

No. 15-1182

IN THE
Supreme Court of the United States

SEQUENOM, INC.,

Petitioner,

v.

ARIOSIA DIAGNOSTICS, INC., *et al.*,

Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED
STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

**BRIEF OF 19 LAW PROFESSORS AS
AMICI CURIAE IN SUPPORT OF
PETITION FOR A WRIT OF CERTIORARI**

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TABLE OF CONTENTS

	<i>Page</i>
TABLE OF CONTENTS.....	i
TABLE OF CITED AUTHORITIES	iii
INTEREST OF <i>AMICI CURIAE</i>	1
SUMMARY OF ARGUMENT.....	1
ARGUMENT.....	3
I. The Lower Courts And The PTO Have Misunderstood The <i>Mayo-Alice</i> Test And Have Created Indeterminate And Over- Inclusive Doctrine On Patent Ineligibility Under § 101.....	3
A. Lower Courts Have Made The <i>Mayo- Alice</i> Test Legally Indeterminate As Evidenced By § 101 Analyses That Conflict With This Court's Past Decisions Affirming Patents As Valid	5
B. Lower Courts And The PTO Have Made The <i>Mayo-Alice</i> Test Over-Inclusive And Are Invalidating Legitimate Patented Innovation	10

Table of Contents

	<i>Page</i>
C. Indeterminate And Over-Inclusive Application Of The <i>Mayo-Alice</i> Test Undermines Twenty-First-Century Innovation In Diagnostic Tests That The Patent System Is Designed To Promote.....	11
II. Adopting A “Claim As A Whole” Requirement Provides A Solution To The Indeterminate And Over-Inclusive Application Of The <i>Mayo-Alice</i> Test	14
A. The “Claim As A Whole” Requirement Is Fundamental To The Patentability Requirements In §§ 102 And 103 Of The Patent Act.....	15
B. This Court Adopted A “Claim As A Whole” Requirement To Solve The Same Problems Of Indeterminacy And Over-Inclusiveness In Patent Infringement Lawsuits.....	18
C. Canons of Statutory Construction Further Support This Court Mandating That Lower Courts And The PTO Assess § 101 Eligibility Only As Applied To A “Claim As A Whole”	20
CONCLUSION	22
APPENDIX.....	1a

TABLE OF CITED AUTHORITIES

	<i>Page</i>
CASES	
<i>Alice Corp. Pty. v. CLS Bank Int'l</i> , 134 S. Ct. 2347 (2014).....	<i>passim</i>
<i>Ariosa Diagnostics, Inc. v. Sequenom, Inc.</i> , 19 F. Supp. 3d 938 (N.D. Cal. 2013), <i>aff'd</i> , 788 F.3d 1371 (Fed. Cir. 2015)	4
<i>Ariosa Diagnostics, Inc. v. Sequenom, Inc.</i> , 809 F.3d 1282 (Fed. Cir. 2015)	4
<i>Aro Manufacturing Co. v.</i> <i>Convertible Top Replacement Co.</i> , 365 U.S. 336 (1961).....	18
<i>Ass'n for Molecular Pathology v.</i> <i>Myriad Genetics, Inc.</i> , 133 S. Ct. 2107 (2013).....	1-2, 21
<i>Bilski v. Kappos</i> , 561 U.S. 593 (2010).....	<i>passim</i>
<i>Cuno Engineering Corp. v.</i> <i>Automatic Devices Corp.</i> , 314 U.S. 84 (1941)	17
<i>Davis v. Michigan Dep't of Treasury</i> , 489 U.S. 803 (1989).....	21

Cited Authorities

	<i>Page</i>
<i>Deere & Co. v. Bush Hog, LLC</i> , 703 F.3d 1349 (Fed. Cir. 2012)	19
<i>Diamond v. Diehr</i> , 450 U.S. 175 (1981)	10
<i>Dolbear v. American Bell Telephone Company</i> , 126 U.S. 1 (1888).....	8, 9
<i>FDA v. Brown & Williamson Tobacco Corp.</i> , 529 U.S. 120 (2000).....	3, 21
<i>Festo Corp. v.</i> <i>Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd.</i> , 535 U.S. 722 (2002).....	15
<i>FTC v. Mandel Brothers, Inc.</i> , 359 U.S. 385 (1959).....	21
<i>Graham v. John Deere Co.</i> , 383 U.S. 1 (1966).....	17
<i>Graver Tank & Mfg. Co. v.</i> <i>Linde Air Products Co.</i> , 339 U.S. 605 (1950).....	19
<i>Gustafson v. Alloyd Co.</i> , 513 U.S. 561 (1995).....	21
<i>Jungersen v. Ostby & Barton Co.</i> , 335 U.S. 560 (1949).....	17

