STATEMENT OF

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BEFORE THE

SUBCOMMITTEE ON INTELLECTUAL PROPERTY
COMMITTEE ON THE JUDICIARY
UNITED STATES SENATE

"The Patent Eligibility Restoration Act –
Restoring Clarity, Certainty, and Predictability to the U.S. Patent System"

JANUARY 23, 2024

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

Thank you for the opportunity to discuss the Patent Eligibility Restoration Act ("PERA") and the importance of enacting bipartisan reforms to 35 U.S.C. § 101. I want to start by particularly thanking the Subcommittee for undertaking the critically important task of modernizing this statute, which in essence first appeared in the Patent Act of 1793. This most fundamental statute broadly defines what subject matter is eligible for a patent in the United States. A lot has changed in the world of technology since 1793, and courts and the Executive Branch will be forgiven for struggling to apply an 18th Century statute to 21st Century technology.

As Chairman Coons and Ranking Member Tillis recognized in introducing PERA, "all 12 judges of the United States Court of Appeals for the Federal Circuit have lamented the state of the law" when it comes to patent eligibility under Section 101.[1] The current state of the law is the result of many court decisions over the decades trying to determine whether modern technologies—such as computer software, DNA processing, and many others—fit into the categories for a patent defined in 1793, or whether they are subject to certain exceptions courts have imposed since then. The

* The views expressed herein are personal to me, and do not represent the views of Sullivan & Cromwell LLP or its clients.

[1] Office of U.S. Sen. Thom Tillis Press Release, *Tillis, Coons Introduce Landmark Legislation to Restore American Innovation* (June 22, 2023), *available at* https://www.tillis.senate.gov/2023/6/tillis-coons-introduce-landmark-legislation-to-restore-american-innovation.

patchwork of decisions over time, struggling to keep up with fast-changing technologies, has created significant confusion and uncertainty as to what is in and what is outside the bounds of the statute. These court decisions also have resulted in certain *de facto* rules—such that diagnostic techniques, for example, are generally not eligible for a patent in the United States—that Congress has never considered, debated, or passed into law. If the United States Government is not to issue patents for certain categories of inventions that would otherwise be part of the categories outlined in Section 101, then it is up to Congress to make that rule. In other words, Congress defined the categories of patent subject matter; if there are to be exceptions to those categories, they must likewise come from Congress.

The current state of the law has caused profound uncertainty amongst inventors, investors, and patent-law practitioners alike. In turn, this uncertainty and confusion has hurt American innovation, competition, and the economy. It also has threatened the Constitutional right to patent protection—a right that James Madison and the Founders saw as vital to the economic strength and growth of our nation.

The current state of the law has even sown confusion amongst the expert ranks of the hardworking patent examiners at the United States Patent and Trademark Office ("USPTO"). To address this issue, the USPTO promulgated guidelines in 2019 that synthesized the relevant caselaw and provided examiners and applicants a significantly improved framework for analyzing eligibility under Section 101. This has dramatically improved the analysis at the USPTO. For example, a study by the USPTO's Chief Economist has shown that "uncertainty about determinations of patent subject matter eligibility in the first action stage of patent examination for the relevant technologies decreased by 44% over the first year following publication of the 2019 [Revised Patent Subject Matter Eligibility Guidance] compared to the previous year."[2]

Courts, however, are independent and not bound by administrative guidelines. As a result, Congressional action is needed to determine affirmatively which categories of inventions should be deemed as statutorily unpatentable. Otherwise, as Justice Clarence Thomas warned, "exclusionary principle[s]" espoused by the Judiciary about Section 101 risk "swallow[ing] all of patent law."[3]

Fortunately, PERA provides the legislative vehicle for the United States to correct the state of the law. PERA expressly outlines certain categories that are not considered to be inventions eligible for a patent, and further indicates that courts are not to create any exceptions that are not in the statute. Once the categories—after debate and adjustment as appropriate—are settled on and passed into law, PERA will bring immediate certainty to Section 101. And it will prevent future uncertainty by "eliminat[ing]" "[a]ll judicial exceptions to patentability" and returning patent-eligibility decision making to Congress and legislative debate.

