I. Introduction

Chairman Durbin, Chairman Coons, Ranking Member Graham, Ranking Member Tillis, and Members of the Subcommittee:

Thank you for this opportunity to speak with you today about the continuing quagmire in patent eligibility jurisprudence and the negative impact on the United States innovation economy.¹

As I have stated in past scholarship, testimony before Congress, amicus briefs, and agency comments, the U.S. patent system has been under an extensive amount of stress from all branches of the federal government for over fifteen years. The Supreme Court has been deciding patent cases at a rate not seen for almost a hundred years,² changing the law in all aspects of the patent system. Among these numerous changes were four decisions between 2010 and 2014 on patent eligibility doctrine under § 101.³ These decisions severely restricted the inventions and discoveries that have long been considered patentable for over two centuries in the U.S. patent system.

¹ Professor Mossoff is speaking on his own behalf, and his testimony does not reflect the views of his employer or of any institution or organization with which he is affiliated.
These four decisions culminated in the “Alice-Mayo inquiry”—a two-factor legal framework that courts and the U.S. Patent & Trademark Office (USPTO) have applied since 2014 in assessing whether an invention or discovery is patentable subject matter under § 101. The Alice-Mayo inquiry has created a tremendous amount of uncertainty for innovators and severely restricted the patent eligibility of high-tech and biopharmaceutical innovations. It has had a negative impact on both inventors and the companies working in the innovation industries that invest millions of dollars in creating the new products and services that drive economic growth, job creation and higher standards of living. Thus, it is undermining the longstanding comparative advantage by the U.S. in the world in securing reliable and effective patent rights for all innovators.

The Alice-Mayo inquiry is one of many recent changes to the U.S. patent system that has called into question the longstanding U.S. claim to a “gold standard” patent system as compared to the rest of the world. As a result of the Alice-Mayo inquiry, the USPTO has denied patent applications or courts have invalidated issued patents in cutting-edge discoveries in medical care, such as treatments for breast cancer, diabetes, and strokes, among others. The USPTO appears to have corrected course in adopting its 2019 patent eligibility guidelines, but these patent examination guidelines are not a panacea. These regulatory guidelines can be easily repealed by a future USPTO director, and they have had no sway with the courts in reviewing the patents issued by the USPTO. Courts continue to apply the Alice-Mayo inquiry to invalidate patents on classic industrial technologies, such as an invention on a new method of manufacturing automobile axles, and, in another notorious case, the courts applied the Alice-Mayo inquiry to conclude that the invention of a new remote-controlled garage door opener is an unpatentable abstract idea.

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4 The two-factor inquiry is (1) determine whether the patent claim is directed to an abstract idea, natural phenomenon, or law of nature that are ineligible for patent protection, and, if it is, then (2) determine if the claim adds something more that transforms it into a patent-eligible application (an “inventive concept”) of one of these ineligible categories or is this additional activity in the claim merely well-understood, routine, and conventional activity in the art. See Alice, 573 U.S. at 217-18; Mayo, 573 U.S. at 75-80.


6 See generally id. (identifying in both the 2019 and 2017 articles many patent applications for significant biomedical tests that were rejected by USPTO). For a few examples of the many patents invalidated by courts, see Cleveland Clinic Found. v. True Health Diagnostics LLC, 760 Fed. Appx. 1013 (Fed. Cir. 2019) (nonprecedential) (invalidating a patent on a biotech-based medical test for detecting heart disease as covering a patent-ineligible law of nature); Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC, 915 F.3d 743 (Fed. Cir. 2019) (invalidating a patent on a biotech-based medical test for identifying neurological disorders as covering a patent-ineligible law of nature); Ariosa Diagnostics, Inc. v. Sequenom, Inc., 788 F.3d 1371 (Fed. Cir. 2015) (invalidating a patent on non-invasive prenatal test using fetal DNA found the blood of the mother as covering a patent-ineligible law of nature and natural phenomenon);


8 See American Axle & Mfg., Inc. v. Neapco Holdings LLC, 967 F.3d 1285, 1288 (Fed. Cir. 2020) (invalidating a patent on a method of manufacturing an automobile axle as claiming a law of nature); see also TDE Petroleum Data Solutions v. AKM Enterprise Inc., 657 Fed. Appx. 991 (Fed. Cir. 2016) (invalidating a patent on a method of operation of an oil derrick as an abstract idea)

This is an alarming shift from the historical approach of the U.S. in securing reliable and effective patent rights in new innovations, which has been a key driver of economic growth in the U.S.\textsuperscript{10} It is even more concerning given the rise of a modern global competitor like China that seeks to compete technologically and economically by developing its own innovation economy, not just defeat the U.S. through military conflicts. Historically, the U.S. became the home to innovators and the R&D financing that drove technological and economic revolutions from the Industrial Revolution to today’s mobile revolution.\textsuperscript{11} Even with period upheavals in U.S. patent policy over the past two centuries, the U.S. forged ahead when other countries hesitated in securing patents in new discoveries and inventions, such as in biotechnology and computer software in the 1980s.\textsuperscript{12} Today, China and European countries are now the ones forging ahead and securing reliable and effective patents in innovation that the U.S. no longer reliably or effectively protects due in part to the closing of the doors to its patent system by the\textit{Alice-Mayo} inquiry.\textsuperscript{13}

