

2017-2508

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

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.

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

BRIEF OF AMICI CURIAE TEN LAW PROFESSORS

Adam Mossoff
Professor of Law
Antonin Scalia Law School
George Mason University
3301 Fairfax Drive
Arlington, Virginia 22201
(703) 993-9577
Professor of Law

Matthew J. Dowd
Dowd PLLC
1717 Pennsylvania Avenue, NW
Suite 1025
Washington, D.C. 20006
(202) 573-3853
mjdowd@dowdpllc.com
Counsel for Amici Curiae

CERTIFICATE OF INTEREST

Counsel for Amici Curiae certifies the following:

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

Dan L. Burk; Richard A. Epstein; Chris Holman; Gus Hurwitz; Adam Mossoff; Kristen Osenga; Michael Risch; Mark F. Schultz; Ted Sichelman; Brenda M. Simon

2. The name of the real party in interest:

Not Applicable

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

Not Applicable

-
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:

Matthew J. Dowd, Dowd PLLC, 1717 Pennsylvania Avenue,
NW, Suite 1025, Washington, D.C. 20006

-
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: November 13, 2017

/s/ Matthew J. Dowd
Signature of counsel

Matthew J. Dowd
Printed name of counsel

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INTEREST OF *AMICI CURIAE*

Amici curiae are ten law professors who teach and write on patent law and policy, and are thus concerned with the integrity of the legal system that secures innovation to its creators and to the companies that commercialize it in the marketplace. Although the *amici* may differ amongst themselves on other aspects of modern patent law and policy, they are united in their professional opinion that this court should reverse the district court because its decision in this case undermines the function of the patent system to promote and to legally secure twenty-first-century innovation. They have no stake in the parties or in the outcome of the case.¹ The names and affiliations of the amici are set forth in Appendix A.

SUMMARY OF ARGUMENT

In recent years, the Supreme Court has repeatedly reminded lower courts and the United States Patent & Trademark Office (“PTO”)

¹ Pursuant to Federal Rule of Appellate Procedure 29(a), all parties have consented to the filing of this amicus brief. 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 *amici* or their counsel contributed money intended to fund preparing or submitting the brief. Fed. R. App. P. 29(c)(5).

that § 101 of the Patent Act is a key requirement in assessing the validity of both patent applications and issued patents. *See, e.g., Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107 (2013); *Bilski v. Kappos*, 561 U.S. 593 (2010). In doing so, the Supreme Court set forth a two-part test for assessing whether an invention is patentable subject matter (the “*Mayo-Alice* test”). *See Alice Corp. Pty. v. CLS Bank Int'l*, 566 U.S. 66 (2014); *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289 (2012). Unfortunately, many lower courts and the PTO have misunderstood how to apply the *Mayo-Alice* test as a patentability requirement within the patent system. As a result, the *Mayo-Alice* test has become infected with indeterminacy and is overly restrictive in application, invalidating legitimate patented innovation with little predictability for inventors or patent attorneys. This frustrates the constitutional function of the patent system in promoting the “progress of the useful Arts.” U.S. Const. art. 1, § 8, cl. 8.

This case exemplifies both of these fundamental problems—indeterminacy and over restrictiveness. The district court’s decision invalidates legitimate innovation deserving of protection by the patent system after it analytically dissected the relevant claim language into

its component elements and thus concluded that it was ineligible subject matter. Appellants in this case detail the many failings by the district court in misapplying the *Mayo-Alice* test, and thus *amici* here identify a further key insight: When lower courts and the PTO apply the *Mayo-Alice* to individual claim elements and do not evaluate the claim as a whole, they are using a methodological approach that conflicts with the Supreme Court's existing precedents. This leads to an overly restrictive application of § 101 in eliminating patent protection for legitimate innovation. The Federal Circuit can easily remedy this problem by providing further instructions to lower courts and to the PTO that they should apply the *Mayo-Alice* test only to the claim as a whole.

The predicate legal requirement of analyzing a claim as a whole is fundamental to many provisions of the Patent Act. It is a requirement in assessing novelty under § 102 and in assessing nonobviousness under § 103. It is also a legal requirement in interpreting a patent claim that has been asserted for either literal or equivalents infringement under § 271. In all of these patent doctrines, the Supreme Court has maintained the basic requirement of assessing patentability or limiting

assertion of patents to the claim as a whole, because this approach solves the same policy problems of indeterminacy and over restrictiveness in these other patent doctrines. The Supreme Court has recognized that this is fundamental to a proper application of § 101 as well. *See, e.g., Diamond v. Diehr*, 450 U.S. 175, 188 (1981) (cautioning against “dissect[ing] the claims into old and new elements and then [ignoring] the presence” of other elements in the claimed invention as a whole that make it patent eligible); *Parker v. Flook*, 437 U.S. 584, 594 (1978) (“[A] patent claim must be considered as a whole.”). For this reason, the Federal Circuit should reverse the district court and remand with further instructions for applying the *Mayo-Alice* test only to the “claim as a whole.”