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[2] *See USPTO releases report on patent examination outcomes after the Supreme Court's Alice decision*, U.S. PATENT AND TRADEMARK OFFICE (Apr. 23, 2020), *available at* https://www.uspto.gov/about-us/news-updates/uspto-releases-report-patent-examination-outcomes-after-supreme-courts-alice.

[3] *Alice Corp. Pty. Ltd.* v. *CLS Bank Int'l*, 573 U.S. 208, 217 (2014).

My testimony proceeds as follows. First, I will document the current statutory landscape and how the different provisions of the patent code are meant to interact with each other. Next, I will describe how we reached the lamentable state of Section 101 law and the inflection point that our nation is faced with. Then, I will discuss administrative reform efforts that the USPTO has taken to remedy the uncertainty surrounding patent examination under current Section 101 jurisprudence. Finally, I will outline the solution to today's problem, which comes in the form of PERA and Congressional debate on patent-eligibility categories.

I commend Chairman Coons, Ranking Member Tillis, and the Members of the Subcommittee for holding this hearing to bring much-needed reforms to Section 101 and to set our nation on a path of innovation and success for the 21st Century.

I. The U.S. Patent Code

Like much of the legal history in the United States, U.S. patent law grew out of the English common law and legal traditions. Colonial judges and the issuance of colony-based patents dominated the patent landscape prior to the American Revolution. Recognizing the need for a federal patent system after burgeoning patent disputes amongst the States, James Madison and the other framers of the Constitution enshrined Congress with the power "[t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries."[4] With the inclusion of the Patent and Copyright Clause in the Constitution, the federal patent system was born. As Madison recognized, "the utility" of the Congressional power to regulate patents "will scarcely be questioned" because "[t]he public good fully coincides . . . with the claims of individuals."[5]

One of the first laws passed by Congress when the new country was founded was the Patent Act of 1790.[6] The law was quickly amended in 1793, and articulated for the first time the categories of invention that are eligible for patent: "any new and useful art, machine, manufacture or composition of matter, or any new and useful improvement on any art, machine, manufacture or composition of matter."[7] This formulation is still, almost verbatim, in today's Section 101.

Subsequently, the U.S. patent system quickly became mired in confusion and litigation, as the Judiciary was left to interpret the Patent and Copyright Clause and sparsely-worded patent laws in the beginning years of our country. Indeed, by the 1830s, "[a] considerable portion of all the patents granted [were] worthless and void, as conflicting with, and infringing upon one another, or upon, public rights not subject to patent privileges" and as "arising either from a want of due attention to the specifications of claim, or from the ignorance of the patentees of the state of the arts and manufactures, and of the inventions made in other countries, and even in our own."[8] As

[4] U.S. Const. art. I, § 8, cl. 8.

[5] THE FEDERALIST NO. 43 (James Madison) (Clinton Rossiter ed., 1961).

[6] *See* Patent Act of 1790, ch. 7, 1 Stat. 109 (1790).

[7] Patent Act of 1793, ch. 11, §1, 1 Stat. 318 (1793).

[8] *Senate Report Accompanying Senate Bill No. 239*, 24th Cong., 1st Sess. (Apr. 28, 1836).

a result, "[t]he country [became] flooded with patent monopolies," which were "embarrassing to bona fide patentees, whose rights [were] thus invaded on all sides" and were "embarrassing to the community generally, in the use of even the most common machinery and long-known improvements in the arts and common manufactures of the country."[9] "Out of this interference and collision of patents and privileges, a great number of lawsuits [arose], which [were] daily increasing in an alarming degree, onerous to the courts, ruinous to the parties, and injurious to society."[10]

In response to these early issues, Congress passed the Patent Act of 1836, which created the Patent Office and instituted a more robust patent examination process led by a professional cadre of patent examiners.[11] In the decades after the Patent Act of 1836, courts created many of the familiar patent-law doctrines and requirements that we know today, such as nonobviousness, limitations on patentable subject matter, the need for a written description to obtain a patent, and the idea of infringement under the doctrine of equivalents.[12]

Over a hundred years later, Congress once again recognized the need to step into the patent space. In one of the most important pieces of patent legislation, Congress passed the Patent Act of 1952, which created Title 35 of the U.S. Code and enshrined much of the judge-made doctrines that had developed since the signing of the Constitution.[13] As relevant to today's hearing, the Patent Act of 1952 codified four patent provisions—Sections 101, 102, 103, and 112—that are meant to interact with each other but, at the same time, are distinct from each other. Each provision is meant to govern the independent requirements of obtaining a patent from the USPTO. For example, if an applicant satisfies the requirements of one provision, the applicant may not satisfy one of the other provisions, in which case a patent should not issue. Understanding the roles of each of these provisions is pivotal to today's hearing on reforming Section 101.