Congress should reform § 101 to reclaim the “gold standard” U.S. patent system by enacting the Patent Eligibility Reform Act (PERA). This bill abrogates the judicially-created\textit{Alice-Mayo} inquiry while also codifies the longstanding legal rules prohibiting patents on truly abstract ideas, such as an idea existing in a person’s mind, or on unmodified facts of nature, such as a gene existing in a person’s body. Equally important, PERA addresses the related procedural failings by courts in applying the\textit{Alice-Mayo} inquiry that have contributed to the patent eligibility quagmire and hampered this key legal engine of the U.S. innovation economy. Thus, PERA requires a court to apply in its patent eligibility analysis the longstanding legal guardrails in all of patent law that have ensured courts properly interpret and protect patents, such as the requirement that a court analyze a claimed “invention as a whole” and that a court not conflate the distinct legal requirements of novelty, nonobviousness, disclosure, enablement, and usefulness in its patent eligibility analysis.

Some commentators may nitpick at potential linguistic imperfections in PERA, and which exist in all laws enacted by Congress. Even the much-admired 1952 Patent Act contained new terms and

\textsuperscript{10} See Stephen Haber, \textit{Patents and the Wealth of Nations}, 23 GEO. MASON L. REV. 811 (2016) (surveying historical evidence and economic studies confirming that patents are a key factor in successful innovation economies); see also infra notes 16-20, and accompanying text (reviewing the economic and historical evidence in Professor Haber’s article and in other sources).

\textsuperscript{11} For example, the inventor of synthetic plastic, Leo Baekeland, immigrated to the U.S. given the focus in this country on applied research and the promise of reliable and effective patent rights that he could commercialize in the marketplace. He received an patent for his breakthrough invention of synthetic plastic in 1909. See U.S. Patent 942,699 (issued Dec. 7, 1909).

\textsuperscript{12} See Madigan & Mossoff, supra note 5, at 942-946 (detailing this historical approach in biotech and software).

legal requirements when it was first enacted in 1952. In fact, many of these arguments against PERA could have been made in 1952 if these same critics existed at that time and were lobbying Congress not to enact the bill that ultimately became the 1952 Patent Act. Congress should not let the perfect become the enemy of the good. Relationally, Congress should look past the misrepresentations of what PERA clearly states and achieves, such as the false claim by the ACLU and other opponents of reform that PERA permits patents on genes as they exist in one’s body.14

The task for reform falls on Congress in ensuring the laws it enacts are properly interpreted and applied by the courts and by the USPTO. The Supreme Court created the Alice-Mayo inquiry and the resulting legal quagmire and negative impact on the innovation economy, and it has denied numerous writ of certiorari petitions over the past decade asking it to revisit or reverse its new legal inquiry for patent eligibility assessments under § 101. The UPSTO is unable to fix this problem given that it is only an administrative agency in the Executive Branch that is legally bound to obey the decisions of the Supreme Court and Court of Appeals for the Federal Circuit. Thus, it falls on Congress to achieve the necessary reform of § 101 to return the U.S. patent system back to its original constitutional function in “promoting the Progress . . . of the useful Arts.”15

Given the widespread confusion today about the function of the patent system as a driver of innovation and economic growth, my written testimony will first describe the historical, economic, and legal evidence on how reliable and effective property rights in inventions—patents—are a key factor in growing innovation economies and flourishing societies. This includes both general empirical evidence on the success of the patent system as a driver of economic growth, and also specific data about the unique features of the historical U.S. patent system in securing new inventions, such as new business methods and computer software programs. This is the necessary legal, economic, and historical framework by which to evaluate PERA and its much-needed reform of patent eligibility doctrine. Second, it details some of the more recent court decisions that dramatically illustrate the continuing problems for innovators caused by the Alice-Mayo inquiry. Third, it addresses the USPTO’s successful 2019 patent eligibility guidelines, which demonstrate that reform is possible, but these guidelines are not an effective solution since they do not control the courts and they can be undone by a future director of the USPTO. Fourth, it reviews the data in some of the more recent studies that detail the negative impact of the patent eligibility quagmire.

The Success of the Patent System as a Driver of Economic Growth and Innovation

Before addressing a specific legal or policy debate in the patent system, it is necessary to first review the legal and economic evidence that sets the framework for evaluating the current legal disputes and data. This is important, if only because there is widespread confusion today about the key role of a patent system in promoting innovation and driving economic growth. The patent system has been a key driver of the U.S. innovation economy for over 200 years, as economists, historians, and legal scholars have repeatedly demonstrated.16 The patent system was central to the


16 See, e.g., ROBERT P. MERGES, AMERICAN PATENT LAW: A BUSINESS AND ECONOMIC HISTORY (2023); JONATHAN M. BARNETT, INNOVATORS, FIRMS, AND MARKETS: THE ORGANIZATIONAL LOGIC OF INTELLECTUAL
successes of the Industrial Revolution in the nineteenth century, the pharmaceutical and computer revolutions in the twentieth century, and the biotech and mobile revolutions in the early twenty-first century. Studies have consistently shown that patent systems that secure reliable and effective property rights to inventors strongly correlate with successful innovation economies.  