ARGUMENT

I. The Lower Courts And The PTO Have Misunderstood The *Mayo-Alice* Test And Have Created Indeterminate And Overly Restrictive Doctrine On Patent Ineligibility Under § 101

The *Mayo-Alice* test has been applied in 488 cases in the past several years. *See #Alicestorm: April Update and the Impact of TC Heartland on Patent Eligibility*, Bilski Blog (June 1, 2017).²

² <http://www.bilskiblog.com/blog/2017/06/alicestorm-april-update-and-the-impact-of-tc-heartland.html>.

Unfortunately, many judges have misapplied the test by analytically breaking up patent claims piecemeal and then invalidating them by finding underlying laws of nature, natural phenomena, or abstract ideas contained in these separate elements. *See Mayo*, 566 U.S. at 71 (recognizing that “all inventions at some level embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas”). These judges have misread a portion of the *Alice* opinion in which the Supreme Court stated that “we consider the elements of each claim both individually and ‘as an ordered combination,’” *Alice*, 134 S. Ct. at 2355. Importantly, they have failed to follow the Supreme Court’s requirement of assessing a claim as a whole, focusing instead solely on the individual elements of each claim.³ Examiners at the PTO and administrative law judges at the Patent Trial & Appeal Board (PTAB)

³ The district court in this case never referred to the “claim as whole” standard, coming closest when citing a case referring to their “character as a whole.” *Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC*, No. 15-cv-40075-IT, 2017 WL 3336275 at *3 (D. Mass. Aug. 4, 2017) (citing *Elec. Power Grp., LLC v. Alstom S.A.*, 830 F.3d 1327, 1335–36 (Fed. Cir. (2016))). It is clear from the nature of its analysis that it did not do this when it applied the *Mayo-Alice* test, as the analysis describes the “focus” of the claims, rather than the content of the claim as a whole. *See id.*

are committing the same fundamental error in applying the *Mayo-Alice* test.

Inventors and patent attorneys are thus left wondering when or how courts will analytically break up a claim into its individual elements, which of course are often comprised of unpatentable laws of nature or abstract ideas. *See Mayo*, 566 U.S. at 70. Inventors, patent attorneys, and the commercial firms working in the innovation industries have little *ex ante* notice as to the legal analysis that judges or patent examiners will employ under the misapplication of the *Mayo-Alice* test. Moreover, when judges and examiners do choose to apply the test to individual elements in each claim, it makes it too easy to find them comprising only unpatentable subject matter and only conventional or routine additional steps, which is also leading to an overly restrictive application of the test, as evidenced in this case.

A. Courts Have Made The *Mayo-Alice* Test Legally Indeterminate As Evidenced By § 101 Analyses That Conflict With The Supreme Court's Past Decisions Affirming Groundbreaking Patents As Valid

This case exemplifies a fundamental error in the lower courts' application of the *Mayo-Alice* test, which has produced indeterminacy in patent law for inventors and patent attorneys. Here, *amici* here

identify a key insight into the nature of this legal indeterminacy: Courts are applying the *Mayo-Alice* test in a way that casts serious doubt about famous nineteenth-century patents that were expressly validated by the Supreme Court. We identify only a few classic examples to make clear the legal conflicts that now exist in patent law between the Supreme Court's patentable subject matter analysis and lower courts' repeated misapplications of the *Mayo-Alice* test.⁴

One example of how the district court's application of the *Mayo-Alice* test in this case reflects the indeterminacy that has come to define § 101 jurisprudence is that the analysis and decision in this case conflicts with the Supreme Court's decision affirming the validity of Samuel F.B. Morse's patent on the electro-magnetic telegraph. *See O'Reilly v. Morse*, 56 U.S. 62 (1853). Many cite *Morse* because the Supreme Court invalidated Claim 8 of Morse's patent as an unpatentable abstract idea, *see, e.g., Alice*, 134 S. Ct. at 2354. 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

⁴ There are too many historical patents to discuss them all within the constraints of this brief. *See* Michael Risch, *Nothing is Patentable*, 67 Fla. L. Rev. 45 (2015) (identifying classic patents called into doubt).

(“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 likely be invalid under the courts’ application of the *Mayo-Alice* test in this and in other cases. This is compelling evidence of the district court’s misunderstanding of the *Mayo-Alice* test.