Indeed, one of the great achievements of the Patent Act of 1952 was to separate the grounds of patentability, each with their own requirements and analysis. This created clarity and predictability in the patent process and greatly improved patent quality. Unfortunately, courts soon thereafter began to confuse these separate provisions. So much so that, by 1979, Judge Giles Rich—the principal author of the Patent Act of 1952—cautioned that the Judiciary needed to be wary of the "commingling of distinct statutory provisions which are conceptually unrelated, namely, those pertaining to the *Categories* of invention in [Section] 101 which May be patentable and to the *Conditions* for patentability demanded by the statute" found in Sections 102, 103, and 112.[14]

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[9] *Id.*

[10] *Id.*

[11] *See* Patent Act of 1836, ch. 357, 5 Stat. 117 (1836).

[12] *See, e.g.*, *Hotchkiss* v. *Greenwood*, 52 U.S. 248 (1850) (nonobviousness); *Le Roy* v. *Tatham*, 55 U.S. (14 How.) 156 (1853) (patentable subject matter); *O'Reilly* v. *Morse*, 56 U.S. 62 (1853) (need for a written description); *Winans* v. *Denmead*, 56 U.S. 330 (1854) (doctrine of equivalents).

[13] *See* Patent Act of 1952, ch. 950, 66 Stat. 797 (1952).

[14] *Application of Bergy*, 596 F.2d 952, 959 (C.C.P.A. 1979) (emphases added).

Forty-five years later, Judge Rich's concern has festered into the significant problem that currently dominates the confused state of the law. Over these years, courts have issued decisions that have rendered certain inventions unpatentable under Section 101, which addresses the subject-matter categories of patentability, when Sections 102, 103, or 112—which, respectively, address the conditional requirements of novelty, nonobviousness, and disclosure and specificity—are better placed to determine whether an invention merits a patent.

In order to return clarity to this area of law, Congress must reiterate that the various statutes should not be commingled and that Section 101 must be accorded its own analysis independent of the other conditions for patentability. Congress also must clarify that only Congress can define what categories of invention are eligible or ineligible for a patent to issue and then specify those categories in legislation.

To aid Congress in this endeavor, it is important to review the relevant statutes.

A. Section 101

The first provision is the statute at issue today—35 U.S.C. Section 101. Mirroring the language of the Patent Act of 1793, Section 101, titled "Inventions patentable," currently 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." This is a positive statute, outlining what categories are eligible for patent. There are no exceptions listed. Specifically, Congress determined that "any new and useful" (1) "process," (2) "machine," (3) "manufacture," or (4) "composition of matter" are subject-matter *categories* worthy of passing the threshold question as to whether a certain invention might deserve the patent protection guaranteed by the Constitution.

To be sure, these are broad categories. But they are broad because invention is by definition new, and we cannot (and should not) predict by statute where human creativity will lead us down the road. What may be unconceivable today could become a "process," "machine," "manufacture," or "composition of matter" conceivable and patentable in the future. The broad nature of these categories forms the genius behind the current patent code. If an invention fits into one of these categories, then it should pass the threshold test of Section 101 and move into the *conditional* tests of Sections 102, 103, and 112. But, as discussed below, further refinement of these categories is needed, in light of modern technologies and the difficulty courts have had recently in determining what is meant to be patentable and what is not.

B. Section 102

Moving past the threshold, categorical provision of Section 101, we arrive at the first *conditional* provision in Title 35—Section 102. As relevant for today, Section 102, titled "Conditions for patentability; novelty," provides: "A person shall be entitled to a patent unless (1) the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention; or (2) the claimed invention was described in a patent . . . or in an application for patent published or deemed published. . . in which the patent or application, as the case may be, names another inventor and was effectively filed before the effective filing date of the claimed invention." The text of Section 102 is clear: If an invention is not novel, then a patent should not issue. Viewing Sections 101 and 102 together, a patent application might fall into one of the categories of Section 101, but it may not be novel under Section 102. If the application does not satisfy Section 102's novelty condition, then that ends the discussion: the USPTO should not issue a patent. Importantly, however, whether something is novel is part of the analysis under Section 102, not 101.