Dr. Zorina Khan, an award-winning economist, has demonstrated that reliable and effective property rights in innovation—patents—were a key factor in thriving markets for technology in the United States in the nineteenth century. Other economists have also identified features of these robust nineteenth-century markets in new technologies—such as an increase in “venture capital” investment in patent owners, the rise of a secondary market in the sale of patents as assets, and the embrace of specialization via licensing business models—as indicators of value-maximizing economic activity that were made possible by reliable and effective patents. All of this remains true today: a twenty-first-century startup with a patent more than doubles its chances of securing venture capital financing compared to a startup without a patent, and this patent-based startup has statistically-significant increased chances of success in the marketplace as well. These are the academic and scholarly analysis that confirm the everyday experience of what most people have seen in Shark Tank, in which the venture capitalists always ask the entrepreneurs if they have patents for their inventions as a precondition to investing in their new products or services.

The real-world results of reliable and effective property rights—whether in land or in inventions—is extensive private investments, development of new products and services, and the creation and growth of new commercial markets in which consumers benefit from new products and services. These have been the consistent features of the U.S. innovation economy from the Industrial Revolution through today’s mobile revolution. They were made possible by a patent system that was as innovative itself as the inventions it promoted and secured in the marketplace.

For example, Professor Michael Risch studied all of the patents issued to inventors in the U.S. between 1790 and 1839. His study makes clear that “early Americans did not think that the patent system secured only ‘technology’ in the narrowest sense of this term, i.e., machines or a particular physical transformation of material objects.” In the first several decades of the U.S. patent

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18 See B. Zorina Khan, The Democratization of Invention: Patents and Copyrights in American Economic Development, 1790–1920, at 9-10 (2005) (“[P]atents and . . . intellectual property rights facilitated market exchange, a process that assigned value, helped to mobilize capital, and improved the allocation of resources. . . . Extensive markets in patent rights allowed inventors to extract returns from their activities through licensing and assigning or selling their rights.”).

19 See, e.g., Lamoreaux, Sokoloff & Sutthiphisal, supra note 16, at 4-5.


21 See Michael Risch, America’s First Patents, 64 FLORIDA L. REV. 1279 (2012).

system, Congress and judges decidedly broke with the English patent system in permitting the patenting of *processes* in the U.S., including issuing many patents on *business methods*.

Professor Risch found that 12.58% of total U.S. patents issued to inventors from 1790-1839 were for processes, and, among these process patents, 7.16% were for inventions that we would now classify as business methods. Business methods have long been recognized as patentable processes from the first years of the U.S. patent system—contrary to the English patent system.

Although the U.S. did not examine patent applications between 1793 and 1836, one will still search the federal court reporters in vain for decisions from this period in which a judge rejected one of these business method patents on the basis that this invention was excluded from the patent system, as opposed to being invalid for lack of novelty or one of the other patentability requirements. This is important because even Justices of the Supreme Court are mistaken about this clear historical fact. Justice John Paul Stevens dissented in *Bilski v. Kappos* in 2010, stating that “[d]uring the first years of the patent system, no patents were issued on methods of doing business.”

This is wrong, as confirmed by Professor Risch’s rigorous empirical study. This is perhaps why Justice Stevens does not quote in his *Bilski* dissent a single court opinion, congressional member, or official in the Patent Office in the early Republic that states that business methods are unpatentable inventions.

As further confirmation of the patentability of business methods that were tested for novelty, usefulness, and disclosure, the Patent Office continued to issue patents on business methods throughout the nineteenth century after patent examination procedures were mandated for all applications in the 1836 Patent Act. For example, Charles Walters and William Walters received a patent in 1896 for their invention of a new process for banks to securely receive deposits & process claims on accounts. This is the drawing in their patent of their business method:

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24 *Id.*
Another example of a business method patent is Patent No. 761,212, which issued to James Dune in 1904 for his invention of a new method for processing commercial security instruments used between merchants and buyers to make transactions more efficient. See U.S. Patent 761,212 (issued May 31, 1904).
As with business method patents, there are similar historical mistakes and confusion about the law in the policy debates about the role of patents in securing innovations in the high-tech sector generally and in computer software specifically. 29 Today’s hearing on PERA by the Senate Subcommittee on Intellectual Property is held on the anniversary of the patent issuing in 1979 to Steve Wozniak for his invention of the first programmable computer. 30 This was the computer that was made and sold by “the Woz” and Steve Jobs while working in their new startup, Apple Computer, Inc. This was just one of the patented inventions that launched Apple, which drove the personal computer revolution in the 1908s along with other new high-tech firms like Microsoft.