Claim 1 is not quoted in Morse, and so to understand this point, it is necessary to quote the relevant language:

What I specially claim as my invention and improvement is—

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. (The only ways in which the galvanic currents had been proposed to be used, prior to my invention and improvement, were by bubbles resulting from decomposition, and the action or exercise of electrical power upon a magnetized bar or needle; and the bubbles and deflections of the needles, thus produced, were the subjects of inspection, and had no power, or were not applied to record the communication. I therefore characterize my invention as the first recording or printing telegraph by means of electro-magnetism. There are various known modes of producing motion by electro-magnetism, but none of these had been applied prior to my invention and

improvement, to actuate or give motion to printing or recording machinery, which is the chief point of my invention and improvement.)

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

Under step one of the *Mayo-Alice* test, according to the district court's application of the test in this case, Morse's Claim 1 begins with a patent ineligible natural phenomenon ("the motive power of magnetism") and ends with an abstract idea ("communication at any distances").

The second step in the *Mayo-Alice* test requires assessing whether the claim also recites merely "well-understood, routine, and conventional activity." *Mayo*, 566 U.S. at 73. According to the district court's approach, each remaining element in Morse's Claim 1 would be deemed to recite conventional activity for the art in his time. First, Morse explicitly acknowledges in his specification that prior to his invention "it had been essayed to use the currents of electricity or galvanism for telegraphic purposes," and he even acknowledges later in Claim 1 that "[t]here 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,” when *assessed individually* were undeniably routine and conventional in the 1830s when Morse invented his electro-magnetic telegraph, and the depositions and testimonial evidence in the case confirms this fact. Morse himself even acknowledges this fact in the lengthy parenthetical in Claim 1.⁵

If applied to Morse’s Claim 1, the district court’s approach in applying the *Mayo-Alice* test to each individual claim element would lead to the conclusion that Morse’s Claim 1 is very likely unpatentable subject matter, contrary to the Supreme Court’s explicit decision. This is not an anomaly, as the vast majority of courts and examiners at the PTO are engaging in similar analytical assessments of only individual claim elements. *See* Part I.B., *infra*. These decisions directly conflict with the Supreme Court’s analysis in *Morse* that Claim 1 in its entirety is valid as a patentable invention. This conflict between the Supreme Court’s precedents and the decision in this case as well as in hundreds of other cases and patent applications leaves inventors and patent

⁵ For a complete analysis of the invention, patent issuance, and litigation of Morse’s electro-magnetic telegraph, see Adam Mossoff, *O’Reilly v. Morse* (Aug. 18, 2014), at <http://ssrn.com/abstract=2448363>.

attorneys with little understanding or *ex ante* notice of the requirements of § 101 under the *Mayo-Alice* test.

This legal indeterminacy is further evidenced by showing how the district court's misunderstanding of the *Mayo-Alice* test would apply to Claim 5 of Alexander Graham Bell's patent on the telephone. U.S. Patent No. 174,465 (issued Mar. 7, 1876). Like Morse's Claim 1, the Supreme Court affirmed Bell's Claim 5 as patentable subject matter in *Dolbear v. American Bell Telephone Co.*, 126 U.S. 1, 531–35 (1888).

Bell's Claim 5 reads as follows:

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.

Applying the *Mayo-Alice* test to Bell's Claim 5, according to the district court in this case, would require the court to break up this claim into its separate parts and would inevitably lead to the same conclusion of invalidity. First, under step one, Claim 5 begins and ends with “vocal and or other sounds,” and concerns generally the mere transmission of those sounds by “electrical undulations.” These concepts are natural phenomena. Under step two, Claim 5 does not recite anything

significantly more than what was then routine, well-understood and conventional: 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 claims in the litigation of Bell's patent of many prior and existing uses of electrical currents in telegraphic communication). Again, contrary to the *Dolbear* Court's analysis and decision, the district court's § 101 analysis in this case leads to the conclusion that Bell's Claim 5 is almost certainly unpatentable subject matter.

Perhaps most surprising is that the first U.S. patent ever granted would be invalid under the district court's application of the *Mayo-Alice* two-step test. The first patent issued in 1790 to Samuel Hopkins for his method of making potash. U.S. Patent No. X00001 (granted July 31, 1790). This method involved well-known steps such as burning and dissolving ash, and Hopkins' "inventive" contribution was in the timing and specific order of the steps. See Henry M. Payntor, *The First Patent* (rev., 1998).⁶ Both of these aspects of Hopkins' patent considered

⁶ http://www.me.utexas.edu/~longoria/paynter/hmp/The_First_Patent.html

individually would be deemed basic facts or concepts of conventional human activity, and under the district court's application of the *Mayo-Alice* test are unpatentable subject matter.