Cited Authorities

	<i>Page</i>
<i>KSR Int'l Co. v. Teleflex Inc.</i> , 550 U.S. 398 (2007)	17
<i>Mayo Collaborative Servs. v.</i> <i>Prometheus Labs., Inc.</i> , 132 S. Ct. 1289 (2012).....	<i>passim</i>
<i>Mercoid Corp. v.</i> <i>Minneapolis-Honeywell Regulator Co.</i> , 320 U.S. 680 (1944).....	15
<i>O'Reilly v. Morse</i> , 56 U.S. 62 (1853).....	6
<i>Parker v. Flook</i> , 437 U.S. 584 (1978).....	15
<i>Peters v. Active Mfg. Co.</i> , 129 U.S. 530 (1889).....	18
<i>Structural Rubber Prods. Co. v.</i> <i>Park Rubber Co.</i> , 749 F.2d 707 (Fed. Cir. 1984).....	16
<i>Teva Pharmaceuticals USA, Inc. v. Sandoz, Inc.</i> , 135 S. Ct. 831 (2015).....	21-22
<i>Verdegaal Bros., Inc. v. Union Oil Co.</i> , 814 F.2d 628 (Fed. Cir. 1987)	16

Cited Authorities

	<i>Page</i>
<i>Warner-Jenkinson Co. v. Hilton Davis Chem. Co., 520 U.S. 17 (1997)</i>	15, 19, 20
<i>White v. Dunbar, 119 U.S. 47 (1886)</i>	19

STATUTES

35 U.S.C. § 101	<i>passim</i>
35 U.S.C. § 102	<i>passim</i>
35 U.S.C. § 103	<i>passim</i>
35 U.S.C. § 271	3, 20, 22

OTHER AUTHORITIES

Adam Mossoff, <i>O’Reilly v. Morse</i> (Aug. 18, 2014), available at http://ssrn.com/abstract=2448363	8
Bernard Chao & Amy Mapes, <i>An Early Look at Mayo’s Impact on Personalized Medicine</i> , 2016 <i>Patently-O Patent L. J.</i> 10, 12, at http://patentlyo.com/media/2016/04/ Chao.2016.PersonalizedMedicine.pdf	11

Cited Authorities

	<i>Page</i>
Bernard Chao & Lane Womack, <i>USPTO is Rejecting Potentially Life-Saving Inventions</i> , Law360 (Dec. 18, 2014), at http://www.law360.com/articles/604808/uspto-is-rejecting-potentially-life-saving-inventions	11
Christopher Beauchamp, <i>Invented by Law: Alexander Graham Bell and the Patent That Changed America</i> (2014).....	9
Michael Risch, <i>Nothing is Patentable</i> , Florida L. Rev. F. (2015), available at http://ssrn.com/abstract=2642361	5-6
<i>Mystery Solved! What is the cost to develop and launch a Diagnostic?</i> , Diaceutics Group, http://www.slideshare.net/Diaceutics/how-much-does-it-cost-to-launch-and-commercialize-a-companion-diagnostic-test (last visited Apr. 19, 2016)	12-13
Robert R. Sachs, <i>Update on Patent Eligibility Decisions for First Quarter, 2016</i> , Bilski Blog (Apr. 2, 2016), at http://www.bilskiblog.com/blog/2016/04/update-on-patent-eligibility-decisions-for-first-quarter-2016.html	3-4, 10
Roche, <i>Annual Report 2014</i> , 33 (2015), available at http://www.roche.com/gb14e.pdf	12

Cited Authorities

	<i>Page</i>
<i>The Importance Of Diagnostics</i> , http://www.biomerieux.com/en/importance-diagnostics (last visited Apr. 19, 2016)	12

CONSTITUTIONAL PROVISIONS

U.S. CONST. art. 1, § 8, cl. 8	2, 12
--	-------

PATENTS

U.S. Patent No. 174,465 (issued Mar. 7, 1876)	8
U.S. Reissue Patent No. 117 (issued June 13, 1848)	7