29 See Adam Mossoff, A Brief History of Software Patents (and Why They’re Valid), 56 ARIZ. L. REV. SYLLABUS 63 (2014) (identifying these historical and legal confusions and explaining why they are incorrect).
Some commentators mistakenly believe that “software patents” are patents on “mathematics” or patents on a “mathematical algorithm,” and thus they should be excluded as unpatentable abstract ideas.\textsuperscript{31} But this is policy rhetoric, not technical fact or a proper representation of U.S. patent law. Of course, computer software programs do use mathematics. But it’s an invalid inference to conclude that computer software programs like word processors, data encryption programs, operating systems, or 5G are “just math.” All inventions use mathematics; physicists love to say that the language of the universe is mathematics.\textsuperscript{32} If taken seriously, the argument that a “web browser, spreadsheet, or video game is just math and therefore it’s not . . . eligible for patent protection”\textsuperscript{33} would invalidate all patents covering all inventions, especially new processes. All inventions of practically applied processes and machines are reducible to mathematical abstractions and algorithms; for example, a patentable method for operating a combustion engine is just an application of the law of PV=nRT, the principles of thermodynamics, and other laws of nature comprising the principles of engineering. Although the Alice Court claimed to recognize this truth that “[a]t some level, ‘all inventions . . . embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas,’”\textsuperscript{34} the legal doctrine it created in the Alice-Mayo inquiry has ultimately led the patent system astray (as will be detailed below).

Closely related to the arguments that software should not be patentable is the argument that open source software is necessarily antithetical to the patent system, because software should be free and not protected by property rights. Although the theory or ideology of open source does advance a communitarian theory of society and resources generally, open source is also a business model that relies on intellectual property rights, such as trademarks and patents. For example, Dennis Ritchie is one of the co-inventors of UNIX, the famous open source operating system that is ubiquitous in our modern interconnected world. But Ritchie was not opposed to patents on software programs. He obtained a patent in 1979 for his invention of a new software program that ran on UNIX: a data protection software program that controlled user access called a SUID bit.\textsuperscript{35}

Arguably, one of the earliest patents on a software program was one that issued to Samuel Morse for his invention of Morse Code, the eponymous binary language system he created for his telegraph. Morse is the inventor of the first functional electromagnetic telegraph, but a key element of his telegraph that made it successful was his equally innovative creation of the dots and dashes (binary) language system used for communicating on his telegraph. In fact, more people today likely know about Morse Code than they know about Morse’s invention of the telegraph. Since Morse Code was an invention on par with his invention of the telegraph itself, Morse claimed it in his many patents that he received on his telegraph system.\textsuperscript{36} Of course, patent lawyers know of

\begin{itemize}
\item \textit{Alice Corp.}, 134 S. Ct. at 2354 (quoting Mayo Collaborative Servs. v. Prometheus Labs., Inc., 132 S. Ct. 1289, 1293 (2012)).
\item Morse Code was covered by Claim 3 in Morse’s original patent on the telegraph. See U.S. Patent 1,647 (issued June 20, 1840). It was ultimately covered by Claim 5 in the last Reissue Patent that Morse received on his telegraph. See U.S. Reissue Patent 117 (issued June 13, 1848).
\end{itemize}
Morse and his famous telegraph because the Supreme Court invalidated Claim 8 in Morse’s Reissue Patent No. 117 in a famous decision in 1854, a court opinion that has been wrongly interpreted to this day as a key decision on the rule prohibiting the patenting of abstract ideas. Yet, in this same opinion, the Supreme Court affirmed the validity of Claim 5 on Morse Code in a single sentence and without any additional comment. Thus, the Supreme Court upheld in 1854 the validity of patent claim on a binary language used for processing and transmission of information on an electronic magnetic machine—an invention that sounds very much like a computer software program today.

This is an admittedly brief overview of the economic, historical, and legal data on the U.S. patent system, and much more information and data can be found in the cited sources (and in many more sources). For the sake of the limits on this written testimony, it is impossible to review all of the relevant evidence and data, but this is sufficient to convey the key point that the U.S. patent system has succeeded because it incentivized new and unforeseeable inventions with the promise of reliable and effective property rights, which then served as a legal platform for commercializing these innovations in the marketplace. For these reasons, the U.S. patent system was recognized as the “gold standard” in securing reliable and effective property rights in the fruits of inventive labors.

The Continuing Patent Eligibility Quagmire in the Courts

Ten years after the Supreme Court decided the last of its four modern patent eligibility decisions, culminating in the Alice-Mayo inquiry in 2014, patent eligibility jurisprudence is now the proverbial millstone around the neck of U.S. innovators. At best, the doctrine remains fundamentally unsettled and indeterminate for inventors, especially innovators in high tech and the life sciences—the two primary drivers of the modern innovation economy. At worst, inventors have achieved a modicum of certainty by adopting to the legal fact that cutting-edge inventions are at substantial risk of invalidation by the courts. They do not apply for patents or they draft patents in ways that no longer properly secure their innovations. In sum, the Alice-Mayo inquiry represents the closing of the doors of the patent system to innovations in healthcare and the high-tech sector of the innovation economy. This jurisprudence is significant for several reasons.