This is significant because Hopkins' patent was signed by Thomas Jefferson as Secretary of State and as a member of the committee created under the 1790 Patent Act who reviewed Hopkins' application. Jefferson was both a drafter of some of the early patent laws and has long been known for his views that patents should be severely restricted in their issuance.⁷ Moreover, Hopkins' patent was issued under the 1790 Patent Act, which was drafted by many of the original Framers of the Constitution who were then serving in Congress. Justices and constitutional scholars recognize legislation from the First Congress as having significant import as to the meaning of the Constitution. *See, e.g., Wisconsin v. Pelican Ins. Co.*, 127 U.S. 265, 297 (1888) (quoting

⁷ For a full discussion of Jefferson's roles in the early development of patent and intellectual property law, *see* Adam Mossoff, *Who Cares What Thomas Jefferson Thought About Patents? Reevaluating the Patent "Privilege" in Historical Context*, 92 Cornell L. Rev. 953, 959–63 (2007); *see also* Justin Hughes, *Copyright and Incomplete Historiographies: Of Piracy, Propertization, and Thomas Jefferson*, 79 S. Cal. L. Rev. 993, 1026–34 (2006) (discussing Jefferson's contradictory views on the legitimacy of patents and copyrights).

1789 Judiciary Act as primary evidence of the meaning of Article III, § 2); Neal Katyal & Paul Clement, *On the Meaning of “Natural Born Citizen,”* 128 Harv. L. Rev. F. 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.” (footnote omitted)). This includes the Copyright and Patent Clause’s authorization for Congress to secure an “exclusive Right” to “Inventors” for their “Discoveries” in order to advance the “progress of . . . useful Arts.” Thus, when a contemporary court reaches a decision that calls into question a patent validly issued under the 1790 Patent Act and signed by Jefferson himself, it is cause to question whether this court has applied the law correctly.

Applying the district court’s understanding of the *Mayo-Alice* test to famous nineteenth-century patents that were expressly affirmed as valid by the Supreme Court reveals a key analytical failing in the district court’s approach to the *Mayo-Alice* test. By breaking claims up into distinct, separate elements, courts are frequently concluding that patent claims are comprised solely of laws of nature, abstract ideas, or natural phenomena, and that there is no inventive concept contained in

these separate elements. This creates indeterminacy, because inventors and patent attorneys working in the innovation industries are unable to predict when or how courts will do this. The evident conflicts between this approach and the Supreme Court's long-standing precedents on patentable inventions, such as *Morse* and *Dolbear*, further heightens this confusion and leaves attorneys with little understanding of how to proceed on the basis of legal analysis.

B. Lower Courts And The PTO Have Made The *Mayo-Alice* Test Overly Restrictive And Are Invalidating Legitimate Patented Innovation

Further evidence of the lower courts' and the PTO's misunderstanding of the *Mayo-Alice* test is that this test has become overly restrictive, sweeping within its prohibition legitimate twenty-first-century innovation deserving of patent protection. In the past few years, district courts (and even the Federal Circuit) are increasingly invalidating patent claims at extraordinarily high rates. As of June 1, 2017, the invalidation rate under the *Mayo-Alice* test in these courts is 67.6%. *#Alicestorm: April Update and the Impact of TC Heartland on Patent Eligibility, supra* (including both Federal Circuit and district court decisions). This follows naturally from the mistaken belief that

the *Mayo-Alice* test requires them to assess each individual element of a claim. These high invalidation rates are not an anomaly either, as the *Mayo-Alice* test has been applied in at least 488 cases since the Supreme Court decided *Alice* in 2014. *See id.*

The PTO has similarly high invalidation and rejection rates in applying the *Mayo-Alice* test. The Section 101 cancellation rate at the Patent Trial & Appeal Board (PTAB) in the Covered Business Method (CBM) program is 97.8%. *See id.* Shortly after *Alice* was decided in 2014, anecdotal reports indicated that many patent applications covering innovative therapeutic treatments and diagnostic tests were being rejected under the *Mayo-Alice* test. *See Bernard Chao & Lane Womack, USPTO is Rejecting Potentially Life-Saving Inventions, Law360 (Dec. 18, 2014).*⁸ More recent data empirically confirms these concerns. For example, one examination unit at the PTO responsible for reviewing personalized medicine inventions (art unit 1634) is rejecting 86.4% of all applications under the *Mayo-Alice* test. *See Bernard Chao*

⁸ <http://www.law360.com/articles/604808/uspto-is-rejecting-potentially-life-saving-inventions>.

