

To Promote Innovation, Congress Should Abolish the Supreme Court Created Exceptions to 35 U.S. Code §101

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Recent Supreme Court decisions¹ have caused havoc in the Biotechnology and Software industries in the U.S. by vastly increasing the number of U.S. patents being invalidated based on the patent eligible subject matter requirements of 35 U.S.C. §101. As a result, the spotlight on 35 U.S.C. §101 is increasing and there are discussions amongst the patent bar for how best to address the unintended consequences. I here argue that Congress should abolish the Supreme Court-promulgated, non-statutory exceptions to 35 U.S.C. §101, in toto, because they: 1) run directly in conflict with the express statutory language of 35 U.S.C. §101 and its Congressional intent; 2) have been extremely difficult to implement in practice by the U.S. Patent and Trademark Office, the District courts and the Court of Appeals for the Federal Circuit; 3) offer no significant benefit that outweighs the havoc and harm caused to public and private innovation-driven industries; 4) run in direct contrast to the laws of other industrialized nations on this narrow legal issue; and 5) otherwise greatly discourage current and future innovators from developing and commercializing their new discoveries and technologies in America.

¹ Mayo Collaborative Sers. v. Prometheus Labs., Inc., 566 U.S. 66 (2012); Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. 576 (2013); Alice Corp. v. CLS Bank Int'l, 573 U.S. 208 (2014).

Mark Twain once commented “A country without a patent office and good patent laws was just a crab, and couldn’t travel any way but sideways or backwards.”²

I. Introduction

The Patent Act, under 35 U.S.C. §101, defines and specifies four independent categories of subject matter of inventions or discoveries that are eligible for patent protection: 1) processes; 2) machines; 3) manufactures; and 4) compositions of matter.³ While it is clear from the 35 U.S.C. §101 statute that Congress intended to give a wide scope to patent eligible subject matter,⁴ the Supreme Court has judicially created three exceptions to this statutory language⁵ and recently has gone further to greatly expand the scope of these exceptions.⁶ This has dramatically narrowed the scope of patent protection available to innovation-driven private and public enterprises, especially affecting stakeholders in the Biotechnology and Software-driven industries.⁷

Three recent Supreme Court decisions⁸ have greatly disrupted new technology-driven industries, including the biopharmaceutical and software engineering industries, by vastly increasing the number of software and biological patents being invalidated based on 35 U.S.C. §101. Even though the Supreme Court advised the lower courts to “thread carefully in construing this exclusionary principle lest it swallow all of patent law,”⁹ the lower courts and the Court of Appeals for the Federal Circuit have used these Supreme Court decisions to strike down and invalidate hundreds of U.S. patents.¹⁰ Moreover, thousands of pending patent applications are

² MARK TWAIN, A CONNECTICUT YANKEE IN KING ARTHUR’S COURT 107 (1889). This quote illustrates my opinion that unless legislative action is taken in 2020 to correct our patent eligibility laws, the U.S. may be set to travel sideways or backwards on the innovation road for some time.

³ The current version of the patent eligibility statute, 35 U.S.C. § 101 (2012), states: “Whoever invents or discovers any new and useful process, machine, manufacture or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.”

⁴ *Id.*

⁵ “We have ‘long held that this provision contains an important implicit exception[:] Laws of nature, natural phenomena, and abstract ideas are not patentable.’” Ass’n for Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. 576, 589 (citing *Mayo*, 132 S.Ct., at 1293).

⁶ See Philip Merksamer, Ariosa Diagnostics v. Sequenom: *Metastasis of Mayo and Myriad and the Evisceration of Patent Eligibility for Molecular Diagnostics*, 31 BERKELEY TECH. L. REV. 495, 531 (2016) (arguing that the Supreme Court expanded the judicial exceptions to patentable subject matter in *Mayo* and *Myriad*).

⁷ See, e.g., *id.* (arguing that the expansions “endanger patentability for molecular diagnostics”).

⁸ *Mayo*, 566 U.S. 66 ; *Myriad*, 569 U.S. 576 ; *Alice*, 573 U.S. 208 .

⁹ *Alice*, 573 U.S. at 217.

¹⁰ See, e.g., *Digitech Image Techs., LLC v. Elecs. for Imaging, Inc.*, 758 F.3d 1344 (Fed. Cir. 2014) (holding that device profile described in patent was not patent eligible, and that method claims in patent did not describe patent eligible subject matter); *Planet Bingo, LLC v. VKGS LLC*, 576 Fed. App’x. 1005 (Fed. Cir. 2014) (holding that method and system claims failed to transform the abstract idea of managing a game of bingo into a patent-eligible invention); *buySAFE, Inc. v. Google, Inc.*, 765 F.3d 1350 (Fed. Cir. 2014) (holding that claims at issue were directed to abstract ideas, and thus were invalid as unpatentable); *Ultramercial, Inc. v. Hulu, LLC*, 772 F.3d 709 (Fed. Cir. 2014) (holding that claims describing a method for distributing media products directed to abstract ideas, and thus were invalid as unpatentable); *In re BRCA1- & BRCA2-Based Hereditary Cancer Test Patent Litig.*, 774 F.3d 755 (Fed. Cir. 2014) (holding that claims for particular diagnostic methods to identify mutations in DNA sequences did not render patentable otherwise ineligible abstract mental process method claims); *Content Extraction & Transmission LLC v. Wells Fargo Bank Nat’l*

failing to overcome the new hurdle that patent applicants are subject to under 35 U.S.C. §101 and are thus becoming abandoned.¹¹

All patent stakeholders have been affected by this seesaw change in patent eligibility laws, including inventors, patent office examiners, patent owners, patent lawyers and judges alike. It is becoming increasingly accepted by this community that as a result of the Supreme Court's recent jurisprudence bringing profound uncertainty to the nation's patent eligibility laws, enormous negative consequences have been felt by American businesses across the nation and especially so in Biotechnology and Software-driven enterprises. Thus, the unintended consequences of these Supreme Court decisions are increasingly giving rise to a discussion amongst the patent bar for options available for addressing the situation we face today.

Accordingly, one currently pressing question in patent law is what can be done to tilt back the balance and help the innovators in America? I here argue that Congress should abolish the non-statutory exceptions to 35 U.S.C. §101 for being against current and future thinkers and entrepreneurial innovators who aim to develop and commercialize tomorrow's new technologies in America. That is, I propose the exceptions that the Supreme Court has created to statutorily defined patent eligible subject matter are creating great uncertainty in the innovation ecosystem and harming new technology development and commercialization in America.

By tracing the roots of the legislative history of the patent eligibility statute (35 U.S.C. §101) to the present day, analyzing the express statutory language and historical as well as recent Supreme Court jurisprudence on this issue, I aim to convince the reader that the Supreme Court was misguided when it recently greatly expanded the scope of their own exceptions to the statutorily defined patent eligible subject matter. These exceptions to what subject matter is patent eligible under the 35 U.S.C. §101 statute have greatly narrowed the scope of patent protection available to innovation-driven private and public enterprises

Nowadays, private and public enterprises see the prospect of protecting their new and future innovations in certain fields, including in Biotechnology and Software-driven fields, as a mountain not worth climbing under the current patent eligibility laws in America. As a result, as discussed *infra*, there has been a huge downturn in research and development at many of the largest biopharmaceutical and software companies, as well as in hospitals and public research-driven enterprises, across the nation. This has in turn had the effect of killing off the prospects of innovative companies, including new Biotechnology and Software startup companies, bringing new innovations in medicine, software, artificial intelligence and the like to the marketplace. Weary of the current laws concerning patent eligibility,

Assoc., 776 F.3d 1343 (Fed. Cir. 2014) (holding the patent claims related to processing information were directed to patent-ineligible abstract ideas).

¹¹ Jasper L. Tran, *Two Years After Alice v. CLS Bank*, 98 J. PAT. & TRADEMARK OFF. SOC'Y 354, 358-59 (2016) (finding that in the two years post *Alice*, the patent office had rejected over 36,000 published patent applications under *Alice*, and over 5,000 of such applications becoming abandoned.)

companies and their investors, as discussed *infra* on investment in new technology,¹² are seeing broken patent eligibility laws incapable of supporting investment and new technology development.¹³

These entrepreneurial technology innovators and their investors are, to borrow a phrase from Mark Twain, seeing a country that in 2019 is traveling sideways or backwards.¹⁴ To perhaps give perspective by way of an example, a brand new medical technology related to non-invasively detecting abnormalities in a fetus during pregnancy, discussed further *infra*, was found to be patent eligible subject matter by both the highest court of the United Kingdom in November of 2017,¹⁵ and also by the Federal Court of Australia in August of 2019,¹⁶ yet that same technology and subject matter remains patent ineligible under current Supreme Court jurisprudence.¹⁷ Thus, if our patent eligibility laws do not change in the U.S., investors and innovative technology entrepreneurs will pivot towards other jurisdictions in well-developed industrialized countries that compete for talent with the U.S.

I here present my thesis that American society stands to benefit from abolishing the non-statutory, Supreme Court promulgated, exceptions to U.S. Code Section 101 altogether. Parts I and II of this article explore the express language of the statute, 35 U.S.C. §101, and its legislative history; and the historical to present day Supreme Court jurisprudence on 35 U.S.C. §101. Parts III and IV draw on the Supreme Court's recently adopted framework for assessing patent eligible subject matter and examine how it has been applied and the reasons why it has created such profound uncertainty in patent laws, and how this has ultimately damaged America's standing as a leader in new technology development and commercialization.

Part V concludes by advocating that abolishing the non-statutory, Supreme Court-created, exceptions to patent eligibility laws will a) modernize and simplify the rules governing U.S. patent laws; b) will harmonize this feature of U.S. patent law with the patent laws of other industrialized societies, much akin to how Congress harmonized important other aspects of U.S. patent laws with patent laws of other industrialized countries when it passed the monumental America Invents Act in 2012; and c) will once again lower the threshold hurdle on patent eligible subject matter and instead rely on other developed and working statutory patentability provisions of the Patent Act to achieve the same goals of not allowing patent protection on standalone mathematical formula, abstract thoughts, and the like.

There is a growing movement advocating that it is now time for Congress to act to fix the untenable situation regarding patent eligibility laws. Proposals have ranged from keeping the exceptions the Supreme Court has created to the statute and having a "practical application" test as skillfully proposed by other Intellectual Property law

¹² Jason Rantanen, *Guest Post on Patent Eligibility and Investment: A Survey*, PATENTLYO (Oct. 16, 2019, 4:41 PM) <https://patentlyo.com/patent/2019/03/patent-eligibility-investment.html> [<https://perma.cc/P3W3-X4TU>].

¹³ *Id.*

¹⁴ TWAIN, *supra* note 2 ("A country without a patent office and good patent laws was just a crab and couldn't travel any way but sideways or backwards.").

¹⁵ *Illumina, Inc. v. Premaitha Health PLC* [2017] EWHC (Pat) 2930, (Eng.).

¹⁶ *Sequenom, Inc. V. Ariosa Diagnostics, Inc.* [2019] FCA 1011, (Austl.).

¹⁷ *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371 (Fed. Cir. 2015).

professors¹⁸ to wholesale repealing of the entire 35 U.S.C. §101 statute from the Patent Act as advocated by David Kappos, the Director of the US Patent and Trademark Office from 2009-2013.¹⁹ In this paper, I advocate not for the wholesale repealing of the statute, but also not for more tinkering to keep in line with the Supreme Court's exceptions to the statutory language of 35 U.S.C. §101, and discussing how lower courts, practitioners and the patent office ought to apply it.

Instead, I argue for keeping the long-standing statute, but removing the three exceptions to the statutory language of 35 U.S.C. §101 that the Supreme Court has unilaterally fashioned and has brazenly vastly expanded in scope recently. Viewing the legislative history of 35 U.S.C. §101, discussed *infra*, it is abundantly clear that the Supreme Court-created exceptions to this statute, especially the recent cases that hugely expand the scope of these judicially-created exceptions, run in direct conflict with not only the express language of the statute itself but also to what Congress has purposefully intended for over 200 years and during the passage of tens of Patent Acts.

Supreme Court's recent activism on this issue, which ironically the Court itself warned had the power to "swallow all of patent law"²⁰ and "eviscerate patent law,"²¹ and the resulting mayhem it has now caused, has greatly harmed the innovation ecosystem in America. There is a growing chorus within the patent bar that the time is ripe for Congress to take some kind of action.

Should Congress abolish the non-statutory exceptions to 35 U.S.C. §101, balance will be restored in a broken aspect of patent law, thereby providing much sought-after certainty back to current U.S. patent law. The enactment of America Invents Act in 2013 was a leap forward and so too would be the case if Congress took significant action concerning 35 U.S.C. §101. This will have the knock-on effect of returning our laws to once again encourage and reward entrepreneurial innovators to take risks and develop, commercialize and bring new technologies to the marketplace. Since the U.S. Constitution mandates Congress to enact laws to "promote the progress of science and the useful arts,"²² such action would be squarely within Congress' mandate.

II. Legislative History of 35 U.S. Code §101

¹⁸ Brief of Professors Jeffrey A. Lefstin and Peter S. Menell as Amici Curiae in Support of Petition for a Writ of Certiorari at 5, *Ariosa Diagnostics Inc. v. Sequenom Inc.* 788 F.3d 1371.

¹⁹ Steven Lundberg, *Dave Kappos Calls for Abolition of Section 101*, THE NAT'L. LAW REVIEW (Oct. 16, 2019, 6:09 PM), <https://www.natlawreview.com/article/dave-kappos-calls-abolition-section-101>.

²⁰ The Supreme Court advised the lower courts in *Alice* to "tread carefully in construing *this exclusionary principle lest it swallow all of patent law.*" (emphasis added). *Alice*, 134 S.Ct. at 2354.

²¹ Two years prior to *Alice*, the Supreme Court in *Mayo* warned that their own judicially created exceptions to the statute have the power to destroy Congress' patent law, stating: "The Court has recognized, however, that too broad an interpretation of *this exclusionary principle could eviscerate patent law.* For all inventions at some level embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas." *Mayo*, 566 U.S. at 71 (emphasis added).

²² U.S. CONST. art. I, § 8, cl. 8.

Under Article I, Section 8, Clause 8 of the U.S. Constitution, Congress has the power to “promote the progress of science and the useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries.”²³ It has recently been proposed by other scholars that the wording of the U.S. constitution itself not only grants Congress the power to create laws that promote the progress of science, but that it also associates inventors with discoveries.²⁴ Congress has exclusive power and lawmakers decide how they will promote the progress in science and the useful arts. One way to consider this is to first attempt to define what kind of subject matter the country wishes to see progress in, and then devise the necessary laws that are tailored to that goal.²⁵ In legal terms, the statute at the heart of this “which subject matter is eligible for a patent?” debate is the patent eligibility statute under 35 U.S.C. § 101.²⁶

The first time Congress passed a law to codify what can and cannot be patent eligible subject matter was in the Patent Act of 1790,²⁷ however, it was initially Thomas Jefferson who first drafted a statute to “promote the progress of science and useful arts.”²⁸ In doing so, Jefferson relied heavily on established English law that aimed to “to promote the progress of science and useful arts. . .by giving the public at large a right to make, construct, use, and vend the thing invented, at as early a period as possible; having a due regard to the rights of the inventor.”²⁹ While The Patent Act of 1793, which Thomas Jefferson authored, repealed the Patent Act from three years prior, it largely embodied the ideology of older English law, ultimately defining patent eligible subject matter to be “any new and useful art, machine, manufacture, or composition of matter, or any new and useful improvement.”³⁰

For the next 160 years, other Patent Acts were passed by Congress, including the Patent Acts of 1794,³¹ 1800,³² 1832,³³ 1836,³⁴ 1837,³⁵ 1839,³⁶ 1842,³⁷ 1870³⁸ and many more. What is generally the takeaway, vis-à-vis the patent eligibility laws, is that the subject matter eligible for patent protection remained largely unchanged for 160 years between 1793 and 1950s. The 1952 Act added certain definitions, however,

²³ U.S. CONST. art. I, § 8, cl. 8.

²⁴ Sherry Knowles & Anthony Prosser, *Unconstitutional Application of 35 U.S.C. § 101 by the U.S. Supreme Court*, 18 J. MARSHALL REV. INTELL. PROP. L. 144 (2018).

²⁵ Indisputably, nowadays, Patent Law is intractably tied to new technology development and commercialization.

²⁶ The U.S. Constitution excludes the word “patent,” but there is also no explicit requirement for Congress to advance certain technologies to progress science. U.S. CONST. art. I, § 8, cl. 8.

²⁷ Patent Act of 1790, Pub. L. No. 1-34, 1 Stat. 109 (1790).

²⁸ *Id.*

²⁹ *Pennock v. Dialogue*, 27 U.S. 1, 18 (1829) (noting “it is obvious to the careful inquirer, that many of the provisions of our Patent Act are derived from the principles and practice which have prevailed in the construction of that of England”).

³⁰ Patent Act of Feb. 21, 1793, § 1, Pub. L. No. 2-53, 1 Stat. 319 (1793).

³¹ Act of June 7, 1794, Pub. L. No. 3-61, 1 Stat. 393 (1794).

³² Act of Apr. 17, 1800, Pub. L. No. 6-25, 2 Stat. 37 (1800).

³³ Act of July 3, 1832, Pub. L. No. 22-162, 4 Stat. 559 (1832).

³⁴ Act of July 4, 1836, Pub. L. No. 24-357, 5 Stat. 117 (1836).

³⁵ Act of Mar. 3, 1837, Pub. L. No. 24-45, 5 Stat. 191 (1837).

³⁶ Act of Mar. 3, 1839, Pub. L. No. 25-88, 5 Stat. 353 (1839).

³⁷ Act of Aug. 29, 1842, Pub. L. No. 27-263, 5 Stat. 543 (1842).

³⁸ Act of July 8, 1870, Pub. L. No. 41-230, 16 Stat. 198 (1870).

neither the 1952 Patent Act nor the recent America Invents Act of 2012 changed the substance of patent eligibility laws as they existed in 1790s.

