

**Answers from Adam Mossoff
to Questions for the Record from Senator Alex Padilla
Senate Committee on the Judiciary, Subcommittee on Intellectual Property**

**“The Patent Eligibility Restoration Act – Restoring Clarity, Certainty,
and Predictability to the U.S. Patent System”
Tuesday, January 23, 2024**

1. What would be a concrete expected outcome for consumers should the *Patent Eligibility Restoration Act* (PERA) become law?

PERA would restore patent eligibility doctrine to the function of this doctrine in the U.S. patent system in the approximately 200 years prior to the Supreme Court’s creation of the *Mayo-Alice* inquiry. This is the patent system that spurred unprecedented economic growth that has benefitted all people. For this reason, consumers have an interest in patented innovation—everyone benefits from new and improved products and services from new drugs and medical treatments to high-tech products like computers and smartphones created by the investment incentives and opportunities provide by patents.

The famous insight in economics that “there is no such thing as a free lunch” has only one exception: innovation. Innovation drives economic growth by increasing the supply of new products and services made available to consumers in the marketplace, which reduces prices and increases overall social welfare. The result of innovation created through the incentives of the patent system has been an ever-increasing supply of new products and services at lower prices for consumers.

Although conventional wisdom and classical economics define patents as monopolies by which the incentive to invent is balanced against restraints on access and higher short-term prices, this is a fundamental misunderstanding of the nature and function of patents. Patents and other intellectual property rights, such as copyright and trademark, are not merely incentives to create, but also incentives to commercialize innovation. They are property rights. Thus, they represent an equal opportunity for any person who creates a new invention to secure the fruits of their labors, just like any person who works as a farmer or worker should have secured to them the fruits of their productive labors. Thus, patents, like all property rights, are the basis for commercialization activities, such as obtaining venture capital financing, entering into license deals, and creating new commercial structures for efficiently placing new products and services into the hands of consumers, such as the franchise business model invented by U.S. patent owners in the nineteenth century.

In the healthcare market, for example, this has meant an ever-increasing supply of cutting-edge medical treatments and increasing availability of older medical treatments that are now “off patent.” Patents not only function for companies to recoup billions in investments and thousands of labor hours in creating new drugs and other healthcare innovations, they facilitate extensive licensing and information-sharing agreements that efficiently distribute these healthcare innovations to patients. These extensive manufacturing, commercial

distribution, and information-sharing agreements were the launch pad for the unprecedented response by the biopharmaceutical sector in inventing, producing, and distributing billions of doses of the COVID-19 vaccines during the pandemic—an achievement never before accomplished by the biopharmaceutical sector since the invention and patent for Aspirin in 1900 and the invention of vaccines in the 18th century.¹ Although drug prices are a subject of policy debate, it is important to recognize that 95% of the essential medicines identified by the World Health Organization are in the public domain; thus, these drugs are available for production by any generic company wishing to sell them in the healthcare market in any country in the world, subject to regulatory approval by health officials.²

In the high-tech sector, the patent system has driven an explosion in new products and services at a rate never before seen in any sector of the global innovation economy. “Several empirical studies demonstrate that the observed pattern in high-tech industries, especially in the smartphone industry, is one of constant lower quality-adjusted prices, increased entry and competition, and higher performance standards.”³ This has occurred in one of the most patent-intensive sectors of the economy.⁴ This empirical evidence contracted the predictions of academics and economists almost twenty years ago that “patent holdup” and “patent thickets” on smartphones and other high-tech devices would raise prices for consumers and stifle innovation.⁵

All of this economic and historical evidence creates a strong presumption that reforming patent eligibility doctrine by returning it back to its longstanding function within the U.S. patent system would benefit consumers. Consumers will benefit from the continued creation of new products and services and more jobs. Overall, the U.S. will continue to experience economic growth and a rising standard of living for all consumers.

¹ See Adam Mossoff & Amesh Adalja, *Patents as a Driver of the Unprecedented Biomedical Response to COVID-19*, INQUIRY (2022), <https://journals.sagepub.com/doi/full/10.1177/00469580221124819>.

² See Steve Brachmann & Gene Quinn, *95 percent of WHO’s essential medicines are off-patent*, IPWATCHDOG (Sep. 12, 2016), <https://www.ipwatchdog.com/2016/09/12/essential-medicines-off-patent/id=72542/>.

³ Letter to Assistant Attorney Gen. Makan Delrahim (Feb. 13, 2018), on file at <https://cpip.gmu.edu/wp-content/uploads/sites/31/2018/02/Letter-to-DOJ-Supporting-Evidence-Based-Approach-to-Antitrust-Enforcement-of-IP.pdf>.

⁴ See Alexander Galetovic, Stephen Haber, & Lew Zaretzki, *An Estimate of the Average Cumulative Royalty Yield in the World Mobile Phone Industry: Theory, Measurement and Results*, 42 TELECOMM. POL’Y 263 (2018), <https://www.sciencedirect.com/science/article/pii/S0308596117302240>; Alexander Galetovic, Stephen Haber, & Ross Levine, *An Empirical Examination of Patent Hold Up*, 11 J. COMP. L. & ECON. 549 (2015), <https://academic.oup.com/jcle/article/11/3/549/800066>.