& Amy Mapes, *An Early Look at Mayo's Impact on Personalized Medicine*, 2016 Patently-O Patent L. J. 10, 12.⁹

C. Indeterminate And Overly Restrictive Application Of The *Mayo-Alice* Test Undermines Twenty-First-Century Innovation In Diagnostic Tests That The Patent System Is Designed To Promote

The district court's indeterminate and overly restrictive application of the *Mayo-Alice* test matters because it contravenes the Supreme Court's admonition in *Bilski* that § 101 should not impede the progress of future innovation. *See Bilski*, 561 U.S. at 605 (Section 101 is a "dynamic provision designed to encompass new and unforeseen inventions."). The massive research and development (R&D) into new technological applications of biotechnological diagnostic testing methods, like the biotechnological diagnostic test in this case, exemplifies the "progress of . . . useful Arts" the patent system is intended to promote and secure to its creators. U.S. Const. art. 1, § 8, cl. 8. This is particularly true in cases such as here, where the invention of the biotechnological diagnostic tool was only made possible by the inventors' identification of an entirely new disease pathway. *See Athena Diagnostics*, 2017 WL 3336275, at *1.

⁹ <http://patentlyo.com/media/2016/04/Chao.2016.PersonalizedMedicine.pdf>.

As the close relationship between biochemical and cellular changes and medical conditions has become clearer in recent years, the value of biotechnological, genetic, and similar *in vitro* diagnostic tools has increased dramatically. Experts now estimate that 66% of all medical treatment decisions are based on the results of *in vitro* diagnostic tests. See Ulrich-Peter Rohr, et al., *The Value of In Vitro Diagnostic Testing in Medical Practice: A Status Report*, 11 PLoS One 1 (2016).¹⁰ Such 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).¹¹

The economics of innovative diagnostic tests reflect exactly the economic justification for the patent system: The cost of applying a biotechnological diagnostic test is relatively low, but the *ex ante* R&D cost is enormous and is not reflected in the marginal cost of the medical test itself. According to one study, the average cost to develop and commercialize a diagnostic testing technology in the United States is

¹⁰ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4778800/pdf/pone.0149856.pdf>.

¹¹ <https://www.roche.com/gb14e.pdf>.

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?* (2013).¹² Screenings for diseases with complex biochemical interactions—like dementia, autoimmune disorders, and cancer—require even greater investments. As the *Bilski* Court recognized, the patent system exists to promote new inventions on the frontier of human technological knowledge, like biotechnological testing methods, which by necessity require massive R&D expenditures that can only be recouped via the protections offered by property rights in innovation.

The district court’s application of the *Mayo-Alice* test in this case is not even “a sufficient basis for evaluating processes similar to those in the Industrial Revolution,” *Bilski*, 561 U.S. at 605, because it calls into question nineteenth-century patented innovation the Supreme Court has deemed valid. In dissecting claims into their individual parts that are easily characterized as unpatentable subject matter, and then finding little or nothing in each of these individualized parts to be an

¹² <http://www.diaceutics.com/?expert-insight=mystery-solved-what-is-the-cost-to-develop-and-launch-a-diagnostic> (last visited Oct. 16, 2017).

“inventive concept,” *Alice*, 134 S. Ct. at 2355, lower courts and the PTO have misconstrued the *Mayo-Alice* test. They have failed to heed the Supreme Court’s warning in *Alice* that we must “tread carefully in construing this exclusionary principle lest it swallow all of patent law.” *Id.* at 2354. As a result, they have created extensive uncertainty in the law and have permitted the test to become overly restrictive in invalidating innovation that should be secured by the patent system, like the prenatal diagnostic testing method in this case. *See also Mayo*, 566 U.S. at 71 (“[T]oo 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 the PTO and the courts must properly balance promoting new innovation while preventing the hindrance of this innovation. *Bilski*, 561 U.S. at 601–02 (discussing the “permissive approach to patentability” in § 101 in comparison to the prohibition on patenting laws of nature, abstract ideas and physical phenomena). The lower courts’ and the PTO’s flawed methodology in applying the *Mayo-Alice* test has tilted the scales too far against new innovation. Reversing the district court will rebalance the patent system by

providing further instruction to the district courts and the PTO as to how to properly apply its *Mayo-Alice* test. It needs to expressly reestablish the basic rule of construction for all patents that the Supreme Court set forth in *Alice*: A claim should be considered as a whole in assessing its patent eligibility under § 101. *See Alice*, 134 S. Ct. at 2355 (claim elements should be evaluated “both individually and ‘as an ordered combination’”).