The current version of the patent eligibility statute, 35 U.S.C. § 101, states:

“Whoever invents or discovers any new and useful process, machine, manufacture or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.”³⁹

A recent article by Knowles and Prosser traces the legislative history of patent eligibility in detail and argues that Congress has largely kept the words “invents” and “discovers” in subsequent statutory language and this has been intentional.⁴⁰ The authors make the point that the reason this is important is that the Supreme Court has effectively ignored the word “discovers” to suit their interpretation of the statute. For example, it is noteworthy that the Supreme Court recently stated in *Myriad*, that: “[g]roundbreaking, innovative, or even brilliant discovery does not by itself satisfy the §101 inquiry.”⁴¹ [emphasis added]. And yet, the express wording of the §101 statute says otherwise: “whoever invents or discovers. . .” Thus, Supreme Court’s recent activism, positing that just by *discovering* something you do not necessarily satisfy the §101 inquiry runs directly against very long standing express statutory language.

As Knowles and Prosser point out, the Patent Act of 1793 defined statutory patent-eligible subject matters as “any new and useful process, machine, manufacture, or composition of matter, or any new or useful improvement thereof” and this language has survived numerous Patent Acts in the ensuing 200+ years. It is telling that Thomas Jefferson, who wrote the statutory language that has survived over 200 years, had in mind that “ingenuity should receive a liberal encouragement.”⁴² The Supreme Court has created exceptions to this statutory language that run directly against not only the long standing statutory language by creating exceptions to what the statute explicitly says would otherwise be patent eligible subject matter, but also these Supreme Court created exceptions to patent eligible subject matter run against the implicit intent of Congress to liberally encourage ingenuity as Jefferson had intended and the ensuing Patent Acts left unchanged for over 200 years.

This statutory intent is and has been for over 200 years to set a low threshold bar to patentable subject matter, which the Supreme Court decades ago had recognized when stating that this includes “anything under the sun made by man,”⁴³ and yet, in direct contrast to the 35 U.S.C. § 101 statute, its legislative history and Congress’s

³⁹ US Patent Act of 1952, 35 U.S.C. § 101 (2012) (emphasis added).

⁴⁰ Knowles & Prosser *supra* note 24.

⁴¹ Ass’n for Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. 576, 591 (2013).

⁴² V WRITINGS OF THOMAS JEFFERSON 75–76 (Washington ed. 1861). *See also* Knowles & Prosser *supra* note 24 (giving a more detailed and thorough discussion on the legislative history of § 101).

⁴³ *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980).

intent, recent Supreme Court jurisprudence now puts a very high bar on this threshold § 101 inquiry of what subject matter is even patent eligible.

III. Supreme Court's Jurisprudence on 35 U.S. Code §101

An issued patent provides a monopoly to the inventor to make, use and sell the invention in the U.S. for a defined period of time.⁴⁴ It may be counterintuitive to the non-patent scholar, however, even if an invention is found to be novel, not obvious, to have utility, and to meet all of the technical requirements for a patent, a patent will not issue unless, as a preliminary threshold matter, the invention is directed to subject matter that the Patent Act, under 35 U.S. Code §101, has defined to be *patent eligible subject matter*.

There are three 19th century Supreme Court cases relating to the patent eligibility issue worthy of discussion here, the oldest of which is the oft quoted *Tatham* decision.⁴⁵ This decision from 1852 is frequently quoted by the Supreme Court and the Federal Circuit, and the quote that is often used from this case is that “a principle, in the abstract, is a fundamental truth; an original cause; a motive; and these cannot be patented, as no one can claim in either of them an exclusive right.”⁴⁶

*O'Reilly v. Morse*⁴⁷ (1853) is the old telegraph case, in which Morse sued O'Reilly based on an invention that related to the use of repeaters to allow for long distance transmission of a telegraph signal.⁴⁸ The Supreme Court noted that Morse had not enabled the full scope of his claim because he enabled only electromagnetic repeaters. The Court referenced the *Neilson* English decision⁴⁹ from a decade prior and concluded that Morse's patent claim⁵⁰ addresses all possible applications of a physical principle, not a specific implementation of the principle. Thus, the court found the patent claim to be ineligible subject matter.⁵¹

In *Tilghman v. Proctor* (1880),⁵² the patent claimed a process by which water could be used at high temperature and pressure to make fatty acids and glycerin. The Supreme Court first considered whether the earlier *Morse* decision held that processes are not patentable. The Court clarified that a patent for a process is different from a patent for a scientific principle, explaining that a patent claim fails if it is not a claim to a particular machine, or a claim to a process for utilizing a principle. Thus, the Court clarified that a patent claim to the principle itself is not patentable subject matter.⁵³

⁴⁴ 20 years from the priority filing date. 35 U.S.C. § 154.

⁴⁵ *Le Roy v. Tatham*, 55 U.S. 156 (1853).

⁴⁶ *Id.* at 175.

⁴⁷ *O'Reilly v. Morse*, 56 U.S. 62 (1853).

⁴⁸ *Id.*

⁴⁹ *Neilson v. Harford*, 151 Eng. Rep. 1266, 8 M&W 806, Web. Pat. Cas. 273 (1844).

⁵⁰ Claim 8 in Morse's patent. "Eighth. I do not propose to limit myself to the specific machinery or parts of machinery described in the foregoing specification and claims; the essence of my invention being the use of the motive power of the electric or galvanic current, which I call electro-magnetism, however developed for marking or printing intelligible characters, signs, or letters, at any distances, being a new application of that power of which I claim to be the first inventor or discoverer." *Morse*, 56 U.S. at 86.

⁵¹ *Id.* at 118-20.

⁵² *Tilghman v. Proctor*, 102 U.S. 707 (1880).

⁵³ *Id.* at 726-27.

A. 20th Century Decisions Relating to 35 U.S. Code §101

In just one decade starting in the 1970s, the Supreme Court decided three patent law cases related to patent eligibility, namely *Gottschalk v. Benson*,⁵⁴ *Parker v. Flook*,⁵⁵ and *Diamond v. Diehr*.⁵⁶ Until the recent trilogy of Supreme Court decisions on patent eligibility within a three year period in the current decade,⁵⁷ discussed *infra*, these older Supreme Court decisions provided the framework of how the Court viewed the patent eligibility requirement under 35 U.S.C. §101.

In 1972, the Supreme Court decided *Benson*,⁵⁸ a prominent decision since it was the Supreme Court's first ruling on the patentability of software. In this decision, the Supreme Court invalidated a patent on a method for converting numbers from one binary format to another. As Justice Douglas wrote for the majority, "the mathematical formula involved here has no substantial practical application except in connection with a digital computer."⁵⁹ It was the Court's view that mathematical algorithms were not eligible subject matter for patent protection, and that such a patent, if allowed to remain valid, would "wholly pre-empt the mathematical formula and in practical effect would be a patent on the algorithm itself."⁶⁰ This was the first instance in which abstract ideas were described as a separate category of ineligible subject matter by the Supreme Court,⁶¹ albeit the Court had previously distinguished between principles, such as laws of nature, and practical applications of those principles.⁶²

It was the belief of many at the time and in the ensuing years after *Benson* that algorithms are laws of nature, and that an algorithm is nothing more than a discovery of a fundamental truth, in contrast to *an invention*, and therefore an algorithm is not eligible subject matter for patenting. The Court did, however, leave some room to patent what it referred to in *Benson* as "a program servicing a computer."⁶³ A computer program or software is nothing more than a complex mathematical algorithm, instructing a computer to solve a problem. Thus, it remains to this day somewhat confusing that *Benson* did not find a mathematical algorithm (computer program) to be patent eligible subject matter, yet the Court suggested it would allow a patent that covered a "program servicing a computer."⁶⁴

In 1978, the Supreme Court decided *Flook*, a decision that was effectively later overruled by the Court in two subsequent decisions in *Chakrabarty* and *Diehr*. In

⁵⁴ 409 U.S. 63 (1972).

⁵⁵ 437 U.S. 584 (1978).

⁵⁶ 450 U.S. 175 (1981).

⁵⁷ See cases cited *supra* note 7.

⁵⁸ *Id.*

⁵⁹ *Benson*, 409 U.S. at 71-72.

⁶⁰ *Id.* at 72.

⁶¹ *Id.* at 68, 72.

⁶² *Le Roy v. Tatham*, 55 U.S. 156, 175 (1852).

⁶³ *Benson*, 409 U.S. at 71.

⁶⁴ *Id.*

Flook, the patent application was for a “Method for Updating Alarm Limits.”⁶⁵ Except for *Flook*’s mathematical algorithm, the method was identical to previous systems.⁶⁶ Although six years earlier the Supreme Court had decided in *Benson* that the discovery of a new formula is not patentable, here in *Flook*, the claimed method differed in that it included a specific application of the algorithm, catalytic conversion of hydrocarbons in the instant case. The Court relied on the old English Neilson⁶⁷ decision and its progeny, to find that *Flook*’s patent claim did not contain patent eligible subject matter because it was a “principle” or a “law of nature.”

Controversially, the Supreme Court in *Flook* focused on the “inventive concept”⁶⁸ rather than merely focusing attention on a patent claim “as a whole.”⁶⁹ The Court opined that “even though a phenomenon of nature or mathematical formula may be well known, *an inventive application of the principle* may be patented. Conversely, the discovery of such a phenomenon cannot support a patent *unless there is some other inventive concept in its application.*”⁷⁰ Interestingly, although *Chakrabarty*⁷¹ and *Diehr* had effectively overruled *Flook*, this case is making a revival since the Supreme Court’s more recent decisions in *Bilski* (2010) and *Mayo* (2012) favorably looked upon and aligned with the *Flook* decision. Yet, the lower courts continue to follow *Diehr* and *Chakrabarty*, as well as the recently decided *Mayo* and *Alice* decisions.

In 1981, three years after *Flook*, the Supreme Court decided *Diehr*. *Diehr*’s invention related to a math equation, a computer program, to determine the curing time for rubber so that one could make better precision molded rubber products.⁷² Here, the invention comprised a software algorithm, as well as some physical items like a molding press, to achieve a specific result of curing rubber. The Court held that the execution of a physical process, controlled by running a computer program, was patent eligible subject matter, noting that although software algorithms could not be patented, the mere presence of a software element did not make an otherwise patent-eligible machine or process an ineligible subject matter for patenting. Therefore, unlike the method claims in *Benson* and *Flook*, the Court found the method in *Diehr* to be patent eligible subject matter because the claims did not “foreclose from others the use of that equation in conjunction with all of the other steps in their claimed process”⁷³ when they were “considered as a whole.”⁷⁴

Thus, the key question in *Diehr* centered on the implementation of the algorithm and how it applied in the method; more particularly, whether the mathematical algorithm “transforms and reduces. . .an article ‘into a different state or thing.’”⁷⁵ The

⁶⁵ Parker v. Flook, 437 U.S. 584, 585..

⁶⁶ *Id.*

⁶⁷ Neilson v. Harford (1841) 151 Eng. Rep. 1266 (Ex.).

⁶⁸ *Flook*, 437 U.S. at 594.

⁶⁹ *Id.*

⁷⁰ *Id.* (emphasis added).

⁷¹ Diamond v. Chakrabarty, 447 U.S. 303, 315–16 (1980).

⁷² U.S. Patent No. 4,344,142 (issued Aug. 10, 1982) (directed to “Direct digital control of rubber molding presses.”).

⁷³ Diamond v. Diehr, 450 U.S. 175, 187.

⁷⁴ *Flook*, 437 U.S. 584, 594.

⁷⁵ *Diehr*, 450 U.S. at 184.

Court in *Diehr* repeated its position that abstract mathematical formulas are not patent eligible subject matter, and that using an abstract mathematical formulas in a physical machine or process is different to a claim solely to an algorithm in the abstract.

As such, in each of *Benson*, *Flook* and *Diehr*, a different vision of the statutory law governing patent eligible subject matter, namely 35 U.S.C. §101, emerged. Yet, what emerged from the final *Diehr* case of this Supreme Court trilogy of cases on patent eligibility from some forty years ago is that the Court underlined two traditional understandings of the law on patent eligibility. First, that abstract principles are not patent eligible, and yet practical applications of those principles are patent eligible,⁷⁶ and second that prior art and issues related novelty, obviousness or inventiveness play no role in determining patent eligibility under 35 U.S.C. §101.⁷⁷

After the *Diehr* decision in 1981 and for approximately the next thirty years, the Supreme Court went quiet on §101, and this allowed most stakeholders and patent professionals to believe that the state of patent eligibility laws articulated in those cases had generally settled and could be relied upon. During this thirty-year period, the Court of Appeals for the Federal Circuit meanwhile began interpreting and relying on the *Diehr* decision to broaden the scope of patent eligible subject matter under the 35 U.S.C. §101 statute. As an example, the Federal Circuit found that business method claims that were previously patent-ineligible subject matter were now potentially patent eligible where such business methods achieve a “useful, concrete and tangible result.”⁷⁸

This was a radical turn taken by the Federal Circuit in *State Street*,⁷⁹ and, unfortunately, the Supreme Court denied *certiorari* in this case to correct the mistake.⁸⁰ The Federal Circuit’s eyebrow raising shift was seen by some as the Court’s apt ability to adapt to new and innovative concepts and technological advances, all the while keeping true to the foundational lessons from the Supreme Court’s *Diehr* decision. Yet, the reality was the bizarre specter of having a surge in business method related patent applications on anything from offering arbitration and

⁷⁶ *Id.* at 187 (“It is now commonplace that an application of a law of nature or mathematical formula to a known structure or process may well be deserving of patent protection.”); at 191 (“We recognize, of course, that when a claim recites a mathematical formula (or scientific principle or phenomenon of nature), an inquiry must be made into whether the claim is seeking patent protection for that formula in the abstract.”).

⁷⁷ *Id.* at 188–89 (“The ‘novelty’ of any element or steps in a process, or even of the process itself, is of no relevance in determining whether the subject matter of a claim falls within the § 101 categories of possibly patentable subject matter.”).

⁷⁸ *State St. Bank & Trust Co. v. Signature Fin. Grp., Inc.* 149 F.3d 1368, 1375 (Fed. Cir. 1998) (quoting *In re Alappat*, 33 F.3d 1526, 1544 (Fed. Cir. 1994)).

⁷⁹ *State St.* overruled the Freeman-Walter-Abele Test, noting it had “little, if any, applicability to determining the presence of statutory subject matter.” *Id.* at 1374. Yet, the court in *State Street* set forth a “‘useful, concrete, and tangible result[s]’” test. *Id.* at 1373 (quoting *Alappat*, 33 F.3d at 1544). The Supreme Court never accepted this test, questioning its viability. *See* *Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc.*, 548 U.S. 124, 136 (2006).

⁸⁰ *See* *State St. Bank and Trust Co. v. Signature Fin. Grp., Inc.*, 525 U.S. 1093 (1999) (denying petition for writ of certiorari).

legal services, tax planning, and even an application aimed at a system for booking toilets. Relying on the Supreme Court's *Diehr* decision and its own interpretation of it, the Federal Circuit and majority of stakeholders and IP professionals considered patent eligibility under 35 U.S.C. §101 to be a "coarse filter"⁸¹ through which the vast majority of patent applications pass with very few 35 U.S.C. §101 rejections being made by examiners at the patent office.

Yet, all this changed when the Supreme Court rendered four patent eligibility decisions spanning 2010-2014, with *Bilski* being the first.⁸²

B. 21st Century Decisions Relating to 35 U.S. Code §101: Supreme Court's Expansion of the Scope of Its Own Exceptions to 35 U.S. Code §101

Almost thirty years after their *Diehr* decision, the Supreme Court decided *Bilski*.⁸³ In *Bilski*, the inventors' patent application claimed methods for hedging risks for commodities trading. After the USPTO rejected the application under 35 U.S.C. §101 for being directed to an abstract idea, the case was appealed and the Federal Circuit heard it *en banc*, perhaps wishing to amend their *State Street* decision which had controversially opened the door for patenting ways of doing business.

The Federal Circuit agreed with the USPTO, and in tune with Supreme Court precedent, held that processes can be patented only if they are implemented by a machine or transformed something into a new or different thing. The court found that *Bilski*'s method was not patent eligible subject matter because "transformations or manipulations of. . .business risks or other such abstractions cannot meet the test because they are not physical objects or substances."⁸⁴ While the Federal Circuit was careful to affirm that business methods are still patentable, the Court did reject their own "useful concrete and tangible result"⁸⁵ test in *State Street*, acknowledging that the *State Street* decision had paved the way for patents on everyday activities that had no connection to technological innovation.

On appeal, the Supreme Court issued a total of three opinions, consisting of a plurality opinion for the Court and two concurring opinions. Although no single opinion was joined by a majority of Justices for all of its parts, in *Bilski*, the Supreme Court affirmed the Federal Circuit's rejection of *Bilski*'s patent claims, but under different reasoning. The Supreme Court in *Bilski* held that the Federal Circuit's "machine-or-transformation" test "is a useful and important clue an investigative tool" for patentability but not the sole or exclusive test for identifying patentable methods. Thus, the Court's failure to provide a bright line workable §101 framework effectively resulted in the uncertainty of patent-eligible subject matter being left for the lower courts to grapple with.⁸⁶

⁸¹ *Research Corporation Tech, Inc. v. Microsoft Corp.*, 627 F.3d 859, 869 (Fed. Cir. 2010).

⁸² *Bilski v. Kappos*, 561 U.S. 593 (2010).

⁸³ *Id.*

⁸⁴ *Bilski*, 545 F.3d at 963.

⁸⁵ *State St.* set forth a "useful, concrete, and tangible results" test. *Id.* at 1373.

⁸⁶ Peter S. Menell, *Forty Years of Wondering in the Wilderness and No Closer to the Promised Land: Bilski's Superficial Textualism and the Missed Opportunity to Return Patent Law to Its Technology Mooring*, 63 STAN. L. REV. 1289, 1304 (2011) (stating "the Supreme Court's methodology and analysis for determining whether a process falls within the scope of patentable subject matter could

After *Bilski* in 2010, the Supreme Court turned to Biotechnology and a subcategory of innovative and highly financially lucrative technologies within this biomedical sector, more specifically, attention turned to patent eligibility of inventions in the field of medical diagnostics. It is in this *Mayo* decision,⁸⁷ the first of the trio of patent eligibility cases the Supreme Court decided in the space of as many years, that an ill-advised radical shift surfaced. It should stand noted that at the time of the *Mayo* decision, there was a chorus amongst many on the patent bar that as a result of the Federal Circuit's expansive interpretation of Supreme Court's *Diehr* decision over many years, there was a glut of low quality superfluous patents being issued which was ultimately having a stifling effect on technological innovation in America. It is in this context that the *Mayo* decision was born.