⁵ See Mark A. Lemley & Carl Shapiro, *Patent Holdup and Royalty Stacking*, 85 TEX. L. REV. 1991, 2044-45 (2007) (stating that “our model suggests that holdup problems in patent cases can be quite significant . . . imped[ing] innovation”).

2. What specific types of inventions would become newly eligible for a patent under PERA, that are currently not patentable?

A range of inventions across all sectors of the innovation economy would become eligible again that have been excluded as such from legal protection by the patent system, including classic industrial inventions, biotech inventions, and high-tech inventions.

There are far too many examples among the thousands of patent claims invalidated by courts and the PTAB applying the *Mayo-Alice* inquiry, and so a listing of illustrative examples will have to suffice here. What follows is a representative list of inventions that the USPTO and courts have long recognized as patentable inventions over the past hundred years. In some of these cases, the inventions represent *industrial processes*, an invention that was defined and recognized by the U.S. patent laws as patentable from as early as the 1790s. It bears emphasizing that these inventions are *patent eligible*, which means these inventions clearly fall under the meaning of “useful Arts” that the Constitution authorizes Congress to promote in creating a patent system. Whether these inventions are in fact new, nonobvious, or properly disclosed, per the patentability requirements set forth in other sections of the Patent Act, remains to be seen—but courts never reached these inquiries and instead summarily rejected them as a matter of law from the patent system as such.

Today, courts and the PTAB are applying the *Mayo-Alice* inquiry and concluding that manufacturing or other industrial processes, electronic devices and processes, and specific medical tests are only “abstract ideas” or “laws or nature” that are summarily excluded from patent protection as such. Some examples of these decisions are as follows:

An award-winning process for manufacturing steel. *See Ficep Corp. v. Peddinghaus Corp.*, 2023 WL 5346043 (Fed. Cir. 2023) (unpublished opinion) (holding that a steel manufacturing method is an unpatentable “abstract idea”).

A computer program for compressing data for increasing storage capacity. *See Realtime Data LLC v. Array Networks Inc.*, 2023 WL 4924814 (Fed. Cir. 2023) (unpublished opinion) (holding a computer program that compresses data to maximize storage capacity on a hard drive or other computer device is an unpatentable “abstract idea”).

A non-invasive medical test for evaluating a body’s rejection of an organ donor recipient. *See CareDx, Inc. v. Natera, Inc.*, 40 F.4th 1371 (Fed. Cir. 2022) (holding a non-invasive diagnostic test for determining rejection of recipient of organ donation is unpatentable “law of nature”).

A digital camera using multiple image sensors. *See Yu v. Apple Inc.*, 1 F.4th 1040 (Fed. Cir. 2021) (holding the use of image sensors in a digital camera is an unpatentable “abstract idea”).

An industrial method for manufacturing an automobile axle. *See American Axle & Manufacturing Inc. v. Neapco Holdings LLC*, 967 F.3d 1285 (Fed. Cir. 2020) (holding an industrial method for making automobile axle is an unpatentable “abstract idea”).

A portable electronic heart monitoring device to diagnose heart attacks and other cardiac events. *See Braemar Manufacturing, LLC v. ScottCare Corporation*, 816 Fed. Appx. 465 (Fed. Cir. 2020) (unpublished opinion) (holding a portable electronic heart monitoring device is an unpatentable “abstract idea”).

A computer system for controlling access to a cellular telecommunications system. *See Ericsson Inc. v. TCL Communication Technology Holdings*, 955 F.3d 1317 (Fed. Cir. 2020) (holding a computer system used in controlling access in modern cellular telecommunications systems is an “abstract idea”).

An electronic, wireless garage door opener. *See Chamberlain Group, Inc. v. Techtronic Industries Co.*, 935 F.3d 1341 (Fed. Cir. 2019) (holding an electronic garage door opener is an unpatentable “abstract idea”).

An innovative antibody test for diagnosing and treating neurological disorders. *See Athena Diagnostics, Inc. v. Mayo Collaborative Services, LLC*, 915 F.3d 743 (Fed. Cir. 2019) (holding an antibody test for neurological disorder is an unpatentable “natural law”).

A diagnostic test for detecting the risk of cardiovascular disease in a patient. *See The Cleveland Clinic Foundation v. True Health Diagnostics LLC*, 859 F.3d 1352 (Fed. Cir. 2017) (holding that diagnostic test for cardiovascular disease is an unpatentable “law of nature”).

An industrial process for operating an oil-drilling derrick. *See TDE Petroleum Data Solutions v. AKM Enterprise Inc.*, 657 Fed. Appx. 991 (Fed. Cir. 2016) (holding that a method of operation of an oil derrick is an unpatentable “abstract idea”).

A list of patent applications for *physical machine inventions*, such as a coffee machine, that examiners rejected as unpatentable “abstract ideas” under the *Mayo-Alice* inquiry is here: Dennis Crouch, *Eligibility and Physical Products*, PATENTLYO (March 1, 2024), <https://patentlyo.com/patent/2024/03/eligibility-physical-products.html>. All of these machines have long been patent-eligible inventions in the U.S. patent system, and they should be protected by patents assuming these inventions are novel, nonobvious, and properly disclosed in the patent applications.