First, patent eligibility jurisprudence is no longer “only a threshold test,” as the Court rightly framed the nature of the § 101 inquiry in the 2010 decision in Bilski v. Kappos. Since 2014, patent eligibility doctrine stopped serving as only a “coarse filter” that is applied before a court applies the more fine-grained doctrinal requirements of novelty, nonobviousness, and disclosure.

38 See O’Reilly v. Morse, 56 U.S. (15 How.) 62, 112 (1854) ("We perceive no well-founded objection . . . to his right to a patent for the first seven inventions set forth in the specification of his claims.").
40 Bilski, 561 U.S. at 602.
Instead, the Alice-Mayo inquiry is now an all-pervasive and principal feature of patent law generally, which is an entirely new development in the U.S. patent system. An empirical study by Robert Sachs in 2019 found that court decisions applying § 101 after 2014 jumped 730% with a 659% increase in the number of litigated patents.\textsuperscript{42} Sachs found that, as “[c]ompared with the five years prior to Alice [reaching back to Bilski in 2009], there has been a 1056% increase in the number of decisions finding ineligible claims, and a 914% increase in the number of invalidated patents” between 2014 (when Alice was decided) and 2019.\textsuperscript{43} I do not have updated statistics since 2019, but I am unaware of any new study that shows a reversal of this trend since 2014 of substantially higher rates of courts applying the Mayo-Alice inquiry to invalidate patents.

Second, courts continue to apply the Alice-Mayo inquiry in a willy-nilly fashion in which they ignore the longstanding rule in patent law that claimed inventions should be construed and assessed as a whole. Instead, courts are dissecting claims into separate elements to thus finding the patent to be invalid given a finding that a particular element of a claimed invention is an abstract idea or law of nature. There are too many examples to review in this testimony, and thus a few illustrative cases will suffice to demonstrate this fundamental problem.

In TDE Petroleum Data Solutions v. AKM Enterprises, the Federal Circuit affirmed a district court’s decision invalidating a patent on a new process for operating an oil drilling rig as an “abstract idea.”\textsuperscript{44} Repeating the same error as the district court, the Federal Circuit focused solely on a single element in the patent claim—the sole element about use of a computer software program—and then concluded that the claimed invention as a whole performed only the “generic computer functions” of this single element.\textsuperscript{45} In effect, the Federal Circuit disintegrated the patented invention down into a single element and reframed the oil-drilling process invention as an invention of generic data analysis by a computer program. The court explicitly ignored other claim elements, such as the express terms “well operation” and other language in the patent that made it clear the claimed invention as a whole was a type of industrial process, one that has long been protected in the U.S. patent system: a drilling process on an oil derrick.

The TDE Petroleum decision is important because it also dramatically highlights the indeterminacy and unpredictability in patent eligibility jurisprudence created by the Alice-Mayo inquiry. The specific patent claim invalidated in TDE Petroleum (Claim 30) paralleled the same linguistic structure, terms, and even used the same substantive meaning of these terms of a patent claim affirmed as valid under § 101 by the Supreme Court in 1981 in Diamond v. Diehr.\textsuperscript{46} The Diehr patent and TDE Petroleum’s patent are essentially the same invention: both are inventions

\footnotesize{thus a determination of eligibility under § 101 is only a threshold question for patentability. Sections 102, 103, and 112 are typically the primary tools for evaluating patentability unless the claim is truly abstract . . . ”); Research Corp. Techs., Inc. v. Microsoft Corp., 627 F.3d 859, 869 (Fed. Cir. 2010) (“[A] patent that presents a process sufficient to pass the coarse eligibility filter may nonetheless be invalid as indefinite because the invention would not provide sufficient particularity and clarity to inform skilled artisans of the bounds of the claim.”) (emphasis added).


\textsuperscript{43} Id.

\textsuperscript{44} See TDE Petroleum Data Solutions, 657 Fed. Appx. at 993.

\textsuperscript{45} Id.

\textsuperscript{46} 450 U.S. 175 (1981).}
of software-based methods for operating industrial processes. The Diehr patent claimed a new process for curing rubber in a machine using a computer program.\(^{47}\) TDE Petroleum’s patent claimed a new process for operating a drill on an oil rig using a computer program. The two patent claims are similar in both their form and substance.\(^{48}\) The Diehr Court rightly held that industrial processes like curing rubber, an invention secured by a patent first issued to Charles Goodyear in 1844,\(^{49}\) are patent eligible under § 101 even if the process is the use of a computer.\(^{50}\) The Supreme Court did not overrule Diehr in any of the four patent-eligibility decisions culminating in the Alice-Mayo inquiry, but courts are now interpreting and applying the Alice-Mayo inquiry in a way that clearly contradict Supreme Court precedent on the patent eligibility of inventions.