In *Mayo*, the Court drew on old case law, including from an old English case *Neilson*,⁸⁸ and Supreme Court's own *O'Reilly*,⁸⁹ and *Funk Brothers*⁹⁰ decisions to then suggest that the real test for determining patent eligible subject matter under 35 U.S.C. §101 was not whether the patent claim had a *practical application*, but rather whether the patent claim had an *inventive application* of an underlying principle.⁹¹

1. *Interpreting Mayo's "Laws of Nature" (2012)*

In *Mayo*, the invention related to a method for optimizing the efficacy of a drug used to treat an autoimmune related gastrointestinal disorder.⁹² In particular, the patent claimed methods for calibrating the dosage of thiopurine drugs used for treating certain autoimmune diseases. In effect, the method involved the doctor administering a thiopurine drug, waiting to take a blood sample later to see if the metabolite of the drug was high or low and then based on this reading, deciding to administer more drug or less. Thus, the claimed methods involved measuring metabolites of the drug to optimize therapeutic efficacy while minimizing toxicity.

hardly be more opaque").

⁸⁷ *Mayo Collaborative Sers. v. Prometheus Labs., Inc.*, 566 U.S. 66 (2012).

⁸⁸ *Neilson v. Harford*, 151 Eng. Rep. 1266 (1841).

⁸⁹ *See O'Reilly v. Morse*, 56 U.S. 62, 132-133 (1853).

⁹⁰ *See Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 131 (1948). In this case, the inventor did not create the strains of bacteria and the strains that were central to this invention, and therefore were 'phenomena of nature' and unpatentable. While mixing different strains into one product was an application of the natural phenomena, the invention was deemed unpatentable subject matter because it amounted to no more than an alternate way to package the product.

⁹¹ *See Mayo* 566 U.S. at 66, 72-73 (emphasis added).

⁹² *Id.* at 74-75. (The independent patent claim at issue in *Mayo* recited "[a] method of optimizing therapeutic efficacy for treatment of an immune-mediated gastrointestinal disorder, comprising: (a) **administering** a drug providing 6-thioguanine to a subject having said immune-mediated gastrointestinal disorder; and (b) **determining** the level of 6-thioguanine in said subject having said immune-mediated gastrointestinal disorder, wherein the level of 6-thioguanine less than about 230 pmol per 8x10⁸ red blood cells indicates a need to increase the amount of said drug subsequently administered to said subject and wherein the level of 6-thioguanine greater than about 400 pmol per 8x10⁸ red blood cells indicates a need to decrease the amount of said drug subsequently administered to said subject."(emphasis added)).

In *Mayo*, the Supreme Court found that the patent claims⁹³ “do nothing more than simply describe the natural relationships between concentrations of certain metabolites in the blood and the likelihood that a dosage of a thiopurine drug will prove ineffective or cause harm,”⁹⁴ stating further that the correlation between the levels of a drug metabolite in blood with either an overdose or underdose of the drug is an unpatentable law of nature. “The relation is a consequence of the ways in which thiopurine compounds are metabolized by the body - entirely natural processes. And so a patent that simply describes that relation sets forth a natural law.”⁹⁵ The Court in *Mayo* articulated its belief that, when a method involves a natural law or abstract idea, it must also contain “*an inventive concept*,” which the Court defined as “other elements or a combination of elements . . . sufficient to ensure that the patent in practice amounts to *significantly more* than a patent upon the natural law itself.”⁹⁶

The Court compared the instant claim to its past precedent in *Diehr* (subject matter held patent eligible) and *Flook* (subject matter held patent ineligible), concluding that the patent claims provide mere “instructions” and that “Because methods for making such determinations were well known in the art, this step simply tells doctors to engage in well-understood, routine, conventional activity previously engaged in by scientists in the field, Such activity is normally not sufficient to transform an unpatentable law of nature into a patent-eligible application of such a law.”⁹⁷

Thus, in *Mayo*, the Supreme Court indicated that the real test for determining patent eligible subject matter under 35 U.S.C. §101 was not whether the patent claim had a *practical application*, but rather whether the patent claim had an *inventive application* of an underlying principle. This amounts to greatly increasing the scope of the Supreme Court created exceptions to the statute that explicitly outlines what can and cannot be patent eligible subject matter. Even the U.S. government warned the Supreme Court in its *Amicus Curiae* in this case, advising that the statutory language should not be discarded and ultimately suggesting to keep a low threshold bar for determining what subject matter is patent eligible and then leaving the higher bars to patentability on other parts of the Patent Act best suited for that task, namely novelty under §102 and obviousness under §103.⁹⁸

2. *Interpreting Myriad’s “Natural Phenomenon” (2013)*

One year after its *Mayo* decision, the Supreme Court confronted the controversial issue of the patent eligibility of genomic inventions. Innovations in these kinds of technologies had taken on great significance, especially since the completion of the Human Genome Project in 2000. In *Myriad*,⁹⁹ the Supreme Court held that genomic DNA was subject matter that is ineligible for a patent under 35 U.S.C. §101 because of the “product of nature” (preexisting substances found in nature) judicial exception. Although case law had found that such products of nature

⁹³ *Id.* at 92.

⁹⁴ *Id.*

⁹⁵ *Id.* at 77.

⁹⁶ *Diamond v. Diehr*, 450 U.S. 175, 192-193 (1981); *Id.* At 72-73 (emphasis added).

⁹⁷ *Id.* at 67.

⁹⁸ *Mayo*, 566 U.S. 66.

⁹⁹ *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576 (2013).

may not be patent eligible, *per se*, prior to this decision, courts took the view that such claims would be patent eligible if the claim included significant artificial changes made to the product of nature, perhaps by purifying, isolating or altering in any way.

Myriad followed just one year after the alarming *Mayo* decision. In *Myriad*, the overarching technology related to the eligibility of isolated DNA sequences, methods for predicting the likelihood of cancer developing in a patient by examining mutations in DNA sequences, and also methods to identify anti-cancer drugs using the isolated DNA sequences. In particular, *Myriad* involved two genes, named BRCA1 and BRCA2, and the discovery that certain mutations in those genes are associated with a predisposition of a patient to developing breast and ovarian cancer.¹⁰⁰ *Myriad*'s invention represented a significant advancement in cancer treatment. Yet, as soon as *Myriad* began a strategy to stop competing laboratories from providing its patent test, health care providers publicized this¹⁰¹ and a group of medical professionals and associations sued *Myriad* in order to invalidate its patents on §101 grounds, arguing that isolated DNA is a product of nature and therefore is patent ineligible subject matter.¹⁰² This case was highly publicized in the media and ultimately went up to the Supreme Court.

Going against three decades of practice to the contrary at the time, Justice Thomas for the Supreme Court held that while claims directed specifically to the complementary DNA (cDNA) for the breast cancer genes, BRCA1 and BRCA2, were patent-eligible, claims to an isolated nucleic acid encoding the BRCA1/2 genes were not patent eligible because they are “a natural product.”

This decision, like *Mayo*, greatly expanded the Supreme Court created exceptions to the patent eligibility laws under the 35 U.S.C. §101 statute. The reason being that with this *Myriad* decision, the Supreme Court reversed thirty years of U.S. Patent Office practice of granting exactly that kind of patent for isolated nucleic acid sequences. To highlight the weight of this decision, the U.S. Patent and Trademark Office had issued over 50,000 U.S. patents relating in part to DNA¹⁰³ and all of these were now subject to this seesaw reversal because of this expansion to the “natural product” exception to the statute that the Supreme Court created under *Myriad*.

Immediately following *Myriad*, the Federal Circuit invalidated patents en masse on the basis of this Supreme Court created exception to statutory language outlining,

¹⁰⁰ See *id.* at 592. For example, claim 1 of U.S. Patent No. 5,747,282 recites: “An isolated DNA coding for a BRCA1 polypeptide, said polypeptide having the [following] amino acid sequenceFalse” For the sake of transparency, the author of this article was a member of the IP law group of a large international law firm in NYC that developed the patent portfolio for this innovator concerning their breast and ovarian cancer technology.

¹⁰¹ Julia Carbone & E. Richard Gold, *Myriad Genetics: In the Eye of the Policy Storm*, 12 GENETICS IN MED 38, S41 -S44 (2010), <http://www.nature.com/gim/journal/v12/n1s/pdf/gim2010142a.pdf>.

¹⁰² See *Ass'n for Molecular Pathology v. U.S. Pat. & Trademark Off.*, 702 F. Supp. 2d 181, 186–89 (S.D.N.Y. 2010).

¹⁰³ Guyan Lian, *Molecules or Carriers of Biological Information: A Chemist's Perspective on the Patentability of Isolated Genes*, 22 ALB. L. J. OF SCI. AND TECH. 133 (2012).

under 35 U.S.C. §101, patent eligible subject matter.¹⁰⁴ As an example, when Professor Dennis Lo and colleagues at Oxford University discovered that cell-free foetal DNA (“cffDNA”) could be detected in the plasma and serum of pregnant women, they obtained U.S., European and Australian patents for methods for detecting this cffDNA using standard techniques their discovery. Their discovery centered around detecting abnormalities and characteristics of unborn children. In the U.S., the Federal Circuit in *Ariosa*¹⁰⁵ invalidated claims for non-invasive methods of detecting cffDNA from a blood sample of a pregnant woman.¹⁰⁶ According to the Court, the only new and useful subject matter in the method “was the discovery of the presence of cffDNA in maternal plasma or serum.”¹⁰⁷

Judge Linn indicated that he concurred “only because” he was bound by the breadth of *Mayo*. He indicated that *Ariosa* “represents the consequence - perhaps unintended - of that broad language in *Mayo* excluding a meritorious invention from the patent protection it deserves.” Indeed, once an *en banc* hearing was denied in *Ariosa*, several Judges on the Federal Circuit used the opportunity to express concern that such discoveries were not able to overcome the Supreme Court’s very high new threshold bar to what the Court unilaterally has determined is and is not patent eligible subject matter. This new high threshold bar, as discussed throughout this article, was created out of thin air and directly conflicts with the statutory language of 35 U.S.C. §101 and its legislative’s intent.

For example, Judge Lourie stated that “it is unsound to have a rule that takes inventions of this nature out of the realm of patent-eligibility . . . But I agree . . . under Supreme Court precedent it had no option other than to affirm” the claims’ patent-ineligibility. Similarly, Judge Dyk said, “we are bound by the language of *Mayo*, and any further guidance must come from the Supreme Court.” On appeal, the Supreme Court passed on the opportunity to correct its decision in *Mayo* by denying *certiorari* in 2016, a decision that disappointed many observers because even though there were 23 amicus briefs filed encouraging the Court to grant *certiorari* in *Ariosa*, the Court did not even ask the Solicitor General’s opinion.¹⁰⁸

3. *Interpreting Alice’s “Inventive Concept” (2014)*

One year after its *Myriad* decision, the Supreme Court considered the patentability of a computer-implemented financial trading exchange system. It is significant to note that before this case was appealed up to the Supreme Court, there was a highly divided *en banc* decision at the Federal Circuit regarding whether this computer-implemented subject matter was eligible for a patent under the 35 U.S.C. §101. Interestingly, Judge Rader, the Chief Judge at the Federal Circuit at the time,

¹⁰⁴ Genetic Techs. Ltd. v. Merial LLC, 818 F.3d 1369 (Fed. Cir. 2016).

¹⁰⁵ *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371 (Fed. Cir. 2015).

¹⁰⁶ *Id.*

¹⁰⁷ *Id.*

¹⁰⁸ Albeit, that stance may be changing since the Supreme Court recently asked for the Solicitor General’s decision on two patent eligibility appeals currently pending before the Court. Currently pending opportunities for the Supreme Court to grant *certiorari* include in *Berkheimer*, *Vanda*, and *Athena Diagnostics*. It remains to be seen; it is interesting that this time, unlike in *Ariosa*, the Supreme Court has indeed invited the Solicitor General to submit a brief in both *Berkheimer* and in *Vanda*; for *Athena Diagnostics*, a petition for *certiorari* is expected to be filed within weeks.

referred to the CAFC's inability to render a majority opinion in *Alice* as "the biggest failure of his career."¹⁰⁹ In his view, interpretation of §101 was settled law, based on *Diehr* and *Chakrabarty*. Of separate note, was Judge Moore's dissent in *Alice*, in which she was joined by three other judges, stating that:

*"I am concerned that the current interpretation of §101, and in particular the abstract idea exception, is causing a free fall in the patent system. The Supreme Court has taken a number of our recent decisions and, in each instance, concluded that the claims at issue were not patent-eligible. See Bilski, Prometheus, Myriad (under consideration). . . holding that all claims are all patent-ineligible under §101. Holding that all of these claims are directed to no more than an abstract idea gives staggering breadth to what is meant to be a narrow judicial exception. And let's be clear: if all of these claims, including the system claims, are not patent-eligible, this case is the death of hundreds of thousands of patents, including all business method, financial system, and software patents as well as many computer implemented and telecommunications patents."*¹¹⁰

As another indication of how split the Federal Circuit was when it decided *Alice*, Judge Newman stated in her dissent in *Alice*:

*"I propose that the court return to the statute, and hold that when the subject matter is within the statutory classes in section 101, eligibility is established. This conforms with legislative intent. See Diamond v. Chakrabarty, 447 U.S. 303, 308, 100 S.Ct. 2204, 65 L.Ed.2d 144 (1980) ("In choosing such expansive terms as "manufacture" and "composition of matter," modified by the comprehensive "any," Congress plainly contemplated that the patent laws would be given wide scope.")"*¹¹¹

Yet, on appeal from the Federal Circuit, Justice Thomas, writing for the Supreme Court, underlined the Court's two-part test for identifying patent ineligible subject matter, namely patent claims to laws of nature, natural phenomena, and abstract ideas. First, the claim is analyzed to see if any of these exceptions to the statute apply.¹¹² If so, then the patent claim is reviewed to determine whether the claim recites additional elements that transform the claim into a patent-eligible application of any of those three exceptions to the statute.¹¹³ The Court described this second step of the test as determining whether the claim incorporates an "inventive concept" that amounts to

¹⁰⁹ Dan Levine, *Insight: Rucker judge juggles tech policy, Supreme Court and the Stones*, REUTERS (Oct. 17, 2019), <https://www.reuters.com/article/us-usa-judge-rader-insight/insight-rocker-judge-juggles-tech-policy-supreme-court-and-the-stones-idUSBRE9BA06D20131211>.

¹¹⁰ *CLS Bank Int'l v. Alice Corp. Pty.*, 717 F.3d 1269, 1313 (Fed. Cir. 2013), *aff'd*, 573 U.S. 208 (2014) (emphasis added).

¹¹¹ *Id.*

¹¹² *Alice Corp. Pty. v. CLS Bank Int'l* 134 S.Ct. 2347 (2014).

¹¹³ *Id.*

more than merely applying the law of nature, natural phenomenon, or abstract idea to a particular technological environment.¹¹⁴ With this framework established, Justice Thomas applied the *Mayo/Alice* two-step process to first determine that the method claims were drawn to the abstract idea of intermediated settlement. The Court then determined that the patented claims amounted to nothing more than implementation of an abstract idea on a computer.

Alice thus confirms that *Mayo*'s test should be used to determine if abstract ideas are ineligible under §101.¹¹⁵ The *Alice* decision reiterated that abstract ideas are not patentable because granting a monopoly to an abstract idea would stifle innovation. And, a claim that recites an abstract idea must include "additional features" to be patentable. *Alice* also confirms that *Mayo*'s two-step analysis should be applied to all types of claims.¹¹⁶

In *Mayo*¹¹⁷ and *Alice*,¹¹⁸ the Supreme Court thus adopted a two-step test for determining patent eligibility under § 101, giving rise to the expansion of the Supreme Court created exceptions. These three Supreme-Court-created exceptions are exceptions to the four categories of subject matter explicitly listed in the 35 U.S.C. § 101 statute as being patent eligible.¹¹⁹ That is, even if an invention falls within one of the four categories of patent eligible subject matter under the statute, it can still be found to be ineligible subject matter because of the Supreme Court created exceptions to the statutory language.

Although the purpose of the *Mayo/Alice* test is to provide a framework for determining patent-ineligible subject matter, for example differentiating an abstract idea from claims to a "patent-eligible application" of any such concept,¹²⁰ it has been very difficult for patent stakeholders, including examiners, inventors, patent owners, patent lawyers, and judges alike to implement and/or interpret because there has been little to no clarity concerning where the boundaries of § 101 are.¹²¹

¹¹⁴ *Id.* at 2355.

¹¹⁵ *Id.*

¹¹⁶ *Id.* at 2355, 2357.

¹¹⁷ *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66 (2012).

¹¹⁸ *Alice*, 134 S.Ct. 2347.

¹¹⁹ The current version of the patent eligibility statute, 35 U.S.C. § 101 (2012), states: "Whoever invents or discovers any new and useful process, machine, manufacture or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title."

¹²⁰ *Alice*, 134 S.Ct. at 2357.