3. How does the current state of the law impact smaller innovators and academic research?

The U.S. has long been regarded as the world leader in securing property rights in technological innovation, granting patents for next-generation inventions and discoveries when the rest of the world hesitated. Professor Zorina Kahn, a leading economic historian, concludes that the U.S. patent system has been successful precisely because it consistently

secured legal protection for the fruits of inventors' labors.⁶ This truth is confirmed by the spread of patent laws across the world throughout the nineteenth and early twentieth centuries that were explicitly modeled on the U.S. system.⁷ This pattern of U.S. leadership in securing patents in the next wave of innovation gave birth to the biotechnology, high-tech, and mobile revolutions of the past fifty years.⁸

With this important background context in mind, the economic impact of returning patent eligibility doctrine back to its historical role in the U.S. patent system—a mere threshold inquiry or coarse filter before the more searching and stringent patentability requirements of utility, novelty, nonobviousness, and disclosure—will be positive. The promise of reliable and effective patent rights in the fruits of their inventive labors will reestablish incentives for innovators, startups, and successful companies to make long-term R&D investments. The result will be the same technological and commercial growth that has been the hallmark of the U.S. innovation economy since the early nineteenth century.

4. How does the approach to subject matter eligibility in PERA compare with that taken by other countries? And is there research showing a difference in quality and access to innovation for consumers, and ability to compete for innovators here in the U.S., relative to those jurisdictions?

I am not an expert on international law or other countries' patent law systems such that I can attest to the doctrinal details of how they adjudicate patent eligibility. With that said, other countries have not followed the U.S. in changing their patent-eligibility rules, and a published study of patent applications in the U.S., China, and Europe in the years after the Supreme Court created the *Mayo-Alice* inquiry in 2014 concluded that a significant number of inventions were secured by patents in China and Europe, but denied patent protection in the U.S.⁹ In 2019, I and my co-author published an updated review of the original dataset, finding 1,310 patent applications were abandoned following either initial or final rejections under the *Alice-Mayo* inquiry for lack of patent-eligible subject matter, and yet these same

⁶ B. Zorina Kahn, *Trolls and Other Patent Inventions: Economic History and the Patent Controversy in the Twenty-First Century*, 21 GEO. MASON L. REV. 825, 855 (2014) (discussing the development of IP institutions in the United States and describing how “[i]ntellectual property institutions were successful in the United States largely because they ensured open access to creative individuals, decentralized decision making and extensive markets for technology, and strong legal enforcement of such rights.”); see also Adam Mossoff, *A Brief History of Software Patents (and Why They’re Valid)*, 56 ARIZ. L. REV. SYLLABUS 62, 79 (2014) (“The American patent system has succeeded because it has secured property rights in the new innovation that has come about with each new era—and it has secured the same property rights for all types of new inventions, whether in the Industrial Revolution or in the Digital Revolution.”).

⁷ See Kahn, *supra* note 6, at 855 (discussing how intellectual property rights played a prominent role in the nineteenth century in the U.S. overtaking other nations as a leader in industry and technology and led to “many countries voluntarily adopting the distinctive U.S. rules and standards”).

⁸ See generally Kevin Madigan & Adam Mossoff, *Turning Gold to Lead: How Patent Eligibility Doctrine is Undermining U.S. Leadership in Innovation*, 24 GEO. MASON L. REV. 939 (2017).

⁹ See Kevin Madigan & Adam Mossoff, *Turning Gold to Lead: How Patent Eligibility Doctrine is Undermining U.S. Leadership in Innovation*, 24 GEO. MASON L. REV. 939 (2017).

inventions had patent family members issued in China, Europe, or both.¹⁰ This data indicates that the U.S. risks losing its global technological leadership, as global competitors like China displace it in securing patents in biotech and high-tech inventions that will lead to new products and services with next-generation technologies.

5. Can you provide an example of a patent denied under the Alice/Mayo framework that best illustrates the concerns you’ve raised about the existing patent system?

Please see my answer to Question 2 above. All of these real-world inventions were rejected as “abstract ideas” or “laws of nature” by courts applying the *Mayo-Alice* inquiry, and they all illustrate dramatically the legal and policy problems created by this decade-old patent-eligibility doctrine. The U.S. no longer predictably secures classic industrial inventions, nor the inventions driving new medical care and high-tech devices in these cutting-edge sectors of the U.S. innovation economy. This undermines the core constitutional function of the patent system in “promoting the useful Arts” that has benefited everyone with new products and services that have modern life a veritable miracle by any historical standard.

6. Mr. Jones’s testimony included proposed alternative approaches to addressing concerns with the state of Section 101. He proposed the two possible alternative approaches: (1) “[] a narrow solution that is targeted specifically and exclusively at any areas of technology for which the current jurisprudence has created significant and empirically demonstrable impediments to obtaining patent protection to the extent that such impediments can be shown to have resulted in clearly insufficient levels of R&D investment.”; (2) “a broader legislative solution that tethers patentability to its underlying policy purpose by explicitly limiting the availability of patent protection to only those inventions that embody an advance in technology.” What are your views on these proposals as compared to the approach of PERA?

These two proposals by Mr. Jones are not proper solutions to the quagmire in patent-eligibility doctrine produced by the Supreme Court, especially as compared to PERA.

