical treatment decisions. *See The Value of Diagnostics Innovation, Adoption and Diffusion into Health Care* (July 2005).[4] Diagnostic tests have immense benefits for patient care and greatly reduce associated costs, including decreasing hospitalization and avoiding unnecessary treatment. *See* Roche, *Annual Report 2014*, at 33 (2015).[5]

The economics of the R&D and commercialization of innovative diagnostic tests reflect the core economic justification for the patent system: The marginal cost of making a diagnostic test is relatively low, but the *ex ante* R&D costs can be enormous. While it is difficult to find

[4] https://dx.advamed.org/sites/dx.advamed.org/files/resource/Lewin%20Value%20of%20Diagnostics%20Report.pdf.

[5] https://www.roche.com/gb14e.pdf.

specific data on R&D expenditures for diagnostic tests as distinct from total R&D expenditures for the biopharmaceutical industry generally, one survey of four industry experts concluded that the average R&D and commercialization costs for a diagnostic test is between $50–$75 million and can exceed $100 million for developing and commercializing novel diagnostic technologies. Diaceutics Group, *Mystery Solved! What is the Cost to Develop and Launch a Diagnostic?* (Jan. 15, 2013).[6] As the *Bilski* Court recognized, the patent system exists to promote new inventions on the frontier of human knowledge, such as the diagnostic testing methods that make possible the proper application of equally cutting-edge therapeutic treatments in the healthcare market. *See* 561 U.S. at 605.

The majority's misapplication of the *Mayo-Alice* inquiry is not even "a sufficient basis for evaluating processes similar to those in the Industrial Revolution," *id.*, because it calls into question nineteenth-century patented inventions the Supreme Court upheld as valid. The majority failed to heed the Supreme Court's warning in *Alice* that we must "tread carefully in construing [the] exclusionary principle lest it

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

swallow all of patent law." *Alice*, 573 U.S. at 217. As a result, they have created an unduly restrictive patent eligibility doctrine under § 101; the majority decision and many other court decisions send the wrong message to innovators that groundbreaking diagnostic tests born of the biotechnological arts in the modern biopharmaceutical industry are virtually per se unpatentable under § 101. *See Mayo*, 566 U.S. at 71 (cautioning that "too broad an interpretation of this exclusionary principle [under § 101] could eviscerate patent law").

This contravenes the guidance by the Supreme Court throughout its modern § 101 decisions that courts must properly balance promoting new innovation while preventing the hindrance of this innovation. *See Bilski*, 561 U.S. at 601–02. The panel's decision tilts the scales too far against new innovation. Granting the petition for rehearing en banc and reversing the panel decision will rebalance the patent system by providing the necessary guidance on how to properly apply the *Mayo-Alice* inquiry to innovative discoveries of new diagnostic tests.

## III. Conclusion

*Amici* urge the Court to grant the petition for rehearing en banc, reverse the panel decision, and provide guidance on how the *Mayo-Alice*

inquiry should be applied to diagnostic tests that exemplify "Discoveries" in the "useful Arts" the patent system is intended to promote and secure to innovators.

Date: April 22, 2019

Respectfully submitted,

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[7] Institutions of all signatories are for identification purposes only. The undersigned do not purport to speak for their institutions, and the views of *amici* should not be attributed to these institutions.

## CERTIFICATE OF COMPLIANCE

This brief complies with the word-length limitation of Federal Rule of Appellate 29(a)(5). This brief contains 2,574 words, excluding the portions set forth in FRAP 32(f) and Federal Circuit Rule 32(b). This brief complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type style requirements of Federal Rule of Appellate Procedure 32(a)(6). The brief has been prepared in a proportionally spaced typeface using Microsoft® Word and 14-point Century type.

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Dated: April 22, 2019

## CERTIFICATE OF SERVICE

I hereby certify that on this day, April 22, 2019, the foregoing was electronically filed and therefore served electronically via the court's ECF/CM system on all counsel of record.

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