¹²¹ *See Synchronoss Techs., Inc. v. Dropbox Inc.*, 226 F.Supp.3d 1000, 1007 (N.D. Cal. 2016) ("This Court agrees with those judges who have observed that even post-*Enfish*, the *Mayo/Alice* test provides limited practical guidance for distinguishing software and computer patents that are valid under § 101 from those that are not."); *Amdocs Ltd. v. Openet Telecom, Inc.*, 841 F.3d 1288, 1294 (Fed. Cir. 2016) ("A search for a single test or definition of what an 'abstract idea' encompasses in the decided cases concerning § 101 from this court, and indeed from the Supreme Court, reveals that at present there is no such single, succinct, usable definition or test."); *Intellectual Ventures I LLC v. Symantec Corp.*, 838 F.3d 1307, 1328 (describing the "semantic gymnastics" entailed in applying the *Mayo/Alice* test to software patents) (Mayer, J., concurring); *BASCOSM Glob. Internet Servs. v. AT&T Mobility*, 827 F.3d 1341, 1354 ("I have come upon no guide to when a claim crosses the boundary between unacceptable abstractness and acceptable specificity.") (Newman, J., concurring); *Device Enhancement LLC v. Amazon.com, Inc.*, 189 F.Supp.3d 392, 400, 401 (D. Del. 2016) (discussing the "still difficult-to-discern requirements of the *Alice* analysis," and the resulting

IV. The Scope of Patent Eligibility Laws Requires Clarity

The time is ripe for Congress to revisit the 35 U.S.C. § 101 statute of the Patent Act. All patent stakeholders working in the field of technology and innovation need clarity concerning the scope of patent eligible subject matter. Some, including other Intellectual Property law professors,¹²² advance the proposition of amending the statute so as to not be out of line with Supreme Court’s promulgated exceptions to the statute. On the other spectrum, others, like the former Director of the U.S. Patent and Trademark Office, have recently advocated for wholesale repealing of the entire 35 U.S.C. § 101 statute from the Patent Act. As it stands, the four recent Supreme Court decisions¹²³ have dramatically narrowed the scope of patent protection for innovation-dependent industries by significantly expanding the judicially-created exceptions to subject matter that is listed in the statute as eligible for a patent.

Here, for the sake of bringing clarity to this area of law, I propose a middle ground that does not repeal the statute that has largely remained unchanged for over 200 years, but equally, does not propose amendments to the statute in order to keep the Supreme Court’s own parallel jurisprudence in place. Instead, I advocate we return to the statutory language and intent, suggesting a timely option for Congress to do away with the three exceptions that the Supreme Court has unilaterally foisted upon the patent-eligible-subject-matter statute, 35 U.S.C. § 101. This position is very similar to the one taken by Judge Newman of the Federal Circuit in the highly divided *Alice* decision.

Discord among patent stakeholders is growing, precipitated by the lack of clarity regarding the scope of subject matter that is eligible for a patent under 35 U.S.C. § 101. For example, not only has David Kappos, the Director of the US Patent & Trademark Office (USPTO) from 2009 to 2013, called for Congress to repeal the entire 35 U.S.C. § 101 statute from the Patent Act on the basis that it is unworkable, but even the current acting Director of the USPTO, as recently as in 2019 and after releasing a dizzying fifth set of guidelines to patent examiners at the USPTO in as many years,¹²⁴ indicated that the landscape of patent-eligible subject matter remains troubling. Senior judges too are concerned with current jurisprudence on 35 U.S.C.

“difficult exercise” under § 101); Order Denying Defendants’ Motion for Summary Judgement at 7, *Ameranth, Inc. v. Genesis Gaming Solutions, Inc.*, 11-cv-00189 AG (RNBx) (C.D. Cal. Jan. 1, 2015) (“True, it is difficult to understand the difference between (1) a claim “directed” to an abstract idea but saved by an “inventive concept,” and (2) a patent not “directed” to an abstract idea in the first place, but that nonetheless can be said to “embody, use, reflect, rest upon, or apply” an abstract idea. *Alice*, 134 S.Ct. at 2354. But in patents, no less than all other areas of the law, Courts must do their best to follow Supreme Court rulings, no matter how unsatisfying.”).

¹²² For example, professors Jeffrey Lefstin and Peter Menell.

¹²³ *Alice*, 134 S.Ct. 2347 (2014); *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576 (2013); *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66 (2012); *Bilski v. Kappos*, 561 U.S. 593 (2010).

¹²⁴ See USPTO, *Subject Matter Eligibility Examples: Abstract Ideas* (January 7, 2019), https://www.uspto.gov/sites/default/files/documents/101_examples_37to42_20190107.pdf (providing examples of how to apply the new patent-eligibility analysis under the 2019 Revised Patent Subject Matter Eligibility Guidance).

§ 101, as discussed *supra* in *Alice*.

Also, the Intellectual Property Owners Association (IPO) recently adopted a resolution to support legislation to amend the statute by adding two subsections. In the IPO statement, they said that the “proposed legislative language would address patent-eligibility concerns *by reversing the Supreme Court decisions and restoring the scope of subject matter eligibility to that intended by Congress . . .*; defining the scope of subject matter eligibility more clearly and in a technology-neutral manner;. . .; and simplifying the. . . eligibility analysis.”¹²⁵ More tellingly, a U.S. Senator recently gave a speech at a conference entitled, “The Supreme Court’s Section 101 Jurisprudence: Dangers for the Innovation Economy,” in which he said that subject matter eligibility is “an area where the jurisprudence is insufficiently clear, and which may necessitate congressional action to provide clarity and consistency.”

Thus, it is clear there is great concern across all sectors of the U.S. economy, especially by stakeholders in the Biotechnology and Software-driven industries, that current law on patent eligibility is unclear and is having deleterious consequences.

The Patent Act, as noted *supra*, defines and specifies four independent categories of subject matter of inventions or discoveries that are eligible for patent protection: 1) processes or methods; 2) machines or apparatuses; 3) manufactures; and 4) compositions of matter.¹²⁶ While it is clear from the Statute that Congress intended to give a wide scope to patent-eligible subject matter, from these four broad categories that are listed in the statute, the Supreme Court has judicially created three exceptions of subject matter ineligible for patent protection: 1) laws of nature; 2) products of nature; and 3) abstract ideas. Thus, under current law, a claimed invention is only patent-eligible under 35 U.S.C. § 101 if it is a process, machine, manufacture, or composition of matter, *and* also if it falls outside the three Supreme Court promulgated judicial exceptions to patent-eligible subject matter.

Jurisprudence on patent-eligible subject matter, governed by 35 U.S.C. § 101, has currently entered a “maw” and the situation will only get worse as new technologies advance because these new advances will challenge courts’ interpretations of certain aspects of patent law.¹²⁷ There is no question that current law governing patent-eligibility under 35 U.S.C. § 101 is uncertain and in upheaval.

One of the key concerns is that the wording of 35 U.S.C. § 101 and Congress’s intent has been to place a low threshold bar to determine what is subject matter eligible for a patent,¹²⁸ and leave for other more stringent areas of the Patent Act, namely specific legal requirements focusing on novelty, non-obviousness, and

¹²⁵ Intellectual Property Owners Association, *Proposed Amendments To Patent Eligible Subject Matter Under 35 U.S.C. § 101* (February 7, 2017), http://www.ipo.org/wp-content/uploads/2017/02/20170207_IPO-101-TF-Proposed-Amendments-and-Report.pdf (emphasis added).

¹²⁶ *Id.*

¹²⁷ Bernard Chao, *Finding the Point of Novelty in Software Patents*, 28 BERKELEY TECH. L.J. 1217, 1224 (2013); Jeremy D. Roux, *The Supreme Court and § 101 Jurisprudence: Reconciling Subject-Matter Patentability Standards and the Abstract Idea Exception*, 2014 U. ILL. L. REV. 629, 658 (2014).

¹²⁸ See *infra* section II of this paper for a discussion on Legislative History of 35 U.S.C. § 101.

description of the technical features of the invention, to deal with the ultimate question of whether the subject matter should receive a patent or not. According to the Supreme Court's own words, the exceptions they created to the 35 U.S.C. §101 statute have the power to "swallow all of patent law"¹²⁹ and to "eviscerate patent law."¹³⁰ This is because 35 U.S.C. §101 was not written or intended to forego an analysis under different statutory sections of the Patent Act of whether major breakthrough discoveries can receive a patent (*i.e.*, by discussing if the discovery is new and not obvious in view of others' work, and in view of how it is technically described).

The Supreme Court has now heard four cases in the area of patent eligibility recently,¹³¹ namely *Bilski* in 2010, *Mayo* in 2012, *Myriad* in 2013 and *Alice* in 2014. After four back-to-back attempts in recent years, the Court has been unable to identify a coherent test that comports with the statute and provides adequate objective guidance to patent examiners, jurists, and practitioners alike. If anything, these decisions have had the opposite effect and have caused havoc in innovation-dependent industries. The four Supreme Court decisions have dramatically narrowed the scope of patent protection for Biotechnology and Software-driven emerging new technologies by significantly expanding the judicially-created exceptions to statutory patent-eligible subject matter.

Although the Supreme Court has previously overruled itself on patent eligibility, namely in the *Chakrabarty* and *Diehr* decisions that effectively overruled *Flook*, it appears unwilling to overrule or at least revise its recent incoherent decisions, most notably in *Mayo*, evidenced by the fact that the Court denied *certiorari* in *Sequenom*, a case that many saw as an opportune moment for the Court to correct itself.¹³² In this latter example, over twenty amicus briefs from a variety of interested parties and industries were filed and yet the Supreme Court did not even ask for the Solicitor General's view.

Thus, if the Supreme Court is unwilling or unable to provide a reasonable, workable test, then legislative options to fix the current status are sorely needed, as discussed *infra* in the last section of this article.

A. U.S. Supreme Court's Own Parallel Law on Patent Eligibility is Inconsistent with 35 U.S. Code §101, and Runs Against the U.S. Constitution

It is clear and uncontroversial that in an area of law where the U.S. Constitution

¹²⁹ See *Alice*, 573 U.S. at 217 (advising the lower courts to "tread carefully in construing this exclusionary principle lest it swallow all of patent law.") (emphasis added).

¹³⁰ See *Mayo*, 566 U.S. at 71 (warning that the Court's own judicially created exceptions to the statute have the power to destroy Congress' patent law: "The Court has recognized, however, that too broad an interpretation of this exclusionary principle could eviscerate patent law. For all inventions at some level embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas.").

¹³¹ *Alice*, 573 U.S. at 212; *Myriad*, 569 U.S. at 579-80; *Mayo*, 566 U.S. at 72; *Bilski*, 561 U.S. at 597.

¹³² *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371 (Fed. Cir. 2015), *cert. denied*, 136 S.Ct. 2511 (2016).

has given sole authority to Congress to create laws consistent with that granted authority, the judicial branch's highest court, namely the U.S. Supreme Court, is then limited to that particular statutory construction.¹³³ Indeed, the Supreme Court has recognized this as such in the 21st century, stating that “when ‘the statute’s language is plain, the sole function of the courts’—at least where the disposition required by the text is not absurd—is to enforce it according to its terms.”¹³⁴ The Supreme Court in *Connecticut Nat’l Bank* cited several cases to support this notion, stating that “courts must presume that a legislature says in a statute what it means and means in a statute what it says there”¹³⁵ and going even further to be clear that “when the words of a statute are unambiguous, then, this first canon is also the last. . . judicial inquiry is complete”¹³⁶ For appeals involving patents, the Court of Appeals for the Federal Circuit possesses national jurisdiction,¹³⁷ with the Supreme Court retaining discretionary authority to review cases on appeal from the Federal Circuit.¹³⁸ However, once the Supreme Court grants certiorari in a case where Congress has created laws, the Court is then limited to that statutory construction.

Accordingly, in this context, when the Supreme Court accepts to a question of patent law related to patent eligible subject matter, the Supreme Court is required to construe the literal meaning of 35 U.S. Code §101, in order to decide if a particular subject matter is or is not patent eligible. And yet, in a trilogy of cases decided in as many years in this decade, discussed *supra*, the Supreme Court has departed from the literal meaning of the statute to instead fashion its own law in the area of patent eligibility by creating exceptions to the statute, thereby unintentionally conflating other existing statutory regimes concerning patentability with the threshold issue of patent eligibility by requiring an “inventive application” in the patent eligible subject matter determination. This is so, even where Congress recently passed the America Invents Act¹³⁹, the biggest fundamental change in Patent Law in sixty years, where major changes were made to the law on patentability but those on patentable subject matter, under 35 U.S. Code §101, were left largely untouched.¹⁴⁰

Congress has been consistent with their intent concerning patent eligible subject matter. Indeed, based on the legislative history of 35 U.S. Code §101, discussed *supra*, and the fact that multiple Patent Acts passed by Congress over a period of some 200 years, including the recently passed America Invents Act, have kept the language of the short 35 U.S. Code §101 statute largely unchanged, it is clear that no exceptions were contemplated. These Supreme Court created exceptions to the statute represent a direct affront to the statute, and run contrary to Congress’s express and implicit intent as well as their mandate to “promote the useful arts” as the U.S.

¹³³ *Connecticut Nat’l Bank v. Germain*, 503 U.S. 249, 253-54 (1992).

¹³⁴ *Hartford Underwriters Ins. Co. v. Union Planters Bank, N.A.*, 530 U.S. 1, 6 (2000) (quoting *United States v. Ron Pair Enterprises, Inc.*, 489 U.S. 235, 241 (1989)).

¹³⁵ *Connecticut Nat’l Bank*, 503 U.S. at 253-54.

¹³⁶ *Id.*

¹³⁷ 28 U.S.C.A. §1295(a)(1).

¹³⁸ 28 U.S.C.A. §1254(1).

¹³⁹ See Leahy-Smith America Invents Act (“AIA”), Pub.L. 112-29, 125 Stat. 284 (2011).

¹⁴⁰ See 35 U.S.C.A. § 101 (“Whoever invents or discovers any new and useful process, machine, manufacture or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.”).

Constitution requires.

Moreover, the statute clearly mentions “Whoever *invents or discovers* any new and useful process, machine, manufacture or composition of matter. . . may obtain a patent therefor, subject to the conditions and requirements of this title.”¹⁴¹ Thus, the Supreme Court’s fascination with “inventive concept” in their recent test for exceptions to the statute fails to consider the word “discovers.” Not only should there be no exceptions to the four statutory categories of patent eligible subject matter as adumbrated in the 35 U.S. Code §101 statute, namely processes, machines, manufactures or compositions of matter, but that any “invention *or discovery*” related to these four statutory listed categories should suffice to pass this low-intended threshold finding of whether a subject matter is deemed patent eligible.

Because it does not fit their new test for their own exceptions to this statute, the Supreme Court fails to acknowledge or discuss, indeed omits, any focus on the word “discovers” in their patent eligibility jurisprudence. There is a reason that the statute includes this word and, if anything, there is nothing to indicate that the word “discovers” ought to have anything less than equal weight to the word “invents” when the statute recites “invents *or discovers*.” And yet, Justice Thomas, writing for the Supreme Court recently in *Myriad* boldly refutes this, stating “groundbreaking, innovative, or even brilliant *discovery* does not by itself satisfy the §101 inquiry.”¹⁴²

Thus, for example, *discovering* certain unique fetal DNA in the blood of a pregnant mother and *inventing* a new method for non-invasively determining important fetal characteristics that is safer for both the fetus and the pregnancy, as discussed *infra*, should simply not be failing the patent eligibility test under 35 U.S. Code §101, as it recently has done.¹⁴³ It may not be patentable if routine methods were used to develop the method, but the mere *discovery* itself ought to pass the 35 U.S. Code §101 threshold inquiry. The patentability requirements as listed in the other statutes of the Patent Act, for example whether it is new and non-obvious in view of what others have done, ought to be what determines whether such a *discovery* should obtain a U.S. patent or not.

As Judge Linn stated in a concurring opinion in *Ariosa* that prior to the invention, prenatal diagnosis involved invasive techniques that could potentially harm the fetus and increase the chance of a miscarriage and that he saw “no reason, in policy or statute. . .why this *breakthrough invention* should be deemed patent ineligible.”¹⁴⁴ Interestingly, after *Ariosa* was decided in the U.S., this same invention was found in November 2017 to be patent eligible subject matter by the highest court of the United Kingdom, and also, as recently as in August 2019, it was found to be patent eligible by the highest court of Australia. With the U.S. Supreme Court refusing to grant *certiorari* in *Ariosa*, this technology and many like it remain patent *ineligible* subject

¹⁴¹ 35 U.S.C.A. § 101 (emphasis added).

¹⁴² *Myriad*, 569 U.S. at 577 (emphasis added).

¹⁴³ *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371,1379 (Fed. Cir. 2015).

¹⁴⁴ *Id.* at 1381 (emphasis added).

matter in the U.S., based on the misguided current Supreme Court jurisprudent on 35 U.S. Code §101.

Further still, as the Supreme Court itself stated in *Chakrabarty*,¹⁴⁵ “Congress has intended patentable subject matter to include anything under the sun that is made by man.”¹⁴⁶ The Court further explained §101 eligibility and its scope, stating that “We have cautioned that courts ‘should not read into the patent laws limitations and conditions which the legislature has not expressed.’ *United States v. Dubilier Condenser Corp*, 289 U.S. 178 (1933). . . In choosing such expansive terms as ‘manufacture’ and ‘composition of matter’ modified by the comprehensive ‘any,’ *Congress plainly contemplated that the patent laws would be given wide scope.*”¹⁴⁷ Thus, no exceptions were contemplated, so long as *any invention or discovery* fell within the four categories of patent eligible subject matter that have been listed in the statute for approximately the last two hundred years. If anything, as is clear from both the express language of the statute and its legislative history discussed *supra*, the patent eligible subject matter under the 35 U.S. Code §101 statute should be given wide scope.

The Supreme Court’s recent trilogy of back-to-back cases on patent eligibility in this decade runs against the wording of 35 U.S. Code §101 and its legislative intent, is inconsistent, and provide next to no analysis of statutory construction or legislative intent. Instead, out of thin air, the Supreme Court has created widely expansive “judicial exceptions” to the federal statute that outlines the threshold inquiry concerning patent eligible subject matter. This contrarian jurisprudence by the Supreme Court on patent eligibility and their focus on “inventive concept” and “significantly more” has caused disarray across the vast majority of stakeholders in industries, as well as the Courts and the patent office, and is otherwise harming the innovation ecosystem in America, as discussed *infra*.

B. Application of the Mayo/Alice Test is Causing Disarray in Courts and the U.S. Patent & Trademark Office

The *Mayo/Alice* test provides a two-criteria test for determining if a subject matter is eligible for a patent or not. First, the claimed invention must be one of the four statutory categories.¹⁴⁸ Second, to qualify for patent eligible subject matter, the patent claim must not be directed to a judicial exception unless the claim as a whole includes additional limitations amounting to *significantly more* than the exception.