INTEREST OF *AMICI CURIAE*

The *amici curiae* includes 19 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 members of 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 grant *certiorari* because the Federal Circuit’s decision in this case undermines the function of the patent system to promote and to legally secure twenty-first-century innovation. The names and affiliations of the members of the *amici* are set forth in Appendix A.¹

SUMMARY OF ARGUMENT

In recent years, this Court has repeatedly reminded the Court of Appeals for the Federal Circuit, district courts, and the United States Patent & Trademark Office (“PTO”) 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*

1. Pursuant to Supreme Court Rule 37.6, *amici curiae* state that no counsel for any party authored this brief in whole or in part, and that no person or entity other than *amici curiae* or its counsel made a monetary contribution to the preparation or submission of this brief. Counsel of record for Petitioners in this case has filed a letter pursuant to Supreme Court Rule 37.3(a) reflecting consent to the filing of *amici curiae* briefs in support of either party. As stated in a letter filed with the Court, counsel of record for Respondents consented to the filing of this brief. *Amici curiae* gave timely notice to Petitioners and Respondents of their intent to file this brief.

v. Myriad Genetics, Inc., 133 S. Ct. 2107 (2013); *Bilski v. Kappos*, 561 U.S. 593 (2010). In doing so, this 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*, 134 S. Ct. 2347 (2014); *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 132 S. Ct. 1289 (2012). Unfortunately, the 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 *over-inclusive* 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-inclusiveness. The Federal Circuit’s decision invalidates legitimate innovation deserving of protection by the patent system after it analytically dissolved the relevant claim language into its component elements and thus concluded that it was ineligible subject matter. Petitioners in this case and other *amici* detail the many failings by the lower courts and the PTO in misapplying the *Mayo-Alice* test, and thus the *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 this Court’s existing precedents and leads to an over-inclusive application of the test that invalidates legitimate innovation.

This Court 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*. This is a predicate legal requirement in assessing novelty under § 102 and in assessing nonobviousness under § 103. It is also a fundamental legal requirement for asserting patents for both literal and equivalents infringement under § 271. In all of these other patent doctrines, this Court has maintained the basic requirement of assessing patentability or limiting assertion of patents to the *claim as a whole* given that this solves the same policy problems of indeterminacy and over-inclusiveness in these other patent doctrines. Accordingly, canons of statutory construction favoring coherent interpretation of separate provisions within a single statutory regime militate in favor of this Court adopting the same express requirement for the *Mayo-Alice* test under § 101. *See FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 133 (2000). For this reason, this Court should grant the petition for *certiorari*, reverse the Federal Circuit, and provide 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 Over-Inclusive Doctrine On Patent Ineligibility Under § 101

The *Mayo-Alice* test has been applied in 253 cases in the past several years. *See* Robert R. Sachs, *Update on Patent Eligibility Decisions for First Quarter, 2016*,

Bilski Blog (Apr. 2, 2016), at <http://www.bilskiblog.com/blog/2016/04/update-on-patent-eligibility-decisions-for-first-quarter-2016.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*, 132 S.Ct. at 1293 (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 this 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 this Court’s requirement of assessing a claim as a whole, focusing instead *solely* on the individual elements of each claim.² Examiners at the PTO and administrative law judges at the Patent Trial & Appeal Board (PTAB) 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

2. The district court in this case gave no more than lip service to considering Sequenom’s claims “as a whole,” *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 19 F. Supp. 3d 938, 952-53 (N.D. Cal. 2013), *aff’d*, 788 F.3d 1371 (Fed. Cir. 2015), but it is clear from the nature of its analysis that it did not do this when it applied the *Mayo-Alice* test. Similarly, the Federal Circuit felt obliged by its misunderstanding of the *Mayo-Alice* test to not assess Sequenom’s claim as a whole. See, e.g., *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 809 F.3d 1282, 1286 (Fed. Cir. 2015) (Lourie, J. concurring in denial of *en banc* rehearing.) (“[A]pplying *Mayo*, we are unfortunately obliged to divorce the additional steps from the asserted natural phenomenon.”).

into its individual elements, which of course are often comprised of unpatentable laws of nature or abstract ideas. *See Mayo*, 132 S.Ct. at 1293. 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 over-inclusive application of the test, as evidenced in this case.