In American Axle v. Neapco Holdings, the Federal Circuit repeated the same methodological and substantive error as it did in TDE Petroleum. In American Axle, the Federal Circuit ignored the express claim elements setting forth physical requirements in the use of a new method of manufacturing a driveshaft used in automobiles.\(^{51}\) Despite the district court alleging that it was following the mandate in patent law to interpret only the “claims as a whole,”\(^{52}\) the district court contradicted this assertion in its actual analysis of the patent by dissecting it into its different elements and then laser focusing solely on the “tuning” elements as the “inventive concept” of the entire patented invention.\(^{53}\) The district court thus concluded that the patented invention was merely an application of the laws of thermodynamics (Hooke’s law and friction damping).\(^{54}\) The Federal Circuit agreed—in two separate opinions.\(^{55}\) In sum, a district court and the Federal Circuit disintegrated a patent claim into its distinct elements, ignored specific physical limitations set forth in some the claim elements, and concluded that the claimed manufacturing method was merely “directed to the utilization of a natural law (here, Hooke’s law and possibly other natural laws).”\(^{56}\)

As Judge Kimberly Moore aptly observed in her (first) dissenting opinion in American Axle, the panel’s reasoning is “goulash [that] is troubling and inconsistent with the patent statute and

\(^{47}\) Id. at 177.

\(^{48}\) The challenged patent claim in Diehr had four elements: (1) a definition of initial data, (2) collection of new data from the machine implementing the industrial process, (3) analysis of the data, and (4) control of the industrial process. Id. at 179 n.5. In TDE Petroleum, Claim 30 had essentially the same steps as the Diehr patent; after a preamble explicitly stating that the claim is directed to running a “well operation,” it detailed several elements in a process for operating an oil-drilling operation on an oil rig using a computer program.


\(^{50}\) See Diehr, 450 U.S. at 184 (“The respondents’ claims describe in detail a step-by-step method for accomplishing [a rubber-curing process]. Industrial processes such as this are the types which have historically been eligible to receive the protection of our patent laws.”).

\(^{51}\) The Federal Circuit ignored the entire patented invention.

\(^{52}\) See American Axle & Mfg., Inc. v. Neapco Holdings LLC, 939 F.3d 1355, 1359-60 (Fed. Cir. 2019), reh’g granted, opinion withdrawn, 966 F.3d 1294 (Fed. Cir. 2020), and opinion modified and superseded on reh’g, 967 F.3d 1285 (Fed. Cir. 2020).

\(^{53}\) See American Axle & Mfg., Inc. v. Neapco Holdings, LLC, 309 F. Supp. 3d 218, 221 (D. Del. 2018)).

\(^{54}\) Id. (quoting American Axle & Mfg., Inc. v. Neapco Holdings, LLC, 309 F. Supp. 3d 218-22 (D. Del. 2018)).

\(^{55}\) See supra note 48.

\(^{56}\) American Axle, 939 F.3d at 1366.
precedent.” Her remark was not hyperbole. All inventions are by necessity applications of abstract ideas and laws of nature, and there is no identifiable limiting principle or rule that constrains courts from choosing to dissect patents and invalidate them as abstract ideas or laws of nature under the Alice-Mayo inquiry. For this reason, courts are now applying the Alice-Mayo inquiry to invalidate patents under § 101 that, if the same analysis and tests were applied historically, would invalidate patents long issued to American innovators. This includes the first U.S. patent issued to Samuel Hopkins in 1790 for his discovery of a new method of making potash58 and Samuel Morse’s first claim on his electromagnetic telegraph (affirmed as valid by the Supreme Court in 1854).59 In American Axle, Judge Moore concluded her (first) dissent with the admonition that the “majority worries about result-oriented claiming; I am worried about result-oriented judicial action.” In her (second) dissent, she rightly identified the majority’s analysis as “chimeric” that is “bound to cause confusion.”60

The USPTO’s 2019 Patent Eligibility Guidelines Demonstrate Reform is Possible

Admittedly, the USPTO’s 2019 patent eligibility guidelines have brought back some stability and certainty back to the examination of the patent applications under the Alice-Mayo inquiry. Andrei Iancu, the USPTO Director at the time, stated that the purpose of the new guidelines was to “improve certainty and reliability” in the agency’s review of patent applications under § 101. Among others, one key reform in the USPTO’s 2019 guidelines, which is reflected in PERA, is to clearly demarcate the patent eligibility inquiry under § 101 from the separate but equally important patentability requirements of novelty (§ 102), nonobviousness (§ 103), disclosure (§ 112), and utility (§§ 101 and 112). One recent empirical study concludes that the 2019 guidelines have achieved this goal.62 (This may account for the slight 0.5% increase in patent applications in 2022, after mostly declining annual patent application numbers in the U.S. since 2018.)