These judicial exceptions have been created by the Supreme Court and are subject matter that the Court has found to be outside of, or exceptions to, the four statutory categories of subject matter that is eligible for patent protection. Specifically, the judicial exceptions include and are limited to abstract ideas, laws of

¹⁴⁵ *Diamond v. Chakrabarty*, 447 U.S. 303, 308 (1980).

¹⁴⁶ *Kappos*, 561 S.Ct. at 641-642 (noting Congress’s intention for statutory subject matter to “include anything under the sun that is made by man”) (quoting *Chakrabarty*, 447 U.S. at 309).

¹⁴⁷ *Chakrabarty*, 447 U.S. at 308 (emphasis added).

¹⁴⁸ *See* 35 U.S.C. § 101 (2012) (“Whoever invents or discovers any new and useful process, machine, manufacture or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.”)

nature and natural phenomena (including products of nature).¹⁴⁹ Thus, inventions that encompass abstract ideas, laws of nature, or natural phenomenon are, in the Supreme Court's view, "basic tools of scientific and technological work"¹⁵⁰ that should be "free to all men and reserved exclusively to none."¹⁵¹

The overarching belief by the Court is that this "reflects a basic judgment that protection in such cases, despite its potentially positive incentive effects, would too severely interfere with, or discourage, development and the further spread of future knowledge itself."¹⁵² For example, under this principle, Einstein may have discovered that anything having mass has an equivalent amount of energy, but he would not have been able to patent his celebrated formula, $E=mc^2$, that shows this relationship, nor could Newton patent his discovery of the law of gravity, nor a lay person patent his/her discovery of a new mineral in the earth. These kinds of discoveries are "manifestations of laws of nature, free to all men and reserved exclusively to none."¹⁵³

35 U.S. Code §101 defines the four categories of patent eligible subject matter as processes, machines, manufactures and compositions of matter,¹⁵⁴ with the latter three categories defining "things" and the first category defining "actions."¹⁵⁵ In particular, the statute defines "process" to mean a "process, art, or method, and includes a new use of a known process, machine, manufacture, composition of matter, or material."¹⁵⁶ Moreover, the Supreme Court has held that the term "machine" includes "every mechanical device or combination of mechanical powers and devices to perform some function and produce a certain effect or result."¹⁵⁷ In *Chakrabarty*, the Supreme Court construed "manufacture" to mean "the production of articles for use from raw or prepared materials by giving to these materials new forms, qualities, properties, or combinations, whether by hand-labor or by machinery,"¹⁵⁸ and the term "composition of matter" has been held to mean "all compositions of two or more substances and. . . all composite articles, whether they be the results of chemical union, or of mechanical mixture, or whether they be gases, fluids, powders or solids."¹⁵⁹

Applying the *Mayo / Alice* framework has caused great uncertainty and disarray

¹⁴⁹ See *Mayo Collaborative Services v. Prometheus laboratories, Inc.*, 132 S.Ct. 1293 (2012); *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S.Ct. 2107, 2116 (2013); *Alice Corp. Pty. Ltd. v. CLS Bank International*, 134 S.Ct. 2347, 2354 (2014).

¹⁵⁰ *Gottschalk v. Benson*, 409 U.S. 63, 67 (1972).

¹⁵¹ *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948).

¹⁵² *Laboratory Corp. of America Holdings v. Metabolite Laboratories, Inc.*, 548 U.S. 124, 128 (2006) (Breyer, J., dissenting).

¹⁵³ *Funk Brothers*, 333 U.S. at 130.

¹⁵⁴ See Manual of Patent Examining Procedure § 2106.03 (more detailed information on the four categories).

¹⁵⁵ See 35 U.S.C. 100(b) ("The term 'process' means process, art, or method, and includes a new use of a known process, machine, manufacture, composition of matter, or material.").

¹⁵⁶ 35 U.S.C. § 100(b).

¹⁵⁷ *Corning v. Burden*, 15 How. 252, 267-68 (1854).

¹⁵⁸ *Diamond v. Chakrabarty*, 447 U.S. 303, 308 (1980).

¹⁵⁹ *Id.*

in courts, and the criticism of this framework has been rapidly growing. Not only does Justice Thomas refuse to define “abstract,” the whole framework has been incredibly difficult in practice to implement and this has led to inconsistencies. By way of an example, after *Alice*, there was a dramatic increase in the number of courts invalidating patents under Section 101. Moreover, in the six months following *Alice*, district courts invalidated well over 50 percent of patents challenged under Section 101. The Federal Circuit similarly invalidated, under Section 101, patents in six decisions in six months.¹⁶⁰

A more recent listing of patent eligibility cases that have been decided since *Bilski* found only 17 out of 70 decisions found patent eligible subject matter.¹⁶¹ In another study, 35 U.S.C. §101 challenges have resolved early in the litigation, often at the pleading stage or a prompt summary judgment motion.¹⁶² In yet another study of the effect of *Alice* two years after the decision, the authors found that courts invalidated patents based on §101 motions at an average invalidation rate of 66%. Moreover, the Federal Circuit decided 37 cases with only three of the cases being upheld – an average invalidation rate of a staggering 92%.¹⁶³ At the USPTO, one study found that in the two years post *Alice*, the patent office had rejected over 36,000 published patent applications under *Alice*, with over 5,000 of such applications becoming abandoned.¹⁶⁴

1. “Inventive Application” and the Problem with “Significantly More”

Under the new *Mayo/Alice* framework for determining patent eligibility, there are two steps. First, one has to determine whether the claim is directed to subject matter that the Court has deemed ineligible, namely an abstract idea, law of nature or a natural phenomenon.¹⁶⁵ Second, one is required to determine whether there is any claim limitation other than that directed to the ineligible subject matter that is “sufficient to ensure that the patent in practice amounts to *significantly more* than a patent upon the ineligible concept itself.”¹⁶⁶ This contribution is called an “*inventive concept*.”¹⁶⁷ Claim limitations that require only “well-understood, routine, conventional” activity, fail to supply the necessary “*inventive concept*.”¹⁶⁸ As such, a claim that is directed to an abstract idea or natural law without an inventive concept is not subject matter that is patent-eligible under 35 U.S.C. § 101 under current law.

¹⁶⁰ *Digitech Image Techs., LLC v. Elecs. for Imaging, Inc.*, 758 F.3d 1344 (Fed. Cir. 2014); *Planet Bingo, LLC v. VKGS LLC*, 576 Fed. App’x. 1005 (Fed. Cir. 2014); *buySAFE, Inc. v. Google, Inc.*, 765 F.3d 1350 (Fed. Cir. 2014); *Ultramercial, Inc. v. Hulu, LLC*, 772 F.3d 709 (Fed. Cir. 2014); *Univ. of Utah Res. Found. v. Ambry Genetics Corp.*, 774 F.3d 755 (Fed. Cir. 2014); *Content Extraction & Transmission LLC v. Wells Fargo Bank Nat’l Assoc.*, 776 F.3d 1343 (Fed. Cir. 2014).

¹⁶¹ *Section 101 Court Cases*, BITLAW, <https://www.bitlaw.com/patent/section-101-cases.html> (last visited Nov. 5, 2019).

¹⁶² Jacob Koering, *The Rise of the Patent-Eligibility Defense: The Absurd Abstraction of Alice*, 2016 ASPATORE 7 (2016).

¹⁶³ *Id.*

¹⁶⁴ Jasper L. Tran, *Two Years After Alice v. CLS Bank*, 98 J. PAT. & TRADEMARK OFF. SOC’Y 354, 358-59 (2016).

¹⁶⁵ *Alice Corp. v. CLS Bank Int’l.*, 134 S.Ct. 2347, 2355 (2014).

¹⁶⁶ *Id.*

¹⁶⁷ *Id.*

¹⁶⁸ *Id.* at 2359.

The problem with this “inventive concept” and finding something “significantly more” than the Supreme Court listed exceptions to eligible subject matter is several fold. First, there is now a clear overlap between the patent eligibility question under 35 U.S. Code §101 and novelty under 35 U.S. Code §102. Thus, to determine what is patent eligible, one is misled into looking for an “inventive concept” which naturally can lead to comparing the invention to what is out there in terms of prior art to see if it is “inventive,” even though this is not permitted. This conflation of novelty with the threshold issue of patent eligibility is not the only problem with this “inventive concept,” “significantly more,” and “routine, conventional activities” analysis one is led to perform. As the reader immediately can ascertain, the subjectivity of concepts such as “significant,” and “inventive concept” and “routine” is such that the implementation of such a test becomes difficult and open to interpretation.

In order to make the point by way of an example, under this current patent eligibility scheme, one led to consider prior art in order to determine if the claimed invention is “significantly more” than the patent ineligible concept, and as such, it becomes very subjective and hard to determine what is considered “more,” let alone what is considered “significant.” To add to that, one is required to determine what is “routine” or “conventional,” which are equally subjective determinations that mislead one to consider others’ work to ascertain what is routine or conventional. The absence of any clear instructions, or definitions of key terms such as what is considered “abstract,” coupled with multiple subjective determinations that now have to be made, all lead to confusion and an incoherent implementation of this new patent eligibility test. This has resulted in a wide disparity in the post-*Alice* decisions from district court judges, administrative law judges and examiners at the U.S. Patent & Trademark Office alike.

Yet another problem with the current framework for determining patent eligibility is that it does not even attempt to have objectiveness and instead wholeheartedly embraces these subjective concepts as discussed above. If one looks back, Congress faced a similar situation in the 1950s. Back then and before the seminal Patent Act of 1952, patent law relied on the subjective “invention” standard for determining patentability. Patents were routinely invalidated for lacking an “inventive” aspect, even though there was no real definition of what makes something “inventive.”¹⁶⁹ Congress then acted to remove this subjective “invention” standard and passed the Patent Act of 1952. The intent was that the scope of patent-eligible subject matter would be broad and that patentability would be determined on an objective, instead of subjective, standard. This led to the codification of section 103, where an *objective* standard of a person having ordinary skill in the art is used to determine if an invention is non-obvious and therefore patentable.¹⁷⁰ In the same 1952

¹⁶⁹ *Hollister v. Benedict & Burnham Mfg. Co.*, 113 U.S. 59, 73 (1885) (invention is “the creative work in the inventive faculty.”); *Atlantic Works v. Brady*, 107 U.S. 192, 200 (1882) (invention is “A substantial invention or discovery.”); *Potts v. Craeger*, 155 U.S. 597, 608 (1895) (invention is the “exercise of the inventive faculty.”); *Cuno Eng’g Corp. v. Automatic Devices Corp.*, 314 U.S. 84, 91 (1941) (invention requires the “flash of creative genius.”).

¹⁷⁰ Judge Rader, Chief Judge of the Federal Circuit, noted that “The central thrust of the 1952 Act

Patent Act, Congress clearly moved away from the concept of “inventiveness” for the patent eligibility analysis.¹⁷¹

As explained by the Judge Rich, who, along with P. J. Federico, was the principal architect of the 1952 Patent Act, “Terms like ‘*inventive application*’ and ‘*inventive concept*’ no longer have any useful place in deciding questions under the 1952 Act, notwithstanding their universal use in cases from the 19th century and the first half of the 20th.”¹⁷² Thus, the Supreme Court’s recent introduction into the patent eligibility analysis of “inventive concept” is expressly what Congress intended *not* to allow in the Patent Act of 1952.

C. Supreme Court’s Subject Matter Eligibility Framework Has Created Profound Uncertainty in the Patent System

Somewhat telling was the fact that less than a year ago the Director of the U.S. Patent and Trademark Office told the Intellectual Property Owners Association (IPO) that the stakeholders in the patent system, including patent examiners, inventors, owners and judges are presently still struggling to understand what type of subject matter is patent eligible.¹⁷³ This incoherence has been precipitated by having the requirements for obtaining a patent overlap with the threshold issue of which subject matter is or is not patent eligible in the first place.

Since the *Alice* decision in 2014, the U.S. Patent and Trademark Office has issued new guidance to patent examiners for how to analyze claims under section 101 no less than five times, evidencing the level of profound uncertainty within the heart of the government agency itself, who one would associate with having expertise in the subject matter. One cannot fault the USPTO, as the pace of any legislative change has been so slow that the patent office has had to educate and provide constant guidelines to the examiner corps in an attempt to provide clarity. Yet, this has not worked. According to a recent in 2017, there was a dramatic rise in the invalidity rates at the USPTO based on §101 after the Supreme Court’s *Alice* decision, as discussed *supra*.

This uncertainty at the patent office resonates well outside, with practitioners experiencing huge disparity not only from examiner to examiner on how patent eligibility guidelines are applied, but also disparity across different technology art groups at the USPTO. Such is the level of profound disillusionment in the Supreme Court’s jurisprudence on patent eligible subject matter that even the courts have been struggling to make sense of it. There has been a staggering rise in the number of district court §101 invalidity decisions following the *Mayo* decision. As an example, there were at most three such decisions in any year prior to the *Mayo* decision¹⁷⁴,

removed ‘unmeasurable’ inquiries into ‘inventiveness’ and instead supplied the nonobviousness requirement of Section 103.” *CLS Bank Intern v. Alice Corp.*, 717 F.3d 1269, 1296 (Fed. Cir. 2013) (J. Rader, concurring in part).

¹⁷¹ *Application of Bergy*, 596 F.2d 952, 961 (Cust. & Pat. App 1979) (emphasis added).

¹⁷² *Id.*

¹⁷³ Andrei Iancu, Remarks at the Intellectual Property Owners Association 46th Annual Meeting (Sep. 24, 2018), <https://www.uspto.gov/about-us/news-updates/remarks-director-iancu-intellectual-property-owners-46th-annual-meeting>.

¹⁷⁴ For example, *Climax Molybdenum Co. v. Molychem, LLC*, No. 02-cv-00311, 2007 WL 3256698 (D. Colo. Nov. 1, 2007); *Perfect Web Techs., Inc. v. Infousa, Inc.*, 89 U.S.P.Q.2d 2001 (S.D. Fla.

however, this increased to an average of eight §101 invalidity decisions per year in the two years following the *Mayo* decision. Moreover, that number increased 10-fold after the *Alice* decision.

The ultimate result is that patent examiners, inventors, practicing IP lawyers, patent owners and even judges have struggled with the Supreme Court’s subject matter eligibility framework. Thus, what remains is a state of confusion amongst all patent stakeholders as to what exactly makes one claim patent eligible subject matter while another is ineligible.

1. Judicial Exceptions under 35 U.S. Code §101 and the Misclassification of Software as an Abstract Idea, and Biomedical Innovations as Law of Nature or Natural Phenomenon

In view of the recent Supreme Court jurisprudence on patent eligible subject matter, in which the Court not only created exceptions to the statute but also recently greatly expanded the scope of those exceptions, and the resultant misclassification of software as an abstract idea, very significant effects have been felt by software-driven and information technologies. As a result of the Supreme Court’s *Bilski/Mayo/Alice* patent eligibility framework, lower courts have invalidated hundreds of patents on computer-related inventions.

For example, patent claims have been invalidated for technologies, including a computer system of generating menus that allow users to select particular categories and items,¹⁷⁵ and a method for processing credit applications over electronic networks.¹⁷⁶ Generally, under this new framework, patent claims that fail to describe solutions to a problem, or identify an “improvement in the functioning of technology,”¹⁷⁷ are now vulnerable under the new 35 U.S. Code §101 framework as not being subject matter that is even patent eligible. Yet, a small number of patents have overcome the new high bar to what is patent eligible subject matter. As an example, the Federal Circuit has upheld patents directed towards an e-commerce system and method,¹⁷⁸ and an information management and database system.¹⁷⁹

Generally, it appears that patent claims fair better if they recite discrete structures to achieve specific results, avoiding broad functional language. However,

2008), aff’d on other ground, 587 F.3d 1324 (Fed. Cir. 2009); *CyberSource Corp. v. Retail Decisions, Inc.*, 620 F. Supp. 2d 1068 (N.D. Cal. 2009), aff’d, 654 F.3d 1366 (Fed. Cir. 2011); *DealerTrack, Inc. v. Huber*, 657 F. Supp. 2d 1152 (C.D. Cal. 2009), aff’d in part, vacated in part, rev’d in part, 674 F.3d 1315 (Fed. Cir. 2012); *Fort Props., Inc. v. Am. Master Lease LLC*, 609 F. Supp. 2d 1052 (C.D. Cal. 2009), aff’d, 671 F.3d 1317 (Fed. Cir. 2012); *Bancorp Servs., L.L.C. v. Sun Life Assurance Co. of Can.*, 771 F. Supp. 2d 1054 (E.D. Mo. 2011), aff’d, 687 F.3d 1266 (Fed. Cir. 2012).

¹⁷⁵ *Apple, Inc. v. Ameranth, Inc.*, 842 F.3d 1229 (Fed. Cir. 2016).

¹⁷⁶ *Dealertrack, Inc. v. Huber*, 674 F.3d 1315 (Fed. Cir. 2012).

¹⁷⁷ *Trading Techs. Int’l, Inc. v. CQG, Inc.*, 675 Fed. Appx. 1001, 1005 (Fed. Cir. 2017).

¹⁷⁸ *DDR Holdings, LLC v. Hotels.com, L.P.*, 773 F.3d 1245 (Fed. Cir. 2014).

¹⁷⁹ *Enfish, LLC v. Microsoft Corp.*, 822 F.3d 1327 (Fed. Cir. 2016).

the infrequent occasion the Federal Circuit upholds a patent application over *Alice*, fails to make Supreme Court's *Alice* decision remain anything but flawed. It is, for example, a basic premise that software *transforms* computer systems into new quantum states that are functionally different. That is, computer software changes a computer system in significantly measurable and useful ways. Thus, computers function to carry out tasks exactly because of this physical transformation of computer systems by software. This by itself ought to be sufficient to avoid labeling of software as merely an "abstract idea."