First, economists have long recognized that the success of the U.S. patent system has been the securing of reliable and effective property rights to all inventors, regardless of their technological innovations. In other words, a key feature of the success of the U.S. patent system is its *technology neutrality*. None of the provisions of the Patent Act setting forth patent eligibility or patentability requirements, such as novelty, utility, nonobviousness, or disclosure are directed to any specific technological area or sector of the innovation economy. From the Patent Act of 1790 through the America Invents Act of 2011, the U.S. patent system has applied the same legal requirements to all inventions. This is the principle of *technology neutrality*. It is the patent law version of the equal protection principle: a right to property should be secured equally to all people regardless of who they are and what they own. Mr. Jones’s first proposal calls for technology-specific or commercial-sector specific amendments to the patent system, which threatens to Balkanize the patent

¹⁰ See Kevin Madigan & Adam Mossoff, *Five Years Later, the U.S. Patent System is Still Turning Gold to Lead*, IPWATCHDOG (Dec. 15, 2019), <https://www.ipwatchdog.com/2019/12/15/five-years-later-the-us-patent-system-is-still-turning-gold-to-lead/id=116984/>.

system and undermine its efficient operation as a property rights system that promotes innovation, especially innovation that is unpredictable and unknown as to what will occur in the future. The Supreme Court expressly recognized this key legal feature in the Patent Act in its proper decision in 1980 when it approved the patent eligibility of new biotech innovations under § 101, stating “Congress employed broad general language in drafting § 101 precisely because such inventions are often unforeseeable.”¹¹

Second, there is further problem with the proposal that Congress can only amend the patent statutes when there are “empirically demonstrable impediments . . . shown to have resulted in clearly insufficient levels of R&D investment.” This creates a standard for patent reform that is, at best, impossible to meet, or, at worst, when it is met and such evidence exists of “empirically demonstrable” reductions in what is deemed to be an “insufficient levels of R&D investment,” the damage to the U.S. innovation economy has already occurred and the U.S. has now lost its technological leadership due to reduced R&D relative to global competitors like China. Moreover, there is an inherent contradiction in Mr. Jones’s claim that this proposal is somehow more determinate or certain than PERA, because he does not offer any empirical basis by which he purports to define what counts as “insufficient levels of R&D.” This is no more empirically known, and it is likely unknowable, than what counts as an “abstract idea” or “law of nature” under the *Mayo-Alice* inquiry. If Mr. Jones’s standard for legal reform were adopted, it would be virtually impossible to amend or extend patent protection to any new innovations being created and deployed from the Industrial Revolution to today’s biotech and mobile revolutions. Certainly, it would have been impossible to enact the 1952 Patent Act, as its reforms would not have met this empirical standard, nor would have any patent statute have met this standard reaching back to the first Patent Act of 1790.

Finally, with respect to his second proposal that patent protections be limited to “advances in technology,” this fails the purported empirical standard proposed by Mr. Jones in his first proposal. On the one hand, it is never clear if new innovations, such as the biotech and computer innovations secured as patent eligible by the Supreme Court in the early 1980s under the broad terms of § 101,¹² represent actual “advances in technology.” What counts as an “advance in technology” is the question at the heart of the reform effort represented by PERA, in which real-world technologies in industrial and consumer machines, drugs, medical tests, and other innovations are now rejected by courts and the USPTO as ineligible from protection by the patent system as such. On the other hand, Mr. Jones appears in his proposal to limit “technology” to an excessively narrow conception of “technology,” such as machines, computer hardware, industrial products, etc. But the U.S. patent system has never limited itself in such ways. From the very beginning, Congress adopted a very expansive conception of the “useful Arts” that is authorized in the Constitution to promote with a patent system, and thus the U.S. protected processes, including even business methods from the first decades of the country through the nineteenth and twentieth centuries, as I explained in my written testimony submitted for the hearing on January 23,

¹¹ *Diamond v. Chakrabarty*, 447 U.S. 303, 316 (1980).

¹² *Id.* (biotech innovations are patent-eligible inventions); *Diamond v. Diehr*, U.S. 175 (1981) (computer software programs applied to real-world processes are patent-eligible inventions).

2024. Thus, Mr. Jones’s second proposal is a radical change to the patent system that would codify an extremely narrow conception of patent eligibility—the same narrow conception of patent eligibility that has plagued innovators since the Supreme Court created the *Mayo-Alice* inquiry as a judicial gloss on § 101.

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**“The Patent Eligibility Restoration Act – Restoring Clarity, Certainty,
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- 1. In 2018 judges on the Federal Circuit issued a concurring opinion to the court’s denial of *en banc* rehearing in *Berkheimer v. HP Inc.*, in which they stated that “the law needs clarification by higher authority, perhaps by Congress, to work its way out of what so many in the innovation field consider are [Section] 101 problems.”**

Has anything changed in your opinion since 2018 that would mitigate the concerns raised by these judges or have things actually gotten worse?

The indeterminacy and excessively restrictive conception of patent-eligible inventions created by the *Mayo-Alice* inquiry continues to impose significant harms on U.S. innovators and the U.S. innovation economy more generally. It is hard to assess if things have become worse, because the *Mayo-Alice* inquiry quickly brought the patent system to a nadir not seen since the Supreme Court created in 1941 the infamous “flash of creative genius” test for a patentable invention.¹ By 1949, Justice Robert Jackson observed “that the only patent that is valid is one which this Court has not been able to get its hands on.”² This indeterminate and incredibly restrictive test for what counts as an innovative act of invention ultimately led Congress to reform the patent system in 1952 by enacting § 103 as a new statutory patentability requirement (now known as “nonobviousness”).³ Innovators today are now in the same situation under the judicially-created gloss on § 101 in the *Mayo-Alice* inquiry they were in 1949, as courts are applying the judicial exclusionary rule,⁴ continuing to rule that numerous legitimate inventions are excluded from the patent system as such (without any inquiry into the novelty, utility, nonobviousness, or disclosure requirements).