However, the USPTO is limited in how much it can achieve with the 2019 guidelines, and ultimately the 2019 guidelines cannot solve the patent eligibility quagmire. First, the USPTO has no authority over how the courts will apply the Alice-Mayo inquiry to the patents that the USPTO grants if it concludes that an application meets all of the patentability requirements: § 101 (patent eligibility), § 102 (novelty), § 103 (nonobviousness), § 112 (disclosure), and utility (§§ 101 or 112). This is not a mere prediction. Shortly after the 2019 guidelines went into effect, the Federal Circuit

57 American Axle, 939 F.3d at 1375 (Moore, J., dissenting).
58 See U.S. Patent No. X00001 (granted July 31, 1790). Hopkins’ novel method comprised well-known steps at the time, such as burning and dissolving ash. His sole discovery was improving the timing and specific order of the steps. See Henry M. Payntor, The First Patent (rev., 1998), http://www.me.utexas.edu/~longoria/paynter/hmp/The_First_Patent.html.
59 See 56 U.S. (15 How.) 62, 112 (1854) (“We perceive no well-founded objection . . . to his right to a patent for the first seven inventions set forth in the specification of his claims.”); see also Adam Mossoff, O’Reilly v. Morse and Claiming a “Principle” in Antebellum Era Patent Law, 71 CASE W. RES. L. REV. 735, 750-51 (2020) (quoting and discussing claim one).
60 American Axle, 939 F.3d at 1375 (Moore, J., dissenting).
63 See infra notes 73-76, and accompanying text.
applied the *Alice-Mayo* inquiry in *Cleveland Clinic v. True Health Diagnostics* to invalidate another patent on a breakthrough diagnostic method for detecting heart disease.⁶⁴ In *Cleveland Clinic*, the patent owner explained that the Federal Circuit should defer to the 2019 guidelines to reach the same conclusion as the USPTO that its invention is patent eligible. The Federal Circuit rejected this argument outright, stating that “we are not bound by [the USPTO’s] guidance.”⁶⁵

Second, and just as important, the reforms represented by the 2019 guidelines can be easily undone by the same administrative fiat by the current or future Director of the USPTO. Thus, the 2019 guidelines cannot offer the necessary promise of long-term permanence and stability for the companies in the biopharmaceutical sector with multi-year time horizons and billions in research and development at stake. Inventors and companies making long-term R&D investment decisions need to rely on a stable set of legal rules in order to research, develop, and commercialize innovative medical treatments and other new technologies. Regulatory changes in examination guidelines that can be potentially changed with each change in the administration in the Executive Branch cannot provide this requisite stability and reliability. For these reasons, while providing greater certainty and stability for patent applicants, the 2019 guidelines can neither prevent the continued willy-nilly application of the *Alice-Mayo* inquiry by courts in invalidating issued patents nor provide the requisite long-term legal certainty and reliability to innovators.

**Data on the Impact of Uncertainty and Unreliability of the *Alice-Mayo* Inquiry**

Some recent data reveals a negative impact on innovators by the weakening of the U.S. patent system and by the *Alice-Mayo* inquiry. First, a recent survey study by Professor David Taylor of investors and representatives from companies in the innovation industries reported as its “first principal finding [that] investors who responded to the survey overwhelmingly believe patent eligibility is an important consideration when their firms decide whether to invest in companies developing technology.”⁶⁶ More specifically, Professor Taylor found that “overall 62% of the investors agreed that their firms were less likely to invest in a company developing technology if patent eligibility makes patents unavailable.”⁶⁷ Similar to other empirical studies,⁶⁸ Professor Taylor found that the significance of the availability of and reliance on patents varied between different sectors of the U.S. innovation economy, such as between biotechnology (higher reliance) and software/Internet services (lower reliance).⁶⁹ In fact, Professor Taylor found the most significant “negative impact of the Supreme Court’s eligibility cases generally on investment . . . in terms of its impact on public health: the biotechnology, medical device, and pharmaceutical industries.”⁷⁰ Still, Professor Taylor’s survey finds that “the results show the Court’s decisions [on

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⁶⁵ See id. at 1020 (“While we greatly respect the PTO’s expertise on all matters relating to patentability, including patent eligibility, we are not bound by its guidance. And, especially regarding the issue of patent eligibility and the efforts of the courts to determine the distinction between claims directed to natural laws and those directed to patent-eligible applications of those laws, we are mindful of the need for consistent application of our case law.”).


⁶⁷ Id. at 2027-28.


The patent eligibility doctrine have negatively impacted each and every area of technological development studied” in his survey, including even in software technologies. The negative relationship identified by Professor Taylor between the ill effects of the Alice-Mayo inquiry and investment decisions is in accord with the many studies summarized earlier that consistently find a positive relationship between reliable and effective patent rights and economic growth.