C. Section 103

Section 103 presents the next conditional requirement in Title 35. Titled "Conditions for patentability; non-obvious subject matter," Section 103 states: "A patent for a claimed invention may not be obtained, notwithstanding that the claimed invention is not identically disclosed as set forth in [S]ection 102, if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains. Patentability shall not be negated by the manner in which the invention was made." Again, the text is abundantly clear: If the patent application discloses an obvious iteration of what has been disclosed previously, then a patent should not issue. So, while a purported invention might fall under one of the categories of Section 101 and might be novel under Section 102, if the purported invention is obvious under Section 103, then it is not worthy of patent protection.

Again, it is important not to commingle the various requirements. Whether a patent application discloses a tiny improvement that is merely an obvious variation of what is already known is to be analyzed under Section 103, not 101.

D. Section 112

Aside from satisfying Sections 101, 102, and 103, a patent application must satisfy another conditional requirement for a patent to issue—Section 112, which outlines a number of technical requirements for what the patent application must disclose and how specific the disclosure has to be. Section 112 also contains requirements for how the patent claims are to be written. Here too, the adequacy of disclosure and the specificity of the claims should be analyzed under Section 112, not 101.

E. Interplay Between Sections 101, 102, 103, and 112

In sum, the U.S. patent code has interconnected but importantly distinct provisions that govern when a patent should issue. Section 101 is a broad, categorical provision. If an invention constitutes a "process," "machine," "manufacture," or "composition of matter," then this threshold provision is satisfied. For a patent to issue, however, the application must also meet the conditional requirements of Sections 102, 103, and 112. All of these provisions represent separate lanes. The analytical standards for compliance with Sections 102, 103, and 112 are well-known to inventors, practitioners, and examiners based on years of caselaw and patent filings. Confusion ensues when these statutory lanes are crossed, such as by considering in Section 101 whether an invention is "new" enough or not described specifically enough, because the standards for such requirements outside Sections 102, 103, and 112 are unclear. In a well-functioning patent system, the categories of patentability under Section 101 should not be commingled with the conditions of patentability outlined in Sections 102, 103, and 112.

II. The Lamentable State of Section 101

As stated from the outset, Federal Circuit judges have lamented the state of Section 101 law. As Judge S. Jay Plager succinctly put it: "[T]he state of the law is such as to give little confidence that the outcome is necessarily correct. The law . . . renders it near impossible to know with any certainty whether the invention is or is not patent eligible" under Section 101.[15] Judge Alan D. Lourie has stated: "Resolution of patent-eligibility issues requires higher intervention, hopefully with ideas reflective of the best thinking that can be brought to bear on the subject."[16] Chief Judge Kimberly A. Moore has explained that the judge-made exceptions to Section 101 are "neither [] good idea[s], nor warranted by the statute," further detailing that a last hope "lies with the Supreme Court or Congress" to reverse these exceptions.[17] And Judge Pauline Newman has opined that "[S]ection 101 jurisprudence warrants attention" because, "[a]s summarized by Senators Chris Coons and Thom Tillis," "courts have clouded the line to exclude [certain inventions] like life-saving precision medicine and diagnostics, and studies showed that investors familiar with the current lack of clarity invest less in critical research and development in areas like medical diagnostics."[18]

While problems surrounding Section 101 have been brewing for some time now, the more-recent story of how we have arrived where we are today begins in 2010. In that year, the Supreme Court began its recent expansion of judicially-created exceptions "not required by the statutory text" of Section 101.[19] On a patent-by-patent basis as cases have made their ways up to the Court, the Court has supplemented the text of Section 101 with three broadly-worded judge-made exceptions

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[15] *Interval Licensing LLC* v. *AOL, Inc.*, 896 F.3d 1335, 1348 (Fed. Cir. 2018) (Plager, J., concurring in part).

[16] *Berkheimer* v. *HP Inc.*, 890 F.3d 1369, 1376 (Fed. Cir. 2018) (Lourie, J., concurring).