Since 2018, courts have continued to invalidate patents on manufacturing or other industrial processes, electronic devices and processes, and specific medical tests, that judges subjectively deem to be only “abstract ideas” or “laws or nature” that are summarily excluded from patent protection as such. These include (among many others in a list too long to include here):

An award-winning innovative process for manufacturing steel. *See Ficep Corp. v. Peddinghaus Corp.*, 2023 WL 5346043 (Fed. Cir. 2023) (unpublished opinion) (holding that a steel manufacturing method is an unpatentable “abstract idea”).

¹ *Cuno Engineering Corp. v. Automatic Devices Corp.*, 314 U.S. 84, 91 (1941).

² *Jungersen v. Ostby & Barton Co.*, 335 U.S. 560, 572 (1949) (Jackson, J., dissenting).

³ *See* Patent Act of 1952, Pub. L. No. 82-593, § 103, 66 Stat. 792, 798.

⁴ *See* *Bilski v. Kappos*, 561 U.S. 593, 601–02 (2010) (“The Court’s precedents provide three specific exceptions to § 101’s broad patent-eligibility principles: ‘laws of nature, physical phenomena, and abstract ideas.’ While these exceptions are not required by the statutory text . . . these exceptions have defined the reach of the statute as a matter of statutory stare decisis going back 150 years.”).

A computer program for compressing data for increasing storage capacity. *See* Realtime Data LLC v. Array Networks Inc., 2023 WL 4924814 (Fed. Cir. 2023) (unpublished opinion) (holding a computer program that compresses data to maximize storage capacity on a hard drive or other computer device is an unpatentable “abstract idea”).

A non-invasive medical test for evaluating a body’s rejection of an organ donor recipient. *See* CareDx, Inc. v. Natera, Inc., 40 F.4th 1371 (Fed. Cir. 2022) (holding a non-invasive diagnostic test for determining rejection of recipient of organ donation is unpatentable “law of nature”).

A digital camera using multiple image sensors. *See* Yu v. Apple Inc., 1 F.4th 1040 (Fed. Cir. 2021) (holding the use of image sensors in a digital camera is an unpatentable “abstract idea”).

An industrial method for manufacturing an automobile axle. *See* American Axle & Manufacturing Inc. v. Neapco Holdings LLC, 967 F.3d 1285 (Fed. Cir. 2020) (holding an industrial method for making automobile axle is an unpatentable “abstract idea”).

A portable electronic heart monitoring device to diagnose heart attacks and other cardiac events. *See* Braemar Manufacturing, LLC v. ScottCare Corporation, 816 Fed. Appx. 465 (Fed. Cir. 2020) (unpublished opinion) (holding a portable electronic heart monitoring device is an unpatentable “abstract idea”).

A computer system for controlling access to a cellular telecommunications system. *See* Ericsson Inc. v. TCL Communication Technology Holdings, 955 F.3d 1317 (Fed. Cir. 2020) (holding a computer system used in controlling access in modern cellular telecommunications systems is an “abstract idea”).

An electronic, wireless garage door opener. *See* Chamberlain Group, Inc. v. Techtronic Industries Co., 935 F.3d 1341 (Fed. Cir. 2019) (holding an electronic garage door opener is an unpatentable “abstract idea”).

An innovative antibody test for diagnosing and treating neurological disorders. *See* Athena Diagnostics, Inc. v. Mayo Collaborative Services, LLC, 915 F.3d 743 (Fed. Cir. 2019) (holding an antibody test for neurological disorder is an unpatentable “natural law”).

A list of patent applications for *physical machine inventions*, such as a coffee machine, that examiners at the USPTO have recently rejected as unpatentable “abstract ideas” under the *Mayo-Alice* inquiry is here: Dennis Crouch, *Eligibility and Physical Products*, PatentlyO (March 1, 2024), <https://patentlyo.com/patent/2024/03/eligibility-physical-products.html>.

If courts and the USPTO are now excluding as such from the patent system inventions in steel manufacturing, automobile manufacturing, oil drilling, electronic garage door openers, and coffee machines, among others, regardless of whether these are new, useful, and nonobvious inventions, then it is reasonable to say that inventors are in an even worse predicament than they were in 2018 when judges on the Federal Circuit called for reform of § 101.

2. **In response to a March 2021 letter from myself and Senator Cotton, the USPTO launched the “Deferred Subject Matter Eligibility Response Pilot Program,” which invited selected patent applicants to defer consideration of subject–matter eligibility issues until other patentability issues are resolved.**

What are your thoughts on deferring consideration of subject–matter eligibility issues during patent examination?

The U.S. Patent & Trademark Office Pilot Program on deferred patent eligibility consideration (“pilot program”) is one possible response to the indeterminacy and restrictive scope of patent eligibility created by the Supreme Court in its *Mayo-Alice* inquiry, but the pilot program is neither a preferred nor complete solution. This is the case for at least several reasons.