II. Adopting A “Claim As A Whole” Requirement Solves The Indeterminate And Overly Restrictive Application Of The *Mayo-Alice* Test

There are many possible solutions to the problems of indeterminacy and over restrictiveness that have infected the lower courts’ and PTO’s application of the *Mayo-Alice* test. *Amici* here offer one effective solution: the Federal Circuit should instruct the district courts and the PTO to apply the *Mayo-Alice* test only to the claim as a whole. The Supreme Court recently instructed lower courts and the PTO to do exactly this, *see Alice*, 134 S. Ct. at 2355, because this is a basic tenet of patent jurisprudence repeatedly and consistently affirmed by the Supreme Court. *See Flook*, 437 U.S. at 594 (“[A] patent claim must be considered as a whole.”); *Mercooid Corp. v. Minneapolis-*

Honeywell Regulator Co., 320 U.S. 680, 684 (1944) (“[A] patent on a combination is a patent on the assembled or functioning whole, not on the separate parts.”).

A. The “Claim As A Whole” Requirement Is Fundamental To The Patentability Requirements In §§ 102 And 103 Of The Patent Act

An express “claim as a whole” requirement is not novel in the legal doctrines crafted by Congress and the courts in the patent system. This has been a long-standing legal test in all of the patentability requirements for all inventions. For this reason, to instruct the district courts and the PTO that they must apply this same requirement in their application of the *Mayo-Alice* test is to ask them to do something they have long understood to be a basic legal requirement in applying legal tests under other provisions of the Patent Act.

For example, in assessing whether an invention is novel under § 102 of the Patent Act, courts have long applied an “identity” requirement, which mandates that a court or an examiner at the PTO find that an entire claim is preempted in the prior art by a single example. *See Structural Rubber Prods. Co. v. Park Rubber Co.*, 749 F.2d 707, 715 (Fed. Cir. 1984) (“[L]ack of novelty (*i.e.*, ‘anticipation’) can

only be established by a single prior art reference which discloses each and every element of the claimed invention.”). The “identity” requirement under § 102 for assessing an invention’s novelty requires that an examiner at the PTO or a court match “each and every element as set forth in the claim . . . in a single prior art reference.” *Verdegaal Bros., Inc. v. Union Oil Co.*, 814 F.2d 628, 631 (Fed. Cir. 1987). In brief, there must be a one-to-one symmetry between a *claim as a whole* and a single pre-existing example of the invention in the prior art in order for the claimed invention to fail the novelty requirement of § 102.

Similarly, in determining nonobviousness under § 103, the Patent Act expressly requires courts to find that “the differences between the claimed invention and the prior art are such that *the claimed invention as a whole* would have been obvious before the effective filing date . . .” 35 U.S.C. § 103 (emphasis added). Tellingly, Congress adopted this statutory language in 1952 to redress a similar situation that the innovation industries now face under § 101: courts had created an insuperable barrier to patentability by analytically breaking up patent claims into their component parts, observing that each single element did not “reveal a flash of genius,” *Cuno Eng’g Corp. v. Automatic*

Devices Corp., 314 U.S. 84, 92 (1941), and thus concluding that the patents were merely obvious developments over the prior art. As Justice Robert Jackson wryly observed in 1949 in language that could easily have been written today about the lower courts' and the PTO's application of the *Mayo-Alice* test: “[T]he only patent that is valid is one which this Court has not been able to get its hands on.” *Jungersen v. Ostby & Barton Co.*, 335 U.S. 560, 572 (1949) (Jackson, J., dissenting).

The solution to this indeterminate and overly restrictive application of the nonobviousness doctrine was in part the adoption of the “invention as a whole” requirement in § 103 in the 1952 Patent Act. This has been a basic requirement of applying nonobviousness doctrine since then. *See Graham v. John Deere Co.*, 383 U.S. 1, 15 (1966). This basic requirement is central to the objective determination of the nonobviousness of a claimed invention, because, as the Supreme Court has observed “inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known.” *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 418–19 (2007).

The same concern about analytically breaking up and reducing all inventions down to “already known” elements in the prior art under §§ 102 and 103 is precisely what the *Mayo* Court referred to when it warned that “too broad an interpretation of this exclusionary principle [under § 101] could eviscerate patent law.” *Mayo*, 566 U.S. at 71. This is why the Supreme Court in both *Mayo* and in *Alice* instructed lower courts and the PTO to consider not just individual elements, but also the claim elements “as an ordered combination.” *Alice*, 134 S. Ct. at 2355. For the similar reasons that the “claim as a whole” requirement has been adopted under the novelty and nonobviousness requirements in the Patent Act, the Federal Circuit should instruct the lower courts and the PTO that they must also apply the same “claim as a whole” requirement in applying the *Mayo-Alice* test under § 101.