[17] *Athena Diagnostics, Inc.* v. *Mayo Collaborative Servs., LLC*, 927 F.3d 1333, 1363 (Fed. Cir. 2019) (Moore, J., dissenting).

[18] *Id.* at 1370 (Newman, J., dissenting) (internal quotation marks omitted).

[19] *Bilski* v. *Kappos*, 561 U.S. 593, 601 (2010).

to patentability. Under the "abstract idea" exception, for example, the Court determined that the concept of financial "hedging," reduced to a mathematical formula, is an "abstract idea" not worthy of being considered a "process" under Section 101.[20] Similarly, the Court held that a "computer-implemented scheme for mitigating 'settlement risk'" in financial transactions also was an "abstract idea," not worthy of receiving a patent.[21] Under another exception—"laws of nature"—the Court held that "processes that help doctors who use [certain] drugs to treat patients with autoimmune diseases determine whether a given dosage level is too low or too high" could not transform "unpatentable natural laws into patent-eligible" processes under Section 101.[22] Finally, under the "natural phenomena" exception, the Court held that the location of an isolated strand of DNA, in which certain mutations dramatically increase the risks of breast and ovarian cancers, is a "product of nature and not patent eligible" under Section 101.[23]

Although these cases naturally dealt with the specific technologies at issue in each, the Court's holdings were broadly worded and later applied by the lower courts to many other inventions and areas of technology. The problem with these judge-made exceptions is at least three-fold.

First, as discussed, many of these decisions commingle the sections of the patent code. For example, in determining that the concept of financial hedging is an "abstract idea," the Supreme Court focused on patent eligibility under Section 101.[24] But financial hedging is not new. Indeed, "Alfred W. Jones is generally believed to have started the first hedge fund in 1949, pursuing a strategy of buying stocks and hedging the positions with short sales."[25] Thus, Section 102's novelty condition—not Section 101's threshold categories for patent eligibility—is arguably the better placed provision to consider the patentable merits of financial hedging. Similarly, the Court used the "laws of nature" exception to Section 101 to determine that the processes doctors use to gauge whether drug administration dosages are too high or too low for patients are unpatentable under Section 101. At the same time, the Court reasoned that these processes are "well-understood, routine, [and] conventional activit[ies] previously engaged in by scientists in the field."[26] If so, aren't novelty (Section 102) and obviousness (Section 103) the better analytical frameworks? The Government, in an amicus brief, raised exactly this question.[27] The Court, dodging this question, responded that the Government's "approach . . . would make the 'law of nature' exception to [Section] 101 patentability a dead letter."[28] According to the Court, the Government's "approach

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[20] *Id.* at 611-612.

[21] *Alice Corp. Pty.*, 573 U.S. at 212.

[22] *Mayo Collaborative Servs.* v. *Prometheus Lab'ys, Inc.*, 566 U.S. 66, 72 (2012).

[23] *Ass'n for Molecular Pathology* v. *Myriad Genetics, Inc.*, 569 U.S. 576, 580 (2013).

[24] *See Bilski*, 561 U.S. at 611-612.

[25] William A. Trent, *Hedge Funds: Past, Present, and Future (Digest Summary)*, CFA INSTITUTE JOURNAL REVIEW (Nov. 1, 2007), *available at* https://rpc.cfainstitute.org/en/research/cfa-digest/2007/11/hedge-funds-past-present-and-future-digest-summary.

[26] *Mayo*, 566 U.S. at 73.

[27] *Id.* at 89.

[28] *Id.*

is therefore not consistent with prior law."[29] The Court's response missed the point. Other statutory provisions of the patent code—as prescribed by Congress—are the proper vehicles to evaluate such a patent claim, irrespective of the Court's prior caselaw. The list of decisions like these in the lower courts goes on and on, yet the problem remains the same: The commingling of these sections through adherence to extrastatutory exceptions to Section 101 creates confusion and unpredictability.

Second, why are there judicially-created exceptions in the first place? If the United States Government decides not to issue patents to certain types of creations that would otherwise fall within the four statutory categories, such as diagnostic techniques, it is up to Congress to consider, debate, and decide what those exclusions are. Courts are not well-suited to consider what are fundamentally major policy issues. The Constitution binds the Judiciary to hearing cases and controversies.[30] As such, courts must take cases as they come, and decisions must be limited to the facts and issues at-hand. This is not conducive to crafting broad patent policy and providing certainty to industry. In addition, decisions in one case as to whether an invention falls in or out of a judicial exception leaves future applicants, litigants, and courts to guess how the exception might apply to their inventions, which are often very different from the precedent.