For example, when a software transforms a computer into a stopwatch or a Tetris video game, the system can be described in a flow chart or printout of the code. That description may be abstract, however, when that same software is read into and actually "overlaid" into the operating memory of a computer system, the software's program steps transform the quantum state of the computer system and reconfigure the information to flow in particular patterns that are tailored to produce useful results. Thus, software cannot be misclassified in this context as merely an abstract idea because once it is implemented and operating in a generic computer, it at the very least physically transforms the computer system and this can be demonstrated by new tangible and measurable outputs from the computer. This is one of the reasons why many have problems with Justice Thomas's refusal in *Alice* to define "abstract."¹⁸⁰ Indeed, if *Diehr* remains good law, then inventions that transform or reduce an article to a different state must be patent eligible.¹⁸¹

Thus, it is important to recognize that anything that causes a tangible physical change and rearrangement of an article into a different state or different thing has always been the hallmark of the patent eligibility determination. Just because in some instances that alteration is unseen, as is the case for some software, should not mean we have a rule that excludes from patent eligible subject matter that transformative software.

The threshold bar of 35 U.S. Code section 101 ought not to be the place a software-driven invention fails because the subject matter is ineligible subject matter; instead, such claims should be found patent eligible subject matter and then later analyzed under other statutory provisions of the Patent Act. This is also a position that Federal Circuit Judge Pauline Newman has held, where she has repeatedly stated in her opinions that section 101 is intended to be a low threshold so that it does not prevent innovation from flourishing.¹⁸²

Since the *Alice* decision, patent claims that have included software have faced a

¹⁸⁰ Justice Thomas declined to provide a working definition for "abstract." *Alice*, 134 S.Ct. at 2357 (2014).

In any event, we need not labor to delimit the precise contours of the "abstract ideas" category in this case. It is enough to recognize that there is no meaningful distinction between the concept of risk hedging in *Bilski* and the concept of intermediated settlement at issue here. Both are squarely within the realm of "abstract ideas" as we have used that term. *Id.*

¹⁸¹ *Diamond v. Diehr*, 450 U.S. 175, 192–93 (1981) (holding that "patent laws were designed to protect (e.g. transforming or reducing an article to a different state or thing), then the claim satisfies the requirements of § 101.").

¹⁸² *See Alice*, 717 F.3d 1269, 1322 (Fed. Cir. 2013) (arguing that section 101 should be a lower threshold).

much higher barrier for receiving patents than other fields. Unfortunately, this has stymied the development of specialized software, such as artificial intelligence. The practical results of which have been that innovation goes where it has the best chance to grow. For example, it should be a warning to law and policy makers that Chinese artificial intelligence start-ups are now, three years after the Supreme Court's *Alice* decision, receiving more funding than U.S. artificial intelligence start-ups. According to a 2018 MIT Technology Review, of the \$15.2 billion invested in artificial intelligence startups globally in 2017, 48 percent went to China and just 38 percent to America. The US is starting to lose out in capital investments in software driven industries, such as artificial intelligence, evidenced by the fact that the U.S. accounted for 77 percent of this investment in 2013, but that has fallen to 50 percent in 2017.¹⁸³

Since *Alice*, patent examiners have presumptively classified many software claims as patent ineligible subject matter on the reasoning that they are abstract ideas, under the Supreme Court's recent interpretation of 35 U.S.C. § 101. Thus, in order to just pass this first hurdle, which traditionally has been a low bar, now applicants must show why their claimed invention is "*something more*" than just a mere abstract idea. This new subjective paradigm, created in *Alice*, has resulted in an all-out attack on software patent claims.

Similarly to the misclassification of software as abstract ideas, the wholesale misclassification of certain biomedical inventions as "laws of nature," or "products of nature," is misplaced. For example, to take the analogy from the discussion of computers and software above, one can think of the human body as the computer. Thus, our bodies are like a physical system that will react differently when, for example, we eat or take medication. Although we may be similar, we are not all the same in how we react to these types of stimuli. These stimuli, be they food intake or drug ingestion for example, physically transform our bodies and our bodies react to that to give an output (we eat, our stomachs are transformed and send a message to our brains to let us know to feel less hungry; or we are in pain, take medication and this transforms our bodies to a different state where less pain is felt). This transformation is all that ought to be necessary to surmount the low threshold bar that Congress has intended section 101 to be when assessing if a subject matter is patent eligible or not.

The Supreme Court's patent eligibility trio cases, *Mayo/Myriad/Alice*, decided in as many years earlier this decade has also had profound effects on these biomedical advances. As a direct result of the *Mayo* decision, discussed *supra*, diagnostic methods that use biomarkers to predict the likelihood of a future disease, as well as diagnostic methods that measure that biomarker, are now largely unable to surmount to new Supreme Court created high threshold bar to what is patent eligible subject matter. One year after this *Mayo* decision, came *Myriad*. In view of *Myriad*, claims to any isolated substance from the body, including genes, proteins, and even cell lines,

¹⁸³ Jackie Snow, *China's AI Startups Scored More Funding than America's Last Year*, MIT TECH. REV. (Feb. 14, 2018), <https://www.technologyreview.com/f/610271/chinas-ai-startups-scored-more-funding-than-americas-last-year/>.

are now facing stiff threshold challenges to whether those discoveries and inventions are patent eligible subject matter under the new patent eligibility scheme, albeit altering genes and other naturally derived substances is more likely to overcome the new 35 U.S.C. §101 threshold.¹⁸⁴

A prime example of how this *Mayo/Myriad/Alice* trilogy of cases is affecting Biotechnology and the development of new medically-focused technologies can be found in the *Ariosa* case.¹⁸⁵ This case is being widely discussed presently within the patent community. The technology involved a new non-invasive pre-natal diagnostic method for determining the gender, blood type, and other characteristics of a fetus, including if the fetus has a genetic disorder that would cause conditions such as Down's Syndrome.¹⁸⁶ While the currently existing technology involved inserting a needle into the fetus itself, potentially harming the fetus and the pregnancy, the new technology in *Ariosa* was the discovery, using existing PCR technology, of a fetal DNA marker in the amniotic fluid of a pregnant woman. This discovery led to a new method for non-invasively diagnosing genetic characteristics of unborn children in a safer manner compared to currently existing technologies.

On appeal, the Federal Circuit explained that the only discovery that the inventors had made was to find cell-free fetal DNA (cffDNA) in maternal plasma, and that thereafter, the inventors just used known laboratory techniques to implement a method for detecting DNA material and determining fetal characteristics. Thus, the Federal Circuit in *Ariosa* held the claimed method “begins and ends with a natural phenomenon,”¹⁸⁷ concluding that the first step of the *Mayo/Alice* test is met because the patent claim is “directed to matter that is naturally occurring”¹⁸⁸ and therefore this was patent ineligible subject matter. Next, the Court analyzed the claim considering “the elements of each claim both individually and ‘as an ordered combination’ to determine whether additional elements ‘transform the nature of the claim’ into a patent-eligible application.”¹⁸⁹

Despite the presence of claims to particular method steps, the court concluded that the claims were insufficient to integrate the naturally occurring material into a patent-eligible application because the steps were “routine, conventional activities,” particularly since the patent application itself indicated that those particular method steps, such as amplification, detection, and correlation, could be done using “standard techniques.”¹⁹⁰ The Federal Circuit then cited *Mayo*: “appending routine, conventional steps to a natural phenomenon, specified at a high level of generality, is not enough to supply an inventive concept. Where claims of a method patent are

¹⁸⁴ Hallie Wimberly, Comment, *The Changing Landscape of Patent Subject Matter Eligibility and Its Impact on Biotechnological Innovation*, 54. Hous. L. Rev. 995, 1006-07 (2017).

¹⁸⁵ *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371, 1374-75 (Fed. Cir. 2015).

¹⁸⁶ *Id.* at 1373, 81. (Sequenom was the exclusive licensee of U.S. Patent No. 6,258,540. Claim 1 of that patent recited: “1. A method for detecting a paternally inherited nucleic acid of fetal origin performed on a maternal serum or plasma sample from a pregnant female, which method comprises amplifying a paternally inherited nucleic acid from the serum or plasma sample and detecting the presence of a paternally inherited nucleic acid of fetal origin in the sample.”).

¹⁸⁷ *Id.* at 1376.

¹⁸⁸ *Id.*

¹⁸⁹ *Id.* at 1375. (emphasis added).

¹⁹⁰ *Id.* at 1377-78.

directed to an application that starts and ends with a naturally occurring phenomenon, the patent fails to disclose patent eligible subject matter if the methods themselves are conventional, routine and well understood applications in the art.”¹⁹¹ Thus, the patent claims were found to be invalid as ineligible subject matter under 35 U.S.C. §101.

Tragically, this same invention has been found to be patent eligible subject matter by the highest court in the UK in late 2017 and by the highest court in Australia in August 2019. As Judge Linn of the Federal Circuit stated, he saw “no reason, in policy or statute. . .why this breakthrough invention should be deemed patent ineligible.” The practical result of this misguided current Supreme Court jurisprudent on 35 U.S. Code §101 has been that the U.S. innovation-focused economy has been harmed and is increasingly becoming negative in outlook.

V. Negative Effect on the U.S. Innovation Economy

According to an in-depth recent study, as a direct result of the difference between U.S. law and the law of other industrialized nations on the issue of what is and what is not patent eligible subject matter, technological development and commercialization in the U.S. has been stymied when compared to the same technologies being developed and commercialized in other developed countries, including in Europe and in China.¹⁹² In their recent article titled “How Patent Eligibility Doctrine Is Undermining U.S. Leadership in Innovation,” the authors examined U.S. patent applications that received section 101 patent ineligibility rejections. The study then compares that same technology to see if it was also rejected as patent ineligible subject matter in Europe or in China.

The results are staggering: over 1700 U.S. patent applications spanning multiple technologies, including everything from drugs and therapeutics, molecular biology, combinatorial chemistry databases, control systems, immunology, microbiology, telecommunications, artificial intelligence, vehicle navigation, data processing, cleaning compositions and information security to name a few, were all found to be ineligible subject matter for patenting in the U.S. under the currently expansive Supreme Court patent ineligibility regime. And yet, those same technologies were all found to be patent eligible subject matter in both the European Union and in China.¹⁹³

¹⁹¹ *Id.*

¹⁹² Kevin Madigan & Adam Mossoff, *Turning Gold into Lead: How Patent Eligibility Doctrine Is Undermining U.S. Leadership in Innovation*, 24 GEO. MASON L. REV. 939, 955 (2017).

¹⁹³ *See Id.* at 941-42. (reporting that about 1,700 patent applications covering the same inventions were rejected as patent ineligible subject matter in the U.S., and yet were considered eligible in both China and the European Union). Abandoned U.S. patent applications included in fields such as (number of applications in each field shown in parentheses): Drug and Therapeutics (474); Molecular Biology and Microbiology (356); Amusement Devices (245); Combinatorial Chemistry (238); Measuring and Testing (83); Databases (80); Multicellular Living Organisms (38); Structural Design (35); Control Systems (21); Business Methods (18); Surgery (17); Chemistry (15); Immunology (15); Computer Graphics (14); Food Or Edible Materials (11); Agriculture (10); User Interfaces (9); Organic Compounds (8); Data Processing (5); Artificial Intelligence (3); Education And Demonstration (3); Electrolysis (3); Vehicle Navigation (3); Communications (2);

Many patent stakeholders have recognized this negative effect of current patent eligibility jurisprudence by the Supreme Court, and as Senator Coons stated on record recently, “Today, U.S. patent law discourages innovation in some of the most critical areas of technology, including artificial intelligence, medical diagnostics, and personalized medicine.”¹⁹⁴ To give an example to Senator Coons’ statement, it is generally accepted in the medical community that a diagnosis of a disease occurs before treatments and cures can be developed. As such, new innovative medical devices typically trail discovery of new diagnostic tests by about a decade.¹⁹⁵ Thus, since the new Supreme Court-promulgated patent eligibility jurisprudence has severely impeded the development and commercialization of new medical diagnostics, it stands given that far fewer medical devices will also be forthcoming in the decade to come. This is yet another negative way the Supreme Court’s jurisprudence on this patent eligibility question has affected technological innovation and commercialization in the U.S.

In short, although the U.S. Constitution requires Congress to promote innovation,¹⁹⁶ the Supreme Court has sadly raised the threshold by unilaterally deciding, without any support from the statutory language, what subject matter is worthy of a patent. Supreme Court’s interpretation is not only contrary to statutory language and intent and quite the opposite of what the U.S. constitution demands, but it is having a real measurable negative effect on the development of new technologies and innovations in the U.S.

A. Damage to U.S. Innovation and U.S. Economic Competitiveness Caused by the Misapplication of the Alice/Mayo Test

The Supreme Court’s Mayo/Alice framework for patent eligibility has now had time to show its effect. Few would argue that its effect has been anything but highly disruptive and destructive in a negative way so far as new technology development and commercialization are concerned. As an example, the Licensing Executives Society, a leading association for intellectual property, technology, and business development professionals, submitted comments this year to Undersecretary of Commerce for Intellectual Property and Director of the U.S. Patent and Trademark Office Andre Iancu. In their statement, like many others in similar tune, they highlight recent Supreme Court precedent relating to patent eligibility and acknowledged that the existing framework for assessing eligibility has proven unduly difficult to

Telecommunications (2); Coatings (2); Information Security (2); Cleaning & Compositions (2); Electro-Chemistry; (2) Marine Propulsion (1); Resins And Rubbers (1); Refrigeration (1); Compositions: Ceramic (1); Video Recording (1); Mineral Oils (1); Radiation Imagery (1); Dentistry (1); Registers (1); Image Analysis (1); Chemical Disinfecting (1); Digital Communications (1); Fluid Sprinkling (1); Power Plants (1); Radiant Energy (1); Error Detection (1); Adhesives (1); Evaporators (1).

¹⁹⁴ *Sens. Coons and Tillis and Reps. Collins, Johnson, and Stivers Release Section 101 Patent Reform Framework*, Chris Coons Press Release, (April 17, 2019), <https://www.coons.senate.gov/news/press-releases/sens-coons-and-tillis-and-reps-collins-johnson-and-stivers-release-section-101-patent-reform-framework>.

¹⁹⁵ *Bilski v. Doll*, 2009 WL 2441060 (U.S.), 7 (U.S.,2009).

¹⁹⁶ Article I, Section 8, Clause 8 of the U.S. Constitution recites “promote the progress of science and the useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries.” U.S. CONST. art. I, § 8, cl. 8 (emphasis added).

implement in a consistent manner and has produced much uncertainty. They go on to state that this uncertainty has made it difficult for inventors, businesses and other stakeholders to predict what constitutes patent eligible subject matter, and to plan and invest accordingly.

Moreover, an interesting study from earlier this year focused on the fundamental question of whether the Supreme Court's new patent eligibility legal framework as outlined in *Mayo/Myriad/Alice* actually impacted decisions to invest in new technology development and commercialization.¹⁹⁷ Based on a survey of 475 venture capital and private equity investors to study the impact of the Court's eligibility cases on their firms' decisions to invest in companies developing technology, this study found that investors overwhelmingly believe patent eligibility is an important consideration when their firms decide whether to invest in companies developing technology, with 74% of investors agreeing that it is a key reason to invest or not to invest and 14% disagreeing. These results are in tune with the notion that patents are an absolutely integral part of capital investment decisions being made to develop newly emerging innovative technologies.

Moreover, investors view patent eligibility as affecting different industries to different levels and factor this into their capital investment decisions. For example, whereas the new patent eligibility laws would minimally impact decisions to invest capital in construction related technologies, the new changes make a huge impact for these venture capital and private equity firms when they view a potential investment opportunity in biotechnology, medical device and pharmaceutical industries.¹⁹⁸

The investors have been turning away from investing in certain innovation-focused industries, such as Biotechnology and Software-driven innovations, as a direct result of the Supreme Court's recent decisions on this issue. In particular, about 200 venture capital and private equity investors indicated that the Supreme Court's recent patent eligibility laws had somewhat negative or very negative effects on their firm's existing investments, while only about 15% of these investors reported somewhat positive or very positive effects.¹⁹⁹ 33% of investors who focus on technologies reported that the new patent eligibility laws impacted their firms' investment behavior, with these investors reporting that they shifted their capital investments away from companies that were developing new software or new technology related to biotechnology, medical device, and pharmaceutical industries.²⁰⁰ This 2019 report adds to the data emerging regarding how the Supreme Court's recent decisions on patent eligibility are harming the innovation economy in the U.S.

¹⁹⁷ David O. Taylor, *Patent Eligibility and Investment*, CARDOZO L. REV., (forthcoming 2019); SMU Dedman School of Law Legal Studies Research Paper No. 414. Available at SSRN: <https://ssrn.com/abstract=3340937>.

¹⁹⁸ *Id.* at 9.

¹⁹⁹ Jason Rantanen, Guest Post on Patent Eligibility and Investment: A Survey, PATENTLYO BLOG (March 6, 2019), <https://patentlyo.com/patent/2019/03/patent-eligibility-investment.html>.

²⁰⁰ *Id.*

It is clear from their statement and other similar statements made by no less than the current acting Director of the USPTO that this *Mayo/Myriad/Alice* test is damaging technological innovation and economic competitiveness by giving very significant reason to pause for decision makers wishing to take risks and invest to develop new emerging technologies, fearful of the fact that the *Mayo/Myriad/Alice* framework is a sign of weak patent protection.

B. Effect on the Biopharmaceutical and Software Industries

1. *Invalidation of Patents Under the Expansive Section 101 Regime Harms Patients and Increases Costs*

Since the *Alice* decision, patent claims that have included software have faced a much higher barrier for receiving patents than other fields. Unfortunately, this has stymied the development of specialized software, such as artificial intelligence (AI). The practical results of which have been that innovation goes where it has the best chance to grow. For example, it should be warning to law and policy makers that Chinese AI start-ups are now, three years after the Supreme Court's *Alice* decision, receiving more funding than U.S. AI start-ups. According to a review published in 2018 by MIT Technology Review, of the \$15.2 billion invested in AI startups globally in 2017, 48 percent went to China and just 38 percent to America. The US is starting to lose out in capital investments in software driven industries, such as artificial intelligence, highlighted by the fact that while the U.S. accounted for 77 percent of such investment before the *Alice* decision, that investment fell to 50 percent three years after the *Alice* decision.