First, in questions of law like the *Mayo-Alice* inquiry, courts are not required to follow the USPTO’s guidelines or decisions resulting therefrom; in fact, the Court of Appeals for the Federal Circuit has explicitly rejected arguments by patent owners that it should defer to the patent-eligibility rules created by the USPTO, stating “we are not bound by [the USPTO’s] guidance.”⁵ Thus, when the USPTO grants a patent under the deferred program, district courts and the Federal Circuit will continue to apply *de novo* the patent-eligibility requirement in § 101, as construed by the Supreme Court in the *Mayo-Alice* inquiry.

Second, and related to the first reason, the pilot program is only a procedural response within the substantive doctrine set forth by the Supreme Court in the *Mayo-Alice* inquiry, and thus the pilot program does not address the legal deficiencies created by *Mayo-Alice* inquiry. The USPTO has no substantive rulemaking authority in its examination of patent applications, and thus it must follow the doctrines created by the Supreme Court in its interpretation of the patent statutes or in its continuing application of longstanding common law doctrines in the patent system, such as, among others, the exclusionary rules for patent eligibility, patent exhaustion, and the doctrine of equivalents.⁶ Thus, USPTO guidelines and other examination practices

⁵ *Cleveland Clinic Found. v. True Health Diagnostics LLC*, 760 Fed. Appx. 1013, 1020 (Fed. Cir. 2019) (nonprecedential) (“While we greatly respect the PTO’s expertise on all matters relating to patentability, including patent eligibility, we are not bound by its guidance”).

⁶ *See, e.g., Bilski v. Kappos*, 561 U.S. 593, 601–02 (2010) (“The Court’s precedents provide three specific exceptions to § 101’s broad patent-eligibility principles: ‘laws of nature, physical phenomena, and abstract ideas.’ While these exceptions are not required by the statutory text . . . these exceptions have defined the reach of the statute as a matter of statutory *stare decisis* going back 150 years.” (citation omitted) (quoting *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980))); *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 739 (2002) (“[T]he doctrine of equivalents and the rule of prosecution history estoppel are settled law. The responsibility for changing them rests with Congress. Fundamental alterations in these rules risk destroying the legitimate expectations of inventors in their property.”) (citation omitted); Craig Allen Nard, *Legal Forms and the Common Law of Patents*, 90 B.U. L. REV. 51, 54 n.12 (2010) (stating that “the entire body of jurisprudence relating to non-literal infringement, claim interpretation, repair-construction, and patent exhaustion is judge-made law”); Adam Mossoff, *Statutes, Common Law Rights, and the Mistaken Classification of Patents as Public Rights*, 104 IOWA L. REV. 2591, 2611–2612 (2019) (discussing same point and highlighting patent eligibility doctrine as “a creation solely of the courts in now classic decisions in the early nineteenth century”).

cannot ultimately resolve the fundamental problems in law and economic policy created by the indeterminacy and cramped eligibility requirements of the *Mayo-Alice* inquiry.

3.

a. How has the current state of patent eligibility inhibited the development of next generation technologies?

The innovators and companies working in the U.S. innovation economy to create new inventions and to efficiently commercialize these inventions the benefit of consumers have identified the negative impact in their activities wrought by the *Mayo-Alice* inquiry.⁷ In one notable study, Professor David 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.”⁸ 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.”⁹ The *negative* relationship identified by Professor Taylor between the ill effects of the *Alice-Mayo* inquiry and investment decisions in new technologies is consistent with numerous economic and historical studies that consistently find a *positive* relationship between reliable and effective patent rights and economic growth.¹⁰

The function of intellectual property rights is to incentive investments in the research and development of new inventions and to incentive investments in the commercial mechanisms to deploy these new innovations in the marketplace. This is an application of the long-recognized economic insight that reliable and effective property rights are a necessary foundation for economic investment and growth of innovation economies.¹¹ Economists and historians have consistently found a strong correlation—the same strong correlation between

⁷ See, e.g., David O. Taylor, *Patent Eligibility and Investment*, 41 CARDOZO L. REV. 2019 (2020).

⁸ *Id.* at 2027-28.

⁹ Taylor, *supra* note **Error! Bookmark not defined.**, at 2030.

¹⁰ See, e.g., 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 PROPERTY* (2021); DANIEL SPULBER, *THE CASE FOR PATENTS* (2021); B. ZORINA KHAN, *INVENTING IDEAS: PATENTS, PRIZES, AND THE KNOWLEDGE ECONOMY* (2020); Stephen Haber, *Innovation, Not Manna from Heaven* (Hoover Institution, Sep. 15, 2020); B. Zorina Khan, *Trolls and Other Patent Inventions: Economic History and the Patent Controversy in the Twenty-First Century*, 21 GEO. MASON L. REV. 825, 837-39 (2014); Naomi R. Lamoreaux, Kenneth L. Sokoloff & Dhanoos Sutthiphisal, *Patent Alchemy: The Market for Technology in US History*, BUS. HIST. REV. (Spring 2013).