This leads to the third part of the problem: The judicially-created exemptions are confusing. The guessing game of how to apply these decisions to other inventions leads to distorted legal outcomes and significant uncertainty. For example, in *Athena Diagnostics* v. *Mayo Collaborative Services*, the panel majority held that medical diagnostic methods for "diagnosing neurological disorders" are not patent eligible because they "are directed to a natural law and lack an inventive concept."[31] The panel majority reached this holding despite acknowledging that "Congress intended statutory subject matter to include anything under the sun that is made by man."[32] This is because the panel majority felt bound by the Supreme Court's exception analysis of an entirely different invention in *Mayo Collaborative Services* v. *Prometheus Laboratories*[33] (referred to as the *Mayo*/*Alice* framework by practitioners), stating: "[W]hether or not we as individual judges might agree or not that these claims only recite a natural law, the Supreme Court has effectively told us in *Mayo* that correlations between the presence of a biological material and a disease are laws of nature."[34] Various judges in four dissents to a denial of rehearing *en banc* voiced dismay over the confusing nature of the judge-made exceptions. The common theme amongst the dissents was the idea that one Supreme court decision—in this case, *Mayo*—could not be read so "broadly" to preclude any and all types of diagnostic methods that the Supreme Court inherently could not have considered in merely one case and controversy involving a separate patent.[35] As Chief Judge

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[29] *Id.*

[30] U.S. Const. art. III, § 2, cl. 1.

[31] *Athena Diagnostics, Inc.* v. *Mayo Collaborative Servs., LLC*, 915 F.3d 743, 746 (Fed. Cir. 2019).

[32] *Id.* at 749 (internal quotation marks omitted).

[33] *See generally* 566 U.S. 66 (2012).

[34] *Athena Diagnostics*, 915 F.3d at 753 & n.4 (internal citations omitted).

[35] *Athena Diagnostics*, 927 F.3d at 1363 (Moore, J., dissenting) ("To the extent that this Court has read *Mayo* so broadly . . . , we have erred. Doing so leaves *Mayo* at odds with the patent

Moore observed, however, the fact is that, "[s]ince *Mayo*, we have held every single diagnostic claim in every case before us ineligible."[36] Indeed, the Chief Judge said, "[w]e have turned *Mayo* into a per se rule that diagnostic kits and techniques are ineligible."[37]

Cases like *Athena Diagnostics* and the *Mayo*/*Alice* framework are indicative of the problem of essentially crafting patent policy through the Judiciary. Entire industries like the medical diagnostics industry—which is incredibly important to medical sciences and human health—are thrown into a state of confusion. Research and development and investment decisions are stymied because inventors and investors alike do not know whether they will receive the patent protections that Madison found as vital to the strength of our nation and our economy. Investments in other cutting-edge technologies like 5G, blockchain, and artificial intelligence (to name a few) also are threatened for this same reason. To be precise: if the United States is to deny patents to entire categories of invention, such as "diagnostic kits and techniques," this is a decision that Congress must debate and decide.

III. The 2019 USPTO Revised Patent Subject Matter Eligibility Guidance

The USPTO examines approximately 650,000 patent applications a year. Therefore, it is imperative for the Office to have predictable and consistent analytical frameworks for examination. The state of Section 101 jurisprudence created much confusion, consternation and unpredictability in examination. As a result, the USPTO has tried to alleviate this problem to the extent possible. For example, in 2019, the USPTO issued the Revised Patent Subject Matter Eligibility Guidance that synthesized the caselaw and clarified what types of inventions courts have excluded from Section 101 under the Supreme Court's *Mayo*/*Alice* framework.[38] Among other things, the guidance clarified that ineligible "abstract ideas" under the Supreme Court's precedent can be grouped as mathematical concepts, certain methods of organizing human activity, and mental processes. The guidance also explained that a patent claim that contains an element from an excluded category does not destroy patentability if the claim, as a whole, integrates that element into a practical application.