In another recent study, published in 2019, surveying close to 500 venture capital and private equity firms about how their investment decisions in new technologies changed since the new Supreme Court created patent eligibility laws came into effect, has provided critical data for an evidence-based evaluation of how the havoc caused by the Supreme Court has affected investments in new technology development.²⁰¹ Professor Taylor makes a compelling evidence-based argument, highlighting the negative impact of the Supreme Court's recent patent eligibility cases, namely *Mayo/Myriad/Alice*, has had on capital investment, and especially so on investment decisions being made on emerging innovative new technologies in the biotechnology, medical device, and pharmaceutical industries. The study points out that these medicine related technologies, even though they are the most impactful in terms of public health, are the most impacted by reduced investments in these industries directly because of the Supreme Court's recent decisions on patent eligibility. The study also makes a point to highlight that their empirical results show that the Supreme Court's recent patent eligibility decisions have negatively impacted each and every area of technological development studied.²⁰²

²⁰¹ David O. Taylor, *Patent Eligibility and Investment*, CARDOZO L. REV. (forthcoming 2019); SMU Dedman School of Law Legal Studies Research Paper No. 414, <https://poseidon01.ssrn.com/delivery.php?ID=076096124100086117074105080088099089121045061078028062023071085075002117064106083110039054098101105044027113118117088099084084010025046038052088016123119125111108127062069039091008123026007111027123024094087002113108026004004127029069026023006066123088&EXT=pdf>.

²⁰² *Id.* at 11.

As a consequence, the results support the idea that the time has come for Congress to at least consider overturning the Supreme Court's new eligibility standard to prevent additional lost investment in technological development in the United States. Indeed, given the results of at least the two recent comprehensive surveys outlined above, it seems likely that the Supreme Court's eligibility decisions have resulted in lost investment in the life sciences that has delayed or altogether prevented the development of medicines and medical procedures. That coupled with China taking market share from the U.S. in emerging new technologies such as artificial intelligence should give pause for lawmakers to turn their attention to this pressing issue.

VI. Congress Should Abolish the Non-Statutory Exceptions to Patent Eligibility Laws

The Supreme Court has decided eight cases in the last forty years concerning the patent eligibility issue, far more than on any other patent law doctrine. It is somewhat telling that four of those eight cases have been decided in the past eight years. And yet, even after multiple attempts to do so, the Supreme Court has been unable to provide a workable standard that comports with the legislative framework. If anything, as discussed *supra*, the current status of how the Supreme Court views the law on patent eligibility is directly inconsistent with statutory language and intent and simply has proved to be unworkable, causing havoc in industries focused on technological innovation.

Patent office examiners, faced with no less than five sets of very detailed guidelines in as many years being issued by the USPTO in view of the ever changing legal landscape on patent eligibility and the sever uncertainty regarding patent eligibility laws, are reminded even in the guidelines issued in 2019 that 35 U.S.C. §101 is not the sole tool for determining patentability, and that 35 U.S.C. §112 , 35 U.S.C. §102, and 35 U.S.C. §103 will provide additional tools for ensuring that the claim meets the conditions for patentability. The Supreme Court has similarly made this clear in *Bilski*:

“The §101 patent-eligibility inquiry *is only a threshold test*. Even if an invention qualifies as a process, machine, manufacture, or composition of matter, in order to receive the Patent Act's protection the claimed invention must also satisfy “the conditions and requirements of this title.” §101. Those requirements include that the invention be novel, see §102, nonobvious, see § 103, and fully and particularly described, see §112.”²⁰³

Yet, the Supreme Court also foresaw the possibility of ensuing mayhem on the wider patent bar and courts using section 101 not as a low hurdle threshold test, but as a lethal dispositive weapon in patent law matters. Thus, the Supreme Court advised the lower courts in *Alice* to “tread carefully in construing this *exclusionary principle*

²⁰³ See *Bilski*, 561 U.S. at 602 (emphasis added).

*lest it swallow all of patent law*²⁰⁴ and in further warning two years prior in *Mayo* that its own judicially created exceptions to the statute have the power to destroy Congress' patent law, stating: "The Court has recognized, however, that too broad an interpretation of this *exclusionary principle could eviscerate patent law*. For all inventions at some level embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas."²⁰⁵

One key problem with the Supreme Court's jurisprudence on this issue is that when coming up with their *Mayo/Alice* framework for determining the contours of their own created exceptions to the explicit language of the 35 U.S. Code §101 statute, neither of the *Mayo* nor *Alice* decisions addressed the legislative history of 35 U.S. Code §101, nor the legislative text or history of the 1952 Patent Act.²⁰⁶

Now that nine years have passed since the *Bilski* decision in 2010, including three other Supreme Court cases on patent eligible subject matter, namely *Mayo* in 2012, *Myriad* in 2013 and *Alice* in 2014, that have actually expanded the reach of the "exclusionary principle test", we are exactly where the Supreme Court warned we could be: that is, the Supreme Court created judicial exceptions to 35 U.S.C. §101 have all but "swallowed all of patent law," and "eviscerated patent law" as the Court itself warned in both *Mayo* and *Alice*.

Faced with daunting uncertainty in this area of patent law, the lower courts and the Court of Appeals for the Federal Circuit have used these Supreme Court decisions, especially the *Mayo* and *Alice* decisions, to strike down and invalidate hundreds of U.S. patents which, as discussed *supra*, has damaged technological innovation and commercialization in America.

A. Back to Basics: Patenting a Law of Nature, Natural Phenomenon, or Abstract Ideas are Prevented by Existing Explicit Statutory Patentability Requirements

The large number of precedential decisions from both the Supreme Court and the Federal Circuit, interpreting and applying 35 U.S.C. § 101 in recent years has created a maw of patent eligibility rulings that have restricted the ability to patent certain technologies and created great inconsistency and uncertainty in the patent system. This is no less reflected by the fact that the Supreme Court has already heard four patent eligibility cases in this decade, namely *Bilski* in 2010, *Mayo* in 2012, *Myriad* in 2013, and *Alice* in 2014, and two more - *Vanda* and *Berkheimer* - are currently pending *certiorari* with the Supreme Court inviting the Solicitor General's view. This has all contributed to a harder environment for obtaining a patent, especially since the threshold bar to assessing whether a subject matter is even patent eligible has been fundamentally raised.

One argument, led by several large technology companies, those with small patent portfolios, has been that patents impede progress and innovation and that protection by way of owning a large number of patents is not necessarily a sign of

²⁰⁴ *Alice Corp. Pty Ltd. V. CLS Bank International*, 134 S.Ct. 2347, 2354 (2014).

²⁰⁵ *Mayo*, 566 U.S. at 71 (emphasis added).

²⁰⁶ See Brief for Petitioner at 26—28, *Sequenom, Inc. v. Ariosa Diagnostics, Inc.*, 136 S.Ct. 2511 (2016) (No. 15-1182), 2016 U.S. LEXIS 4087.

quality and gets in the way of others innovating. While some aspects of this argument resonate, namely that having large numbers of low-quality patents is counterproductive, the means by which the Supreme Court has set out to reign in patent law, starting especially mainly in 2012 with its *Mayo* decision, has caused disarray and been counterproductive. It has even reached the point where last year the Supreme Court decided that a U.S. patent was merely a “public franchise”²⁰⁷, which shocked observers because such a government franchise can technically be withdrawn at any time.

While the judicial exceptions to 35 U.S.C. §101 have had the effect of making it much harder for certain inventions to be prosecuted towards an allowance at the U.S. Patent and Trademark Office, and while these judicial exceptions are aligned with the policy of having a smaller number of high quality patents as suppose to many weak patents, the tool with which the Supreme Court has done this, namely 35 U.S.C. §101, has had unintended consequences on technological innovation across multiple industries. This has been especially felt in the Biotechnology and Software industries in America.

This Supreme Court created uncertainty in the patent eligibility law has had real-world practical consequences, including for example, the highly regarded Cleveland Clinic and other major public and private research and development focused institutions beginning to refrain from researching and developing certain types of innovative technologies because they cannot be patented.²⁰⁸ Further, no patent protection also means investors are unwilling to provide the capital necessary to develop basic innovative research and turn research into developed medical diagnostics and software-driven technologies that can be deployed in hospitals and laboratories.²⁰⁹

Thus, the Supreme Court was misguided to create this uncertainty in patent laws and use the Patent Act’s 35 U.S.C. §101 to do so. If the goal has been to not allow patents for laws of nature, natural phenomenon or abstract ideas, the Supreme Court should have refrained from creating exceptions to patent eligible subject matter under 35 U.S.C. §101 in their three back-to-back cases starting in 2012 with *Mayo*. Instead, the focus should have remained on other statutory language from the Patent Act, namely existing statutes 35 U.S.C. §102 (requirement for the invention to be *new*), 35 U.S.C. §103 (requirement for the invention to be *nonobvious*) and 35 U.S.C. §112 (requirement for a detailed *description* of the invention) to evaluate patent claims at issue.²¹⁰ Indeed, this article advances the position that this strategy would simplify the subject matter eligibility analysis for the U.S. Patent and Trademark Office, courts, patent owners, practitioners and the public alike by prohibiting any

²⁰⁷ See *Oil States Energy Services, LLC v. Greene’s Energy Group, LLC, et al.*, 138 S.Ct. 1365 (2018).

²⁰⁸ Brenden Gingrich, Simone Ward, *Cleveland Clinic II: Has the Federal Circuit Undermined Patent Office Guidance and Eliminated an Important Tool for Patenting Diagnostics?*, JDSupra (May 9, 2019), <https://www.jdsupra.com/legalnews/cleveland-clinic-ii-has-the-federal-23420/>.

²⁰⁹ *Id.*

²¹⁰ (emphasis added).

determination of “inventiveness”²¹¹ and patentability issues under 35 U.S.C. §§ 102, 103, and 112 from the §101 analysis.

Indeed, the Supreme Court has made this clear: “The §101 patent-eligibility inquiry is *only a threshold test*. Even if an invention qualifies as a process, machine, manufacture, or composition of matter, in order to receive the Patent Act’s protection, the claimed invention must also satisfy “the conditions and requirements of this title.” Those requirements include that the invention be novel, see § 102, nonobvious, see § 103, and fully and particularly described, see § 112.”²¹²

Interestingly, in *Mayo*, the U.S. government had argued that virtually any step beyond a statement of law of nature itself should transform an unpatentable law of nature into a potentially patentable claim and this ought to be sufficient to satisfy §101. That is, the bar for what is and is not eligible subject matter should be set low. The government’s view was that any potentially invalid patent claims would not be able to pass the other hurdles found in other statutes of the Patent Act. The U.S. government in their Amicus brief to the Court urged the Supreme Court not to depart so far from the statutory language and to ultimately keep a low threshold bar for determining what subject matter is even patent eligible and then leaving the higher bars to patentability on other parts of the Patent Act best suited for that task, namely novelty under §102 and obviousness under §103.

This is a position this article agrees with, yet I take one more step and suggest Congress should abolish all three of the Supreme Court created exceptions to the explicit statutory language under 35 U.S.C. §101 because the judicially-created exceptions run directly in opposition to both the statute and its legislative history, as discussed *supra*.

Yet, in 2012, in its *Mayo* decision, the Supreme Court explained that the approach urged by the U.S. government would make the “law of nature” exception to §101 a “dead letter” and is not consistent with *Bilski*, *Diehr*, *Flook*, and *Benson*. That is, even though, with the exception of the *Chakrabarty* case, the Supreme Court has hardly ever discussed the legislative history of 35 U.S.C. §101,²¹³ the Court backed its more radical, activist current jurisprudence on 35 U.S.C. §101, especially in *Mayo*, by merely referencing its own prior, much less radical, older cases to effectively back its own parallel law alongside the 35 U.S.C. §101 patent eligibility statute. Justice Breyer, writing for a unanimous Supreme Court in *Mayo*, refused what he called “the Government’s invitation to substitute §§ 102, 103, and 112 inquiries for the better established inquiry under §101.” The Court resisted calls by the government in *Mayo* to heavily reduce the influence of §101 and rely more on the traditional patent-eligibility inquiry under §§ 102, 103, and 112. In the Court’s view, articulated in *Mayo*, shifting the inquiry more on the other provisions of the Patent Act “risks creating significantly greater legal uncertainty, while assuming that those

²¹¹ Or “Inventive Concept” as is required under the *Mayo/Alice* framework.

²¹² See *Bilski* 561 U.S. at 602 (emphasis added).

²¹³ See *Chakrabarty*, 447 U.S. 303, 307 (1980). Although the Supreme Court in *Chakrabarty* refers to the legislative history of 35 U.S.C. §101, it is only limited to interpreting the word “manufacture” and “composition of matter” since this case related to a modified bacterium that could process and break down hydrocarbons.

sections can do work that they are not equipped to do.”²¹⁴

However, many patent scholars, including myself, disagree. 35 U.S.C. §101 is not the “better established inquiry.” As the Supreme Court itself has stated in *Bilski*, “The §101 patent-eligibility inquiry *is only a threshold test*.”²¹⁵ Justice Rehnquist, writing for the court in *Diehr*, even explained that considering novelty under Section 101 was wholly inappropriate (the new test requires under Section 101 requires an “*inventive concept*”).²¹⁶ Academic positions and inconsistency aside, now that seven years have passed since the radical *Mayo* decision, the results are self-evident and point to uncertainty in this area of patent law and this has harmed technological innovation and new technology development and commercialization in the U.S.²¹⁷ Sadly, *Mayo* has resulted in patent stakeholders thinking about other statutory categories of novelty, non-obviousness and even description of the technology, all under the 35 U.S.C. §101 patent eligibility analysis. This has the effect of greatly elevating the importance of 35 U.S.C. §101, while making the other traditionally more stringent statutory requirements of the Patent Act superfluous.

Another problem of the current *Mayo/Alice* patent eligibility test is that it by elevating the threshold hurdle of what is patent eligible subject matter so high and contrary to the statute, potentially newly emerging breakthrough technologies fail at this preliminary threshold step, without even having any kind of substantive determination of the technology in view of a single prior art reference or what others have done to render any such breakthrough obvious. Also, the current *Mayo/Alice* patent eligibility framework does not factor in claim construction to any great level. This is even though such claim construction, including using intrinsic evidence from the specification and extrinsic evidence from treatises and experts, is a key feature of a patentability analysis.

If the Supreme Court were adamant to continue its judicial exceptions to 35 U.S.C. §101 jurisprudence, a potential way forward would be for the Supreme Court to go back to the law of patent eligibility that existed before it unilaterally expanded the scope of patent ineligible subject matter in its *Mayo/Myriad/Alice* trilogy of cases. Currently pending opportunities include granting *certiorari* in pending litigations

²¹⁴ *Mayo Collaborative Services v. Prometheus laboratories, Inc.*, 566 U.S. 66,90 (2012).

²¹⁵ See *Bilski* 561 U.S. at 602: “The §101 patent-eligibility inquiry **is only a threshold test**. Even if an invention qualifies as a process, machine, manufacture, or composition of matter, in order to receive the Patent Act’s protection, the claimed invention must also satisfy ‘the conditions and requirements of this title.’” §101. Those requirements include that the invention be novel, see §102, nonobvious, see § 103, and fully and particularly described, see §112.” (emphasis added).

²¹⁶ *Diehr*, 450 U.S. at 188-189 (1981).

²¹⁷ Taylor, David O., *Patent Eligibility and Investment*, CARDOZO L. REV. (forthcoming).

such as in *Berkheimer*,²¹⁸ *Vanda*,²¹⁹ and *Athena Diagnostics*.²²⁰ It remains to be seen what transpires next, albeit it is interesting that the Supreme Court has this time invited the Solicitor General to submit a brief in both *Berkheimer* and in *Vanda*, and for *Athena Diagnostics*, a petition for *certiorari* is expected to be filed within weeks.

B. Harmonizing U.S. Patent Laws with Other Industrialized Nations

To add to the notion that the time is ripe for the U.S. Congress to act to reign in the caustic harm that the judicially created exceptions to 35 U.S.C. §101 are causing to U.S. businesses and position on the global innovation landscape, one can review how other industrialized countries patent laws are addressing or have previously addressed similar situations. To make this point, I focus on just one recent example and examine how the same technology is being treated by patent laws of other industrialized nations, specifically concerning patent eligibility laws of the U.S., the United Kingdom and Australia.

As recent as in August of 2019, the Australia's High Court decided that a discovery that there are cell free fragments in a pregnant woman's blood that contain a detectable level of cell-free fetal DNA and that this can be used to determine fetal abnormalities, such as Down Syndrome, in a non-invasive manner *is* patent eligible subject matter. This exact same discovery, involving the same litigants, has been determined *not* to be patent eligible subject matter in the U.S. because the invention falls under the U.S. judicially created exception to 35 U.S.C. §101 for being "naturally-occurring" subject matter.²²¹ Moreover, the High Court of Justice in the United Kingdom recently also heard this same issue, involving the same legal issue and technology.²²² There, in 2017, Justice Henry Carr of the UK High Court, similar to Justice Beach's August 2019 decision from Australia's High Court, found that such a patent claim *is* patent eligible subject matter²²³, thereby even further contrasting the

²¹⁸ *Berkheimer v. HP Inc.*, 881 F.3d 1360, 1367 (Fed. Cir. 2018) (this case is viewed by some patent professionals to be the most consequential development in patent eligibility since the Supreme Court introduced its two-part eligibility framework in *Mayo* and *Alice*. *Alice* and *Mayo* caused lower courts to invalidate thousands of claims from hundreds of patents for failure to claim patent-eligible subject matter under 35 U.S.C. § 101. *Berkheimer* tempers the impact of *Alice* and *Mayo* on procedural grounds and may insulate patent claims from § 101 challenges.

²¹⁹ *Hikma Pharmaceuticals USA Inc. v. Vanda Pharmaceuticals Inc.* (This case focused on a situation where the implementing the step of method of treatment was straightforward, however, the question remained if the method was patent eligible subject matter. *Amici Curiae* briefs from both the Intellectual Property and Innovation Professors and The Association for Accessible Medicines ("AAM") focused on this issue, that *Vanda* conflicts with *Mayo* and *Flook*. The Professors' brief states: "The Federal Circuit's decision effectively overturns this Court's precedents, thwarts the proper development of patent eligibility law, and will lead to countless improperly issued patents.")