B. The Supreme Court Adopted A “Claim As A Whole” Requirement To Solve The Similar Problems Of Indeterminacy And Over Inclusiveness In Patent Infringement Lawsuits

The Supreme Court has long maintained doctrinal symmetry in the “claim as a whole” requirement between the patentability requirements and the assertion of patents against infringers. In the late nineteenth century, for example, the Supreme Court laid down the

now-famous aphorism: “That which infringes, if later, would anticipate, if earlier.” *Peters v. Active Mfg. Co.*, 129 U.S. 530, 537 (1889). In sum, to assert a patent against an infringer, each and every element in *the claim as a whole* must be found in the allegedly infringing product or process. The Court has explained that “if anything is settled in the patent law, it is that the combination patent covers only the totality of the elements in the claim and that no element, separately viewed, is within the grant.” *Aro Mfg. Co. v. Convertible Top Replacement Co.*, 365 U.S. 336, 344 (1961). Just as the “claim as a whole” requirement ensures proper limits in assessing patentability, the same requirement prevents indeterminacy and over inclusiveness from self-aggrandizing assertions by patent-owners against alleged infringers.

More recently, the Court was faced directly with the same concern about indeterminacy and over inclusiveness in the assertion of patents against “equivalents,” in which an alleged infringing product or process has merely formal differences from a patented invention and thus substantially performs the same function in the same way and achieves the same result. *See Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 29–30 (1997). Justice Hugo Black famously referred to the

doctrine of equivalents as “treating a patent claim ‘like a nose of wax.’” *Graver Tank & Mfg. Co. v. Linde Air Prods. Co.*, 339 U.S. 605, 614 (1950) (quoting *White v. Dunbar*, 119 U.S. 47, 51 (1886)). In *Warner-Jenkinson*, the Supreme Court acknowledged the legitimate policy concerns about indeterminacy and over-inclusiveness that are entailed in going beyond the literal terms of a patent claim. *Warner-Jenkinson*, 520 U.S. at 28-29 (“We do . . . share the concern . . . that the doctrine of equivalents, as it has come to be applied since *Graver Tank*, has taken on a life of its own, unbounded by the patent claims.”).

The Supreme Court nonetheless reaffirmed the validity of the long-standing infringement doctrine known as the doctrine of equivalents in *Warner-Jenkinson*, but Justice Clarence Thomas’s opinion for the unanimous Court responded to these concerns by expressly adopting what has come to be known as the “all elements rule” for an assertion of equivalent infringement. *Id.* at 29–30. Similar to the same rule for literal infringement, an assertion of infringement by equivalents requires assessing the substantial similarity of an allegedly infringing product or process by reference to every element *in a claim as a whole*. See, e.g., *Deere & Co. v. Bush Hog, LLC*, 703 F.3d

1349, 1356 (Fed. Cir. 2012) (“[T]he doctrine of equivalents must be applied . . . so that *every claimed element* of the invention—or its equivalent—is present in the accused product.”) (citing *Warner-Jenkinson*, 520 U.S. at 40) (emphasis added).

Again, the Court adopted a *claim as a whole* requirement in response to legitimate concerns about indeterminacy and over inclusiveness in the application of patent infringement doctrines, both for literal infringement and for the doctrine of equivalents. Overly inclusive and indeterminate assertions of patents against alleged infringers represents the converse policy concern that overly restrictive and indeterminate exclusions of new inventions from patent protection under §§ 101–103. Thus, just like the patent validity analyses under §§ 102 and 103, the Supreme Court has held that infringement analysis under § 271 contain a predicate legal requirement that a *claim as a whole* must be applied to a third-party’s product or process in order to support a finding of infringement.

C. Canons of Statutory Construction Further Support Mandating That District Courts And The PTO Assess § 101 Eligibility Only As Applied To A “Claim As A Whole”

The Canons of statutory construction further support the Federal Circuit expressly adopting a “claim as a whole” requirement for the *Mayo-Alice* test under § 101. Although the “exclusionary principle” applied in patentable subject matter cases is judge-made law, *Mayo*, 566 U.S. at 71, it is derived from a construction of § 101 and its predecessor statutes reaching back to the mid-nineteenth century. *See Alice*, 134 S. Ct. at 2354 (“We have long held that this provision contains an important implicit exception: Laws of nature, natural phenomena, and abstract ideas are not patentable. We have interpreted § 101 and its predecessors in light of this exception for more than 150 years.”) (quoting *Myriad*, 133 S. Ct. at 2116) (internal citations omitted). In this regard, the Supreme Court has held that it is a “fundamental canon of statutory construction that the words of a statute must be read in their context and with a view to their place in the overall statutory scheme.” *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 133 (2000) (quoting *Davis v. Mich. Dep’t of Treasury*, 489 U.S. 803, 809 (1989)).