This guidance has been a tremendous success. As the USPTO Chief Economist explained, the 2019 guidance "caused a further, and much larger, decrease in the percentage of first office action

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statutes."); *see id.* at 1364 (Newman, J., dissenting) ("The majority's position is a flawed interpretation of the Court's decision in *Mayo*. . . . The Court did not hold that methods of diagnosis are subject to unique patent-eligibility rules. We have mistakenly enlarged the Court's holding, in substance and in application."); *id.* at 1371 (Stoll, J., dissenting) ("Our inflexible following of *Mayo* has created flawed decisions that are inconsistent with the precepts of *Mayo* and our patent system as a whole."); *id.* (O'Malley, J., dissenting) ("I agree with all my dissenting colleagues that our precedent applies the Supreme Court's holding in *Mayo* . . . too broadly.").

[36] *Id.* at 1352 (Moore, J., dissenting).

[37] *Id.* at 1354.

[38] *See 2019 Revised Patent Subject Matter Eligibility Guidance*, U.S. PATENT AND TRADEMARK OFFICE, 84 Fed. Reg. 50 (Jan. 7, 2019), *available at* https://www.govinfo.gov/content/pkg/FR-2019-01-07/pdf/2018-28282.pdf.

Section 101 rejections" than previous USPTO efforts.[39] Indeed, the likelihood of "receiving a first office action with a rejection for patent-ineligible subject matter . . . decreased by 25%."[40] Further, "[u]ncertainty in patent examination for [] affected technologies decreased by 44% in the 12 months following the issuance" of the guidance.[41] This helped reverse the 31% increase in the likelihood of receiving a rejection and the 26% increase in uncertainty that followed the Supreme Court's decision in *Alice*. Simply put, the data showed that this guidance had a positive impact on Section 101 analysis at the USPTO, to the public's benefit. Since then, much of these materials has been adopted in the USPTO's Manual of Patent Examination Procedure.[42]

While proceedings at the USPTO on Section 101 are therefore more predictable at this time, none of this changes the judicial approach in court, where confusion remains. This is because the USPTO's examination system and post-grant proceedings at the Patent Trial and Appeal Board are separate from the courts. The USPTO cannot take the lead on fixing the state of Section 101 jurisprudence because Congress has the constitutional mandate to craft patent law, which the administration and courts must follow. I think we can all agree that an all-encompassing discovery of nature, such as Isaac Newton's discovery of gravity, should not be patentable. But the point is that Congress should decide what should be patentable, and any exceptions to patentability should likewise be debated and clearly defined by Congress.

Technology has changed a lot since the Patent Act of 1793. However, Congress has not addressed the categories defined for patentable subject matter since then. Until now. I commend Senators Coons, Tillis and the Subcommittee for introducing PERA, holding this hearing, and hopefully advancing this important legislation.

IV. The Solution

There are multiple possible frameworks that would solve the confusion created by the current state of the law. In one approach, the statutory framework would have three components: (1) the eligibility categories are clearly defined; (2) any exceptions to those categories also are clearly defined; and (3) the conditions for when inventions that contain elements in an exempted category are still eligible for patentability are clearly specified. This is the general framework that PERA follows, although other frameworks also are possible.

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[39] Office of the Chief Economist, *Adjusting to Alice: USPTO patent examination outcomes after Alice Corp. v. CLS Bank International* 6, U.S. PATENT AND TRADEMARK OFFICE (Apr. 2020), *available at* https://www.uspto.gov/sites/default/files/documents/OCE-DH_AdjustingtoAlice.pdf.

[40] *Id.* at 1.

[41] *Id.*

[42] *See Manual of Patent Examination Procedure*, Ninth Edition, Revision 10.2019 (revised June 2020) §§ 2103-2106.07(c), U.S. PATENT AND TRADEMARK OFFICE, *available at* https://www.uspto.gov/web/offices/pac/mpep/index.html.