Other studies have provided additional data that the U.S. patent system is in distress, and that the U.S. innovation economy is faltering in important respects. The World Intellectual Property Organization (WIPO) reported a 1.6% drop in U.S. patent filings in 2018—the first decline since 2009 when the U.S. was in the midst of the Great Recession. In fact, the decline in U.S. patent applications in 2018 was not associated with either an economic recession or war, the two factors that have historically correlated with declines in patent applications in the U.S. Although patent applications increased again in 2019, they decreased in the ensuing years and only began to reverse this trend in 2022 with a moderate 0.5% increase over 2022. While it may be tempting to attribute the continued decline in U.S. patent filings in both 2020 and 2021 to the COVID-19 pandemic, the European Patent Office, South Korea, and China all experienced an increase in patent filings in 2021 while the U.S. experienced another decrease in patent filings that same year. Another revealing chart in the WIPO 2023 report on intellectual property data shows a flattening in the trend in U.S. patent filings since shortly after 2010, compared to varying positive growth trends in patent filings in the European Patent Office, South Korea, and China:

![Trend in patent applications for the top five offices, 1883-2022](https://www.wipo.int/edocs/pubdocs/en/wipo_pub_941_2023.pdf)

Source: Figure A6.

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71 Id. at 2028.
72 See supra notes 16-20, and accompanying text (summarizing these studies).
Lastly, in an article published in 2017, Kevin Madigan and I reported on a dataset created by Robert Sachs and David Kappos of 17,743 patent applications that had been filed in the United States, China, and Europe. As we explain in the article, the dataset identified 1,694 patent applications among 17,743 applications that received initial or final § 101 rejections and were ultimately abandoned in the United States, only to be granted patents by the European Patent Office, China, or both. Given that patent prosecution is an ongoing activity, Sachs continued to monitor the status of applications in the original dataset, and in September 2019 provided us with a revised dataset in which he revisited the data to examine the applications in more detail. As expected, Sachs found that a number of the applications now have issued U.S. family members (which means a related patent was issued), and some that were abandoned have had the abandonments withdrawn and were either pending or had been issued as patents. Moreover, some of the rejections were withdrawn prior to abandonment.

The revised Sachs-Kappos dataset further corrected for false positives of applications that were rejected under § 101 but for reasons other than the judicially created Alice-Mayo inquiry in assessing the patent eligibility of an invention or discovery. The revised dataset confirms that 1,310 applications were abandoned following either initial or final rejections under the Alice-Mayo inquiry for lack of patent eligible subject matter, and yet had issued patent family members in either China or Europe. Even accounting for the correction (1,310 versus the originally reported 1,694), the number of patent applications that fell victim to the Alice-Mayo inquiry, while being granted in foreign jurisdictions, is significant. It calls into question the “gold standard” status of the U.S. patent system as a driver of next-stage innovation. Even after the USPTO adopted the 2019 patent eligibility guidelines, which has had a positive effect on the examination of patent applications under the Alice-Mayo inquiry, innovators know that a patent will still be challenged in the courts, where they face the same uncertainty or even high probability of invalidation.

Another important finding in the 2019 revised Sachs-Kappos dataset is the stark overlap in legal grounds of rejection in the 1,310 applications that confirms an oft-repeated point that the Alice-Mayo inquiry conflates different patentability requirements in the different provisions of the Patent Act. Coding for different types of rejections in §§ 101, 102, 103 and 112 confirmed that the “inventive step” inquiry in step two of the Alice-Mayo inquiry blends the nonobviousness inquiry under § 103 with the patent eligibility inquiry under § 101. The largest single overlap in legal grounds for rejection was between §§ 101 and 103, with 379 (29%) of the total 1,310 applications. If the rejection(s) combined §§ 101, 103 and 112, the percentage jumps to over 50%, confirming that nonobviousness and overbreadth are being conflated with patent eligibility in significant numbers. This data reinforces the importance of the provisions in PERA that prohibit courts from conflating the separate patentability assessments under the different provisions of the Patent Act.

77 See Madigan & Mossoff, supra note 5.
79 See Bloss, supra note 62.
Conclusion

In the past two hundred years, Congress has repeatedly abrogated Supreme Court decisions and corrected doctrinal requirements in the patent statutes many times.\(^{80}\) It should do so again by enacting PERA and correct the Supreme Court’s mistaken interpretation of the patent eligibility requirement set forth in § 101. In fact, § 103 in the 1952 Patent Act was enacted by Congress for the same purpose. Section 103 abrogated numerous decisions by the Supreme Court reaching back almost a decade invalidating patents under an extremely restrictive “invention” test first created by the Supreme Court in 1941. In 1949, Justice Robert Jackson sardonically wrote “that the only patent that is valid is one which this Court has not been able to get its hands on.”\(^{81}\)

Justice Jackson’s lament in 1949 could just as easily have been written today about the Supreme Court’s judicial creation of the *Alice-Mayo* inquiry a decade ago. Similar to its enactment of § 103 in 1952, Congress should reform § 101 today. Congress should enact PERA, abrogating the *Alice-Mayo* inquiry and reestablishing the longstanding patent eligibility doctrine as only a threshold inquiry among the several distinct and separately enforceable patentability requirements of novelty (§ 102), utility (§ 101), nonobviousness (§ 103), disclosure (§ 112). In its procedural and substantive reforms, PERA achieves this laudable goal. Along with other necessary legislative reforms of the patent system, this return the U.S. back to the “gold standard” patent system that created and sustained U.S. technological leadership for the past two centuries.

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