²²⁰ *Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC*, 915 F.3d 743 (Fed Cir. 2019). Here, the Federal Circuit issued an opinion this year, holding that *Athena's* medical diagnostic methods were directed toward laws of nature and thus patent ineligible under 35 U.S.C. § 101. The inventors had discovered that about 20% of patients with the neurological disorder myasthenia gravis (MG) generate autoantibodies to a membrane protein called MuSK. The asserted patent claims recited steps to detect autoantibodies that bind to MuSK.

²²¹ *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371 (Fed Cir. 2015).

²²² *llumina, Inc v. Premaitha Health Plc* [2017] EWHC 2930 (Pat) (Eng.).

²²³ *Id.* Justice Henry Carr of the High Court of Justice in Great Britain wrote in *llumina* "I do not accept that, properly construed, claim 1 is a claim to a discovery as such. The claims are not directed to information about the natural world, but rather to a practical process, namely a 'detection method' which uses information about the natural world. Claim 1 is directed to the detection of foetal DNA

U.S. position to that of both the U.K. and Australia's highest courts on the same legal issue involving the same technology.

The particular technology and legal issue in the above-referenced example concerned whether the discovery that there are fragments of fetal DNA in the blood of a pregnant woman and that this can be used to provide a non-invasive way to determine fetal characteristics was patent eligible subject matter or not. The U.S. position has been that this is patent ineligible subject matter under 35 U.S.C. §101 because the presence of the cell free fragments of fetal DNA in maternal blood was a *natural phenomenon* and the claims did not contain an *inventive concept* sufficient to "transform" the natural phenomenon into a patent eligible subject matter²²⁴ The test itself has applications of great value, namely it is an improved technique that does not require taking fetal or placental samples for screening for chromosomal abnormalities that could affect a baby's health and development, such as trisomy 21 (Down syndrome), sex chromosome aneuploidies (SCAs, abnormal numbers of X or Y chromosomes), determining the gender of a baby and the like.

The patents at issue here included U.S. Patent No. 6,258,540 B1 (the '540 patent), entitled: "Non-invasive prenatal diagnosis", and counterpart European Patent No. 0994963 B1 (the '963 patent) and Australian Patent No. 727919 B2 (the '919 patent). Since the commercial potential for the pre-natal diagnostic market is enormous, patent litigation ensued between the innovator and copycats in this same technology in several international jurisdictions, including the U.S., Great Britain, and Australia.

The consistency between Australia's highest court's recent decision in August 2019 and the UK's highest court's decision in November 2017 on this same legal issue involving the same technology, finding the technology to be patent eligible subject matter in both UK and AU, further contrasts current U.S. law and puts the U.S. position directly at odds with positions taken on the same issue by other industrialized nations with well-developed legal systems. This complete difference of law between the U.S. and other developed nations on patent eligible subject matter has had practical negative results for the U.S. and not just in the biomedical field, as evidenced by a recent study analyzing in detail, technological sector by sector, how the patent eligibility laws in the U.S. have undermined its leadership role in

in a sample of plasma or serum. Such samples do not exist in the natural world and must be artificially created. The claimed method of detection is also an artificial process which does not exist in the natural world. The claim is to a practical process of implementing a discovery, for practical applications. The actual contribution, as a matter of substance, does not fall solely within the excluded subject matter and is technical in nature."

²²⁴ *Sequenom*, 788 F.3d at 1376, 1378. Here, a U.S. patent governing a method of detecting fetal DNA in the pregnant mother's serum was found to be directed to patent ineligible laws of nature and natural phenomenon, and thus the patent was deemed to be invalid. The Federal Circuit decided that the patent claims were generally directed to detecting the presence of a naturally occurring thing or a natural phenomenon, cell-free fetal DNA in maternal blood. Moreover, the Federal Circuit found that the other elements of the claim, including using PCR to amplify the DNA from blood, did not transform the ineligible patent claim into a patent-eligible application of the natural phenomenon, with the reason being that those additional elements were well-understood, conventional activities.

innovation.²²⁵

As Judge Randall Rader, recently retired former Chief Judge at the Court of Appeals for the Federal Circuit noted recently, “Frankly, there is no country in the world that does what we do here. We have once again, set ourselves on a course which is out of harmony with the rest of the world’s intellectual property standards.”²²⁶

C. Signs of Hope: Congress’s Willingness to Revisit 35 U.S.C. §101 and Available Legislative Options

As a result of the very negative impact on U.S. private and public enterprises conducting biomedical research with the aim of commercializing their innovations and the wider negative impact on the Biotechnology industry in the U.S. at large, there have been recent proposals to legislate and change the laws governing patent eligible subject matter. 221a The aim of the lawmakers is to encourage innovators to again take risks and pursue their ideas, knowing that U.S. patent laws will be on their side in their efforts to commercialize and bring new technologies to the U.S. marketplace. 221b

As of Fall, 2019, such change is currently being considered by the U.S. Congress. 221c Indicating that this may be forthcoming, Senator Chris Coons (D-DE) recently gave a speech at a conference entitled, “The Supreme Court’s Section 101 Jurisprudence: Dangers for the Innovation Economy.” 221d Senator Coons said that subject matter eligibility is “an area where the jurisprudence is insufficiently clear, and which may necessitate congressional action to provide clarity and consistency.” 221e Indeed, on April 18, 2019, Senators Thom Tillis (R-NC) and Chris Coons (D-DE), along with Representatives Doug Collins (R-GA), Hank Johnson (D-GA), and Steve Stivers (R-OH), released a bipartisan framework for 35 U.S.C. § 101 reform, where they outlined specific goals that lawmakers should address.²²⁷

Fast forward to now, Fall of 2019, a group of Senators and House of Representatives are currently considering fixing the Supreme Court created patent eligibility problem, especially since the Federal Circuit has been unable or unwilling

²²⁵ See Kevin Madigan & Adam Mossoff, TURNING GOLD INTO LEAD: HOW PATENT ELIGIBILITY DOCTRINE IS UNDERMINING U.S. LEADERSHIP IN INNOVATION, 24 GEO. MASON L. REV. 939, 956 (2017) (reporting that over 1,600 patent applications covering the same inventions were rejected as patent ineligible subject matter in the U.S., and yet were considered eligible in either China or the European Union or both). Abandoned U.S. patent applications included in fields such as (number of applications in each field shown in parentheses): Drug and Therapeutics (474); Molecular Biology and Microbiology (356); Amusement Devices (245); Combinatorial Chemistry (238); Measuring and Testing (83); Databases (80); Multicellular Living Organisms (38); Structural Design (35); Control Systems (21); Business Methods (18); Surgery (17); Chemistry (15); Immunology (15); Computer Graphics (14); and others. 220a.

²²⁶ Eli Mazour, *The Most Interesting Man in the Patent World Fights to Improve America’s Patent System*, IP WATCHDOG (September 19, 2017), <https://www.ipwatchdog.com/2017/09/19/most-interesting-man-patent-world/id=87983/>.

²²⁷ Senators Chris Coons, Thom Tillis, and Representatives Doug Collins, Hank Johnson, and Steve Stivers, Draft Outline of Section 101 Reform, <https://www.tillis.senate.gov/services/files/3491a23f-09c3-4f4a-9a93-71292704c5b1>; Tryn T. Stimart and Jean E. Dassie, Legislators Propose Framework To Reform Patent Eligibility Under Section 101 (July 22, 2019) (attributing authorship of draft reform) <http://www.mondaq.com/unitedstates/x/827762/Patent/Legislators+Propose+Framework+To+Reform+Patent+Eligibility+Under+Section+101>.

to define the contours of what is and is not patent eligible subject matter in view of the Supreme Court's recent jurisprudence on the issue²²⁸ These closed-door roundtable talks between lawmakers seek to come up with legislative language, and it is anticipated that bills will be introduced in both the House and the Senate in Fall of 2019 or sometime in 2020. 223a Indeed, the Supreme Court even appeared to invite Congress in *Mayo* to provide guidance, stating that the Court “recognized the role of Congress in crafting more finely tailored rules where necessary.”^{223b} Many major patent stakeholders are also encouraging Congress to act; for example, both the Intellectual Property Owners Association and the American Intellectual Property Law Association, both large well-regarded professional IP associations, have written to Congress asking the lawmakers to undo the *Mayo/Alice* framework through legislation.²²⁹ This is opportune time for Congress to do so because the time is ripe and it is necessary. But, what should Congress do regarding patent eligibility?

Professors Lefstin and Menell have proffered a legislative proposal of focusing on a “practical application” of an abstract idea, natural law, or natural phenomenon,²³⁰ with the logic behind this proposal being that this would be aligned with pre-*Mayo* jurisprudence. This position also has some backing from the ABA's Section of Intellectual Property Law, evidenced by their submission of comments to the U.S. Patent and Trademark Office that largely agree with this “practical application” test.²³¹ Moreover, Professors Lefstin and Menell, well known patent law scholars,

²²⁸ Gene Quinn, *America's Patent System Favors the Few and Inhibits Innovation—But Change Could Be Coming* (March 28, 2019) <https://www.ipwatchdog.com/2019/03/28/americas-patent-system-favors-the-few-inhibits-innovation-but-change-could-be-coming/id=107807/> (As of Summer 2019, Senator Chris Coons (D-DE), Senator Thom Tillis (R-NC), Congressman Doug Collins (R-GA) and Congressman Hank Johnson (D-GA) currently have a four-principle framework for legislatively fixing patent eligibility laws. Their framework recites: “Guiding Principles for Section 101 Reform. 1. Patent eligibility should not turn on the existence of related technology or the current state of the art. In other words, subject to meeting all other requirements of the patent statute, especially novelty, obviousness, enablement, written description, and definiteness, any useful invention should be eligible for protection regardless of whether it is new or old, conventional, known, or using other terms relevant to determining obviousness or anticipation. 2. When assessing the eligibility of patent claims, those claims must be construed as a whole, with each limitation in a claim given equal weight, and none dismissed or discounted as ‘routine,’ ‘known,’ ‘conventional,’ mere ‘data gathering,’ mere “post-solution activity,” or the like. It is impermissible to carve up a claim into different parts and assess the eligibility of the parts of a claim separately, rather eligibility must consider the claimed invention as a whole. 3. Diagnostic and life science technologies should be eligible for patent protection per se, subject to meeting the other existing statutory requirements, and should not be considered a law of nature, natural phenomena, or otherwise patent ineligible subject matter. 4. Any reform to Section 101 should statutorily codify a definition and/or exception(s) to patent eligibility. Any statutory exception(s) should not use the existing judicial exceptions of abstract ideas, laws of nature, or natural phenomena. Any statutory exceptions should be the sole and exclusive basis for excluding subject matter from eligibility and may not be expanded upon by courts. Any definition of eligible subject matter should be adaptive to include new technologies not yet invented.”).

²²⁹ Dennis Crouch, *AIPLA On Board with Statutory Reform of 101* (May 16, 2017), <https://patentlyo.com/patent/2017/05/aipla-statutory-reform.html>.

²³⁰ *See* Brief for Sequenom as Amici Curiae in Support of Petition for a Writ of Certiorari, *Sequenom, Inc. v. Ariosa Diagnostics, Inc.*, No. 15-1182 2016 WL 1605520 (U.S.), pp. 2, 15-16, 24.

²³¹ *See* Donna P. Suchy, *Re: Supplemental Comments Related to Patent Subject Matter Eligibility*,

submitted a supplementary statement, as recent as in Summer of 2019, to the Committee on the Judiciary, Subcommittee on Intellectual Property Hearings on “The State of Patent Eligibility in America.”²³²

Yet, from a pure practical standpoint, especially one that patent examiners can easily apply when examining patent applications in the trenches with little time and many Office Actions to write, the “practical application,” test is a very reasonable approach, yet may be difficult to universally implement. Indeed, to have some 10,000 patent examiners and over 200 Administrative Patent Judges at the USPTO trained to then effectively examine based on what would remain a convoluted legal framework when the vast majority of examiners are not even attorneys, and to do this examination consistently in a technology-neutral way, may be too ambitious.

Other proposals, including one from David Kappos, the Director of the US Patent & Trademark Office (USPTO) from 2009 to 2013, have invited Congress to repeal the entire 35 U.S.C. §101 statute from the Patent Act on the basis that it is unworkable and is outdated since it has virtually remained unchained since the 18th century.^{227a} And although the Intellectual Property Owners Association’s position may have evolved, they adopted a resolution recently to support legislation to amend the statute by adding two subsections.^{227b} In their statement, they indicated that the “proposed legislative language would address patent-eligibility concerns *by reversing the Supreme Court decisions and restoring the scope of subject matter eligibility to that intended by Congress . . .*; defining the scope of subject matter eligibility more clearly and in a technology-neutral manner; . . .; and simplifying the . . . eligibility analysis.”²³³

I respectfully proffer yet another option, and one I rank highly on available options, and that is to encourage the lawmakers to look at Europe or even Japan, both equally industrialized nations with developed legal frameworks, and analyze their patent laws as a model framework on this patent eligibility issue.

For example, Paragraph 2 of Article 52 of the European Patent Convention states:²³⁴

(1) European patents shall be granted for any inventions, in all fields of technology, provided that they are new, involve an inventive step and are susceptible of industrial application.

(2) The following in particular shall not be regarded as inventions within the meaning of paragraph 1:

(March 28, 2017) (includes January 18 letter as attachment), available at <https://www.uspto.gov/sites/default/files/documents/RT2%20Comments%20ABA-IPL%20%28Mar.%2028%20Rev%29.pdf>. The ABA submitted a formal reform proposal in May 2017.

²³² Menell, Peter S. and Lefstin, Jeffrey A., *Reforming Patent Eligibility: Supplementary Statement of Professors Jeffrey A. Lefstin and Peter S. Menell*, UC HASTINGS LAW (June 4, 2019), available at SSRN: <https://ssrn.com/abstract=3399499> or <http://dx.doi.org/10.2139/ssrn.3399499>.

²³³ Gene Quinn, *IPO adopts resolution supporting legislation to amend 35 U.S.C. § 101* (January 31, 2017), <https://www.ipwatchdog.com/2017/01/31/ipo-adopts-resolution-legislation-amend-101/id=77818/>.

²³⁴ European Patent Convention art. 52, 1065 U.N.T.S. 199 (2001), <https://www.epo.org/law-practice/legal-texts/html/epc/2016/e/ar52.html>.

- (a) discoveries, scientific theories and mathematical methods;
 - (b) aesthetic creations;
 - (c) schemes, rules and methods for performing mental acts, playing games or doing business, and programs for computers;
 - (d) presentations of information.
- (3) Paragraph 2 shall exclude the patentability of the subject-matter or activities referred to therein only to the extent to which a European patent application or European patent relates to such subject-matter or activities as such.

Under this framework, the European Patent Office determines the patentability based on a pair of hurdles: an eligibility hurdle (Article 52 EPC), which requires the claimed subject matter to have a technical character; and a patentability hurdle (Articles 54, 56 EPC), which requires the claimed subject matter to contribute a technical solution to a technical problem.²²⁹ Thus, any legislative fixes to current U.S. patent eligibility laws, could model itself to be a “threshold,” like Article 52 of the European Patent Convention, and thereby list subject matter that doesn’t possess technical character, such as mathematical methods, methods for performing mental acts or doing business, and presentations of information.

This may be an easier approach to implement in practice, especially at the U.S. Patent and Trademark Office with its approximately 10,000 patent examiners. Indeed, it appears that as of Fall 2019, a bipartisan framework for 35 U.S.C. § 101 reform is under consideration by a number of Senators and House Representatives, and one of their goals is indeed to name a short exclusive list of categories, much like in Europe. Under consideration are to list and thereby explicitly exclude mental activities, pure mathematical formulas, products that exist solely and exclusively in nature, fundamental scientific principles and economic principles.^{229b}

It remains up for discussion what the final bills will say and how lawmakers will attempt to remedy the current status of affairs. One thing remains obvious, 35 U.S.C. §101 cannot remain as is because America’s leadership position on innovation and entrepreneurial new technology development and commercialization is at stake.

Congress’s light fix would be to effectively set aside the *Mayo* decision; a proper fix would be to effectively set aside the three back-to-back Supreme Court decisions on patent eligibility, namely *Mayo* (2012), *Myriad* (2013) and *Alice* (2014), and thereby abolish, *in toto*, the Supreme Court created exceptions to the statutory language and intent governing patent eligible subject matter found in 35 U.S.C. §101.²³⁵

VII. Conclusion

²³⁵ *Mayo Collaborative Sers. v. Prometheus Labs., Inc.*, 566 U.S. 66 (2012); *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576 (2013); *Alice Corp. v. CLS Bank Int’l*, 573 U.S. 208 (2014).

The Patent Act, as noted above, defines four independent categories of subject matter that are eligible for patent protection: 1) processes; 2) machines; 3) manufactures; and 4) compositions of matter.²³⁶ While it is clear from the Statute that Congress intended to give a wide scope to patent eligible subject matter, from these four broad categories that are listed in the statute, the Supreme Court has judicially created three exceptions of subject matter that the Court considers are ineligible for patent protection: 1) laws of nature; 2) products of nature; and 3) abstract ideas. Thus, under current law, a claimed invention is only patent-eligible under 35 U.S.C. §101 if it is a process, machine, manufacture, or composition of matter, *and* also if it falls outside the three Supreme Court promulgated judicial exceptions.

For all the reasons outlined *supra*, this paper advances the proposition that American society stands to benefit from abolishing the non-statutory, Supreme Court promulgated, exceptions to U.S. Code Section 101 altogether. These Supreme Court created exceptions to the statutory language have no foundation and have caused great uncertainty in patent laws. This has negatively affected certain technology-focused industries and otherwise damaged America's standing as a leader in new technology development and commercialization. As outlined *supra*, the time is ripe for Congress to act to correct the patent eligibility legal landscape and thereby promote innovation; to do so, they have good options at hand.

²³⁶ 35 U.S.C. § 101 (2012).