A. PERA Identifies The Categories Of Inventions That Should Be Patent Eligible.

The Constitution gives Congress the authority to craft patent law. Since 1793 and through today, Congress has defined four broad categories of inventions that are eligible for patent: (1) "process," (2) "machine," (3) "manufacture," and (4) "composition of matter." PERA does not change these categories; these categories remain broadly defined because innovation and invention are uncertain. What might be unconceivable today as a "process," "machine," "manufacture," or "composition of matter" might be conceivable tomorrow. Then, the conditional requirements of Sections 102, 103, and 112 should kick in and provide the framework for the novelty, obviousness, and disclosure and specificity analyses. PERA maintains this statutory scheme by stating that, "Sections 102, 103, and 112 . . . will continue to prescribe the requirements for obtaining a patent, but no such requirement will be used in determining patent eligibility." The statutes would no longer be commingled under PERA.

B. PERA Defines The Exceptions To Section 101.

If there are to be exceptions to the statutory categories, Congress should define them by statute, as part of its mandate to write patent laws. In other words, if the United States Government is to deny patents on certain categories of "process, machine, manufacture or composition of matter," the statute should clearly identify those categories. By eliminating confusing judicial exceptions, and clearly articulating what categories are in and what categories are out of the patent system, Congress will increase certainty and predictability, and will foster innovation, research and development, and investment, securing a bright future for American innovation and the economy well into the 21st Century and beyond.

To that end, PERA first eliminates "[a]ll judicial exceptions to patent eligibility." Then, PERA defines five categories that should not be patentable if they are claimed "as such," or on their own: (1) a "mathematical formula that is not part of a claimed invention;" (2) a "process that is substantially economic, financial, business, social, cultural, or artistic, even though not less than 1 step in the process refers to a machine or manufacture;" (3) a "process that is a mental process performed solely in the human mind[] or occurs in nature wholly independent of, and prior to, any human activity;" (4) an "unmodified human gene, as that gene exists in the human body;" and (5) an "unmodified natural material, as that material exists in nature." Whether these categories should be excluded, whether they should be amended, and whether others should be added, are issues Congress should debate. Once Congress decides, however, no further exceptions should be read into Section 101, without further legislation. In so doing, Congress will provide clarity to participants in the intellectual property space, industry, and the markets. Congress also will end the guessing game caused by current jurisprudence.

C. Congress Must Clearly Articulate When Inventions That Contain Elements In An Exempted Category Are Still Eligible for Patent.

Although certain subject matter is to be excluded from patent eligibility if it is claimed "as such" (on its own), this subject matter should not automatically destroy eligibility if it is part of a more complex invention that also claims eligible subject matter. The eligibility framework should articulate when such a combination becomes eligible. For example, although a mathematical

formula on its own is not eligible, a process for curing rubber that contains a formula may be.[43] PERA addresses this issue by clarifying the definition of what is "useful," and therefore patent eligible, to mean "that the invention or discovery has a specific and practical utility." It is important for the statute to specify that claims that contain matter that would otherwise be excluded if recited "as such," can still be eligible if they articulate an invention that "has a specific and practical utility." Because, as Justice Thomas recognized, "[a]t some level, 'all inventions . . . embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas.'"[44] Ensuring that examiners and courts do not write-off a patent on a statutory invention that merely includes some matter in an excluded category is pivotal to protecting the Constitutional right to patent protection.

V. Conclusion

In sum, after some 230 years, it is necessary to modernize Section 101. The state of Section 101 law has sown confusion amongst participants in the intellectual property space, has stymied research and development, investment, and innovation, and has hurt competition and the U.S. economy. Thankfully, the necessary reforms can be accomplished through PERA. These reforms will provide much needed clarity, predictability, and reliability to the U.S. patent system. And patents will once again, in the words of Thomas Jefferson, "give[] a spring to invention beyond [] conception."[45]

[43] *See Diamond* v. *Diehr*, 450 U.S. 175, 187 (1981) ("[R]espondents here do not seek to patent a mathematical formula. Instead, they seek patent protection for a process of curing synthetic rubber. Their process admittedly employs a well-known mathematical equation, but they do not seek to pre-empt the use of that equation. Rather, they seek only to foreclose from others the use of that equation in conjunction with all of the other steps in their claimed process."); *id.* at 192-193 ("Because we do not view respondents' claims as an attempt to patent a mathematical formula, but rather to be drawn to an industrial process for the molding of rubber products, we affirm [eligibility under Section 101.]").

[44] *Alice Corp.*, 573 U.S. at 217 (quoting *Mayo*, 566 U.S. at 71).

[45] Thomas Jefferson, *Letter to Benjamin Vaughan* (June 27, 1790).