The “overall statutory scheme” of the Patent Act, *id.*, makes clear that the repeated and consistent use of “invention” in § 102 and § 103 comports with the similar usage of “invents” in § 101. Section 101 uses the verb, as opposed to the noun, simply because the purpose of this first substantive provision of the Patent Act is to identify the specific types of inventions that may be patented. It is these types that fall within the broader category of “invention” by reference in the later substantive provisions, such as § 102 and § 103.

The Supreme Court implicitly relied on this canon when it expressly adopted in its modern patent-eligibility jurisprudence under § 101 that “a patent claim must be considered as a whole.” *Flook*, 437 at 594; *see also Diehr*, 450 U.S. at 188 (cautioning against “dissect[ing] the claims into old and new elements and then [ignoring] the presence” of other elements in the claimed invention as a whole that make it patent eligible). In fact, the Supreme Court recognized in *Mayo* that the scope of application of § 101 may even overlap with § 102 when assessing the eligibility of an invention for protection under the patent system. *See Mayo*, 566 U.S. at 90 (“We recognize that, in evaluating the significance of additional steps, the § 101 patent-eligibility inquiry and,

say, the § 102 novelty inquiry might sometimes overlap.”). “A court must therefore interpret the statute ‘as a symmetrical and coherent regulatory scheme,’ *Gustafson v. Alloyd Co.*, 513 U.S. 561, 569 (1995), and ‘fit, if possible, all parts into a harmonious whole,’ *FTC v. Mandel Brothers, Inc.*, 359 U.S. 385, 389 (1959).” *Brown & Williamson*, 529 U.S. at 133.

Finally, in its recent decision in *Teva Pharmaceuticals USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831 (2015), the Supreme Court implicitly reaffirmed this canon of statutory construction. In *Teva*, the Supreme Court maintained that different doctrines in the Patent Act, such as claim construction under § 271 and nonobviousness analysis under § 103, should be construed consistently with each other. *Id.* at 840 (rejecting another approach to claim construction because “[i]t is in tension with our interpretation of related areas of patent law, such as the interpretation of ‘obviousness’”). Thus, the predicate legal requirement of construing a *claim as a whole* that runs throughout all of the patentability and infringement doctrines in the patent system should be applied with equal force in the *Mayo-Alice* test under § 101.

III. Conclusion

Amici urge the Federal Circuit to reverse the district court, and to clarify for the lower courts and the PTO the meaning of the *Mayo-Alice* test by requiring its application to only a “claim as a whole.”

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Respectfully submitted,

/s/ Matthew J. Dowd

Matthew J. Dowd
Dowd PLLC
1717 Pennsylvania Avenue, NW
Suite 1025
Washington, D.C. 20006
(202) 573-3853
mjdowd@dowdpllc.com

ADDENDUM
Full Listing of *Amici Curiae*¹³

Dan L. Burk
Chancellor's Professor of Law
University of California, Irvine School of Law

Richard A. Epstein
Laurence A. Tisch Professor of Law
New York University School of Law

Chris Holman
Professor of Law
UMKC School of Law

Gus Hurwitz
Assistant Professor of Law
Nebraska College of Law

Adam Mossoff
Professor of Law
George Mason University School of Law

Kristen Osenga
Professor of Law
University of Richmond School of Law

Michael Risch
Professor of Law
Villanova University School of Law

¹³ 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.

Mark F. Schultz
Associate Professor
Southern Illinois University School of Law

Ted Sichelman
Professor of Law
University of San Diego School of Law

Brenda M. Simon
Associate Professor of Law
Thomas Jefferson School of Law

CERTIFICATE OF COMPLIANCE

This brief complies with the word-length limitation of Federal Rule of Appellate 29(a)(5). This brief contains 6,376 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.

/s/ Matthew J. Dowd

Matthew J. Dowd

Dowd PLLC

1717 Pennsylvania Avenue, NW

Suite 1025

Washington, D.C. 20006

(202) 573-3853

mjdowd@dowdpllc.com

Dated: November 13, 2017

CERTIFICATE OF SERVICE

I hereby certify that on this day, November 13, 2017, the foregoing was electronically filed and therefore served electronically via the court's ECF/CM system on all counsel of record.

/s/ Matthew J. Dowd

Matthew J. Dowd

Dowd PLLC

1717 Pennsylvania Avenue, NW

Suite 1025

Washington, D.C. 20006

(202) 573-3853

mjdowd@dowdpllc.com

Dated: November 13, 2017