¹¹ See Stephen Haber, *Patents and the Wealth of Nations*, 23 GEO. MASON L. REV. 811, 811 (2016) (“There is abundant evidence from economics and history that the world’s wealthy countries grew rich because they had well-developed systems of private property. Clearly defined and impartially enforced property rights were crucial to economic development”); see also HERNANDO DE SOTO, *THE MYSTERY OF CAPITAL: WHY CAPITALISM TRIUMPHS IN THE WEST AND FAILS EVERYWHERE ELSE* 74 (2000) (“Perhaps the most significant cost was caused by the absence of institutions that create incentives for people to seize economic and social opportunities to specialize within the marketplace. We found that people who could not operate within the law also could not hold property efficiently or enforce contracts through the courts Being unable to raise money for investment, they could not achieve economies of scale or protect their innovations through royalties and patents.”).

reliable and effective property rights in land and other tangible assets—between reliable and effective patent rights and growing innovation economies.¹²

Ultimately, given the function of the patent system as a driver of new technologies and new commercial activities and markets, there is a necessary time lag between the destabilization of the legal reliability of property rights in inventions and the observable impact this has on new technologies. For example, 5G was deployed in the telecommunications sector after approximately a decade of research and development, and the average drug approved for use by patients is the result of approximately 10-15 years and billions of dollars invested in research and development.

The *Alice-Mayo* inquiry is only ten years old. Thus, as basic matter of economics, we will not observe the full impact of this legal doctrine on next-generation technologies, such as reduced rates of new drugs or of new high-tech innovations in AI or mobile devices, until well after the point in which the negative investment decisions identified by Professor Taylor and others begin to reveal their influence in fewer products and services. This reduction in innovation by the destabilization of patents, or the outright withdrawal of legal security in property rights in new inventions previously protected by the patent system, is not an uninformed predictive theory, it is well-established by economics and history. If Congress waits until after this well-established causal relationship repeats itself in the next decade, it will be too late to undue to the damage in terms of lost innovation, hampered economic growth, and reduced quality of life, especially in comparison to global competitors like China that are implementing legal systems, such as a reliable patent system, for the purpose of displacing the U.S. as the longstanding global technological leader.

b. Can you quantify, in easy to understand terms, the economic impact of the current state of patent eligibility?

The current state of the law is, at best, unpredictable or, at worst, predictable for an inventor who knows that there will be no legal protection in the fruits of one's productive labors. Given the economic reality of the innovations secured by the patent system, which by necessity are developed into commercial products after many years of research and development, we will not see the specific data on these negative effects until many years after the creation of a legal doctrine. Still, the early evidence in surveys and other reports, as well as the comparative data on rejections of patent applications in the U.S. in which the same inventions were secured by patents in China and Europe, is creating an early picture that confirms what economics and political theory predict will happen to economies when people are not guaranteed rights to property and contract in their work product. In sum, the initial data is demonstrating a trend of reduced patenting, reduced innovation, and ultimately reduced economic growth and technological leadership relative to global competitors like China.

¹² See Stephen Haber, *Patents and the Wealth of Nations*, 23 GEO. MASON L. REV. 811 (2016); Jonathan M. Barnett, *Patent Tigers: The New Geography of Global Innovation*, 2 CRITERION J. INNOVATION 429 (2017).

This entirely consistently with what we know from history, political theory, and economics about the key function of the protection of property and contract rights in growing innovation economies. As a matter of economic and moral principles, an inventor is just like a farmer who labors for a year in tilling soil, planting seeds, growing the crops, protecting the crops from insects and other threats, and harvesting the crops for sale in the market to the benefit of consumers. Today, inventors working on new technologies like 5G in our mobile devices or new drugs for cancer, diabetes, and hepatitis, invest billions of dollars and labor for more than a decade to create the final products used by consumers. Inventors and farmers deserve to be protected in the fruits of their productive labors. As an economic matter, inventors and farmers will not invest the time, money, and effort if they do not have certainty and security in the exclusive use of the values they create, and without reliable and effective property rights, there will be no contracts, licenses or other commercial innovations to efficiently and cheaply deploy new inventions as consumer products and services. This is the moral and economic function of all property rights—whether in farms, factories, computers, or inventions.

c. In other words, how much is the current uncertainty costing our economy in terms of jobs, innovation, and development?

As noted in the prior answer (Question 3(b)), the patent system fosters what economists call “dynamic efficiency” in the U.S. innovation economy through incentivizing the creation and commercialization of new inventions. Right now, we are all benefiting from research and development programs that began approximately a decade or more ago, such as in the initial investments in 5G, AI, and the CRISPR gene editing and mRNA technologies. These new products and services, and the economic activities, jobs, and overall growth in the innovation economy they created are the result of the reliable and effective patent rights secured to innovators—before the Supreme Court created the *Mayo-Alice* inquiry and the resulting quagmire in patent eligibility doctrine.

The fundamental commercial uncertainty created for inventors since 2014 in whether they will be protected in their inventive labors reduces their incentive to invest in highly risky, long-term research and to develop these new technologies and medical treatments. More specifically, this uncertainty redirects investments toward other less risky and less innovative commercial activities, such as investments in entertainment sectors and food services. In the aggregate, one might see continued or even increased overall levels of venture capital investments, but these investments are not being made in the sectors of the economy that produce innovation in the twenty-first century, such as the life sciences and high-tech.