A. Lower Courts Have Made The *Mayo-Alice* Test Legally Indeterminate As Evidenced By § 101 Analyses That Conflict With This Court’s Past Decisions Affirming 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, the *amici* identify a key insight into the nature of this legal indeterminacy: lower courts are applying the *Mayo-Alice* test in a way that casts serious doubt about famous nineteenth-century patents that were expressly validated by this Court. We identify only a few classic examples to make clear the legal conflicts that now exist in patent law between this Court’s patentable subject matter analysis and the lower courts’ repeated misapplications of the *Mayo-Alice* test.³

3. There are too many historical patents to discuss them all within the constraints of this brief. *See* Michael Risch, *Nothing is*

One example of how the lower courts' 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 this 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 to *Morse* because this 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, this 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 likely be invalid under the lower courts' application of the *Mayo-Alice* test in this and in other cases. This is compelling evidence of the lower courts' 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:

First. . . what I specially claim as my invention and improvement, is 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

Patentable, Florida L. Rev. F. (2015), available at <http://ssrn.com/abstract=2642361> (identifying classic patents called into doubt). Moreover, petitioner identifies how the analysis adopted by the lower courts in this case would cast doubt on the first patent issued in 1790 on a method for making potash. Pet. Br. 24-25.

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* test, according to both the district court’s and the Federal Circuit’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*, 132 S. Ct. at 1294. According to the lower courts’ 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.⁴

If applied to Morse's Claim 1, the district court's and Federal Circuit's approach in applying the *Mayo-Alice* test to each individual claim element would lead to the conclusion that Morse's Claim 1 is arguably unpatentable subject matter, contrary to this 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 this Court's analysis in *Morse* that Claim 1 in its entirety is valid as a patentable invention. This conflict between this Court's precedents and the decisions in this case as well as in hundreds of other cases and patent applications leaves inventors and patent 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 lower courts' 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, this Court affirmed Bell's Claim 5 as patentable subject matter in *Dolbear v. American Bell Telephone Company*, 126 U.S. 1, 531-35 (1888). Bell's Claim 5 reads as follows:

4. 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), available at <http://ssrn.com/abstract=2448363>.

The method of and apparatus for transmitting vocal or other sounds telegraphically . . . by causing electrical undulations, similar in form to the vibrations of the air accompanying the said vocal or other sounds.

Applying the *Mayo-Alice* test to Bell's Claim 5, according to the lower courts 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 likely 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, and thus are patent ineligible. Under step two, Claim 5 does not recite anything significantly more that was not 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 lower courts' § 101 analysis in this case leads to the conclusion that Bell's Claim 5 is arguably unpatentable subject matter.

Applying the lower courts' understanding of the *Mayo-Alice* test to famous nineteenth-century patents that were expressly affirmed as valid by this Court reveals a key analytical failing in the lower courts' 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 this 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 Over-Inclusive 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 over-inclusive, sweeping within its prohibition against patenting laws of nature, abstract ideas or physical phenomena, *Diamond v. Diehr*, 450 U.S. 175, 185 (1981), legitimate twenty-first-century innovation deserving of patent protection. In the past few years, district courts and the Federal Circuit are increasingly invalidating patent claims at extraordinarily high rates. As of April 2, 2016, the invalidation rate under the *Mayo-Alice* test in the lower courts is 70%. *See* Sachs, *Update on Patent Eligibility Decisions for First Quarter, 2016, supra*. (averaging an invalidation rate of 96.8% in the Federal Circuit and 66.2% in the district courts). This follows naturally from the lower courts' 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 253 cases since this Court decided *Alice Corp. v. CLS Bank* in 2014. *See id.*

The PTO has similarly high invalidation and rejection rates in applying the *Mayo-Alice* test. The invalidation rate at the Patent Trial & Appeal Board (PTAB) in the Covered Business Method program is 98%. *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), at <http://www.law360.com/articles/604808/uspto-is-rejecting-potentially-life-saving-inventions>. 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 & Amy Mapes, *An Early Look at Mayo's Impact on Personalized Medicine*, 2016 Patently-O Patent L. J. 10, 12, at <http://patentlyo.com/media/2016/04/Chao.2016.PersonalizedMedicine.pdf>.

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

The lower courts' indeterminate and over-inclusive application of the *Mayo-Alice* test matters because it contravenes the *Bilski* Court's admonition 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 genetic diagnostic testing methods, like the prenatal 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.

As the close relationship between genes and medical conditions has become clearer in recent years, the value of genetic diagnostic tools has increased dramatically. Experts now estimate that 60-70% of all medical treatment decisions are based on the results of diagnostic tests. *See The Importance Of Diagnostics*, <http://www.biomerieux.com/en/importance-diagnostics> (last visited Apr. 19, 2016). 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*, 33 (2015), available at <http://www.roche.com/gb14e.pdf>.

The economics of innovative diagnostic tests reflect exactly the economic justification for the patent system: the cost of applying a genetic 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 between \$50-75 million and can exceed \$100 million for developing and commercializing novel diagnostic technologies. *Mystery Solved! What is the cost to develop and launch a Diagnostic?*, Diaceutics

Group, <http://www.slideshare.net/Diaceutics/how-much-does-it-cost-to-launch-and-commercialize-a-companion-diagnostic-test> (last visited Apr. 19, 2016). Screenings for diseases with complex genetic interactions—like diabetes, heart disease, 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 genetic 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 lower courts’ application of the *Mayo-Alice* test in this and other cases 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 this Court has deemed valid. In breaking up 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 “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 *Alice* Court’s warning 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 over-inclusive in invalidating innovation that should be secured by the patent system, like the prenatal diagnostic testing method in this case. *See also Mayo*, 132 S. Ct. at 1293 (“too broad an interpretation of this exclusionary principle [under § 101] could eviscerate patent law”).

This contravenes the guidance by this 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. This Court needs to rebalance the patent system by providing further instruction to the lower 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 this 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 Provides A Solution To The Indeterminate And Over-Inclusive Application Of The *Mayo-Alice* Test

There are many possible solutions to the problems of indeterminacy and over-inclusiveness that have infected the lower courts’ and PTO’s application of the *Mayo-Alice* test. In addition to those offered by Petitioner and other *amici*, the *amici* here offer one more solution: this Court should instruct the lower courts and the PTO to apply the *Mayo-Alice* test only to *the claim as a whole*. This 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 this Court. *See also Parker v. Flook* 437 U.S. 584, 594 (1978) (“[A] patent claim must be considered as a whole.”); *Mercoïd 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.”).

Granting *certiorari* and reversing the Federal Circuit is necessary in this case for the same reason this Court granted *certiorari* in *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd.*, 535 U.S. 722 (2002). This Court needs to prevent the lower courts from undermining the functioning of the patent system when these courts are failing to follow the legal rules and tests set forth in past Supreme Court decisions. *Id.* at 739 (chastising the Federal Circuit for having “ignored the guidance of *Warner-Jenkinson*, which instructed that courts must be cautious before adopting changes that disrupt the settled expectations of the inventing community” (citing *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 28 (1997))).

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 lower 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) (“lack 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 alleged invention in the prior art.

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 Engineering 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: “the 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 over-inclusive 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 approach 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 Justice Anthony Kennedy recently 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*, 132 S. Ct. at 1293. This is why this 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, this Court 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. This Court Adopted A “Claim As A Whole” Requirement To Solve The Same Problems Of Indeterminacy And Over-Inclusiveness In Patent Infringement Lawsuits

This 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, this 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. This 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 Manufacturing 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 predicate requirement prevents indeterminacy and over-inclusiveness from self-aggrandizing assertions by patent-owners against alleged infringers.

More recently, this 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 Products Co.*, 339 U.S. 605, 614 (1950) (quoting *White v. Dunbar*, 119 U.S. 47, 51 (1886)). In *Warner-Jenkinson*, this 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.”).

This 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, similar to the situation before the adoption of § 103 in the 1952 Patent Act, this Court adopted a *claim as a whole* requirement in response to legitimate concerns about indeterminacy and over-inclusiveness in the lower courts’ application of patent infringement doctrines, both for literal infringement and for the doctrine of equivalents. Thus, just like the patent validity analyses under §§ 102 and 103, this 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 This Court Mandating That Lower Courts And The PTO Assess § 101 Eligibility Only As Applied To A “Claim As A Whole”

Canons of statutory construction further support this Court 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*, 132 S. Ct. at 1293, 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, this 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.” *Brown & Williamson Tobacco Corp.*, 529 U.S. at 133 (quoting *Davis v. Michigan 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.

In fact, this 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*, 132 S. Ct. at 1304 (“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 decision just last year in *Teva Pharmaceuticals USA, Inc. v. Sandoz*,

Inc., 135 S. Ct. 831 (2015), this Court implicitly reaffirmed this canon of statutory construction. In *Teva*, this 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.

CONCLUSION

The *amici* urge this Court to grant the petition for a writ of *certiorari*, to reverse the Federal Circuit, 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.”

Respectfully Submitted,

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