In the past several decades, the biopharmaceutical and high-tech sectors have been the primary source of economic growth, new jobs, and new innovative products and services—from the mobile revolution to the new drugs that have turned diseases like hepatitis or cancer that were death sentences forty years ago into manageable conditions in living a normal life. In the high-tech sector, the patent system has driven an explosion in new products and services at a rate never before seen in any sector of the global innovation economy. “Several empirical studies demonstrate that the observed pattern in high-tech industries, especially in the smartphone

industry, is one of constant lower quality-adjusted prices, increased entry and competition, and higher performance standards.”¹³ Notably, this incredible innovation and economic growth has occurred in one of the most patent-intensive sectors of the economy, and contrary to the theoretical predictions of legal academics and economists that “patent holdup” and “patent thickets” would kill innovation in mobile devices and lead to higher consumer prices.¹⁴

Legal and commercial uncertainty in these two core sectors of the U.S. innovation economy in the twenty-first century will lead to reduced economic growth, lost jobs, and fewer new products and services. The data is already indicating the beginning stages of these developments, as we are approximately one decade away from the creation of the *Mayo-Alice* inquiry. If current indications continue in the same trendline, there will be continued losses in innovation, jobs, and economic growth in the two patent-intensive sectors of the U.S. innovation economy—the high-tech and biopharmaceutical sectors.

- 4. One of the key concerns from innovators is that, absent additional clarity in this space, we’re going to start seeing American companies start developing their inventions overseas in jurisdictions which have broader standards of patent eligibility.**

Do you agree with that concern and, if you do, what evidence have you seen to suggest that technological inversion is already occurring?

In the twenty-first century in which global telecommunications technologies and the development of sophisticated global supply and distribution chains make possible efficient transfer of technologies and investments throughout the world, commonsense dictates that innovators and firms will move their investments, R&D activities, patents, and ultimately their manufacturing and commercial activities based on these patents to other jurisdictions. Even before modern telecommunications technologies in mobile devices and efficient cargo-container shipping, inventors historically moved jurisdictions to create and patent their inventions. There are many examples, but two famous inventors who emigrated to the U.S. for precisely this reason are Nikola Tesla, the inventor of AC electrical systems and the first wireless electronic transmission systems, and Dr. Leo Baekeland, the inventor of the first synthetic plastic (trademarked as “Bakelite” after his name) and now known as the Father of the Plastics Industry. As in the past, when innovators moved to the U.S. given the promise of reliable and effective property rights in the fruits of their inventive labors, innovators today will shift to other jurisdictions that offer the same promise of reliable and effective patents in

¹³ Letter to Assistant Attorney Gen. Makan Delrahim from 13 Officials, Former Officials & Scholars (Feb. 13, 2018), <https://cpip.gmu.edu/wp-content/uploads/sites/31/2018/02/Letter-to-DOJ-Supporting-Evidence-Based-Approach-to-Antitrust-Enforcement-of-IP.pdf>.

¹⁴ See Alexander Galetovic, Stephen Haber, & Lew Zaretzki, *An Estimate of the Average Cumulative Royalty Yield in the World Mobile Phone Industry: Theory, Measurement and Results*, 42 TELECOMM. POL’Y 263 (2018), <https://www.sciencedirect.com/science/article/pii/S0308596117302240>; Alexander Galetovic & Stephen Haber, *The Fallacies of Patent-Holdup Theory*, 13 J. COMP. L. & ECON. 1 (2017), <https://academic.oup.com/jcle/article/13/1/1/3060409>; Alexander Galetovic, Stephen Haber, & Ross Levine, *An Empirical Examination of Patent Hold Up*, 11 J. COMP. L. & ECON. 549 (2015), <https://academic.oup.com/jcle/article/11/3/549/800066>.

those jurisdictions. It is even easier today than in the past, as Telsa and Baekeland physically moved to the U.S. from their native countries to invent and work in the U.S., but this is no longer required of innovators who seek to move their R&D and commercial work to other countries, specially global competitors who explicitly are seeking to displace the U.S. as the global technological leader, such as China. Thus, significant historical evidence and economic principles inform us that technological innovation and growth in innovation economies occur where reliable and effective property rights are secured to individuals and companies, but I do not have more specific data on this shift occurring right now other than the study of comparative patent grants detailed in my answer to Question 5.

- 5. In 2019 you testified that you conducted a study of U.S. patent applications from 2014 to 2017 and found that of nearly 1,700 patent applications rejected by the USPTO on eligibility grounds under the current *Mayo-Alice* framework, virtually all of them were granted by China, the European Patent Office, or both.**

These findings seem to confirm the worst fears of retired Judge Paul Michel and others, that Europe and China are embracing patent protections on promising inventions while the U.S. makes it harder – or impossible – to protect these innovations.

Are you still concerned about this trend today, and do you think legislation like PERA can stop the flow of innovation overseas?

Yes, global competitors, especially China, have a comparative advantage to the current U.S. patent system, which is significantly weakened given the indeterminate and restrictive patent eligibility doctrine, among other changes to the U.S. patent system in the past fifteen years. With respect to patent eligibility doctrine in the U.S., nothing has substantively changed in the law since the publication of Kevin Madigan's and my article in 2017.¹⁵

As a preliminary matter, we published an update to our article in 2019, clarifying and updating the data. This included correcting some accidental false positives in the original dataset on patent applications at the USPTO that received initial or final § 101 rejections and were ultimately abandoned in the United States, only to be granted patents in Europe, China, or both.¹⁶ The updated 2019 dataset confirms that 1,310 patent applications in the U.S. were abandoned following initial or final rejections under the *Alice-Mayo* inquiry, and yet had issued patent family members in either China or Europe. Even accounting for the corrected number of patent applications— 1,310 patent applications versus the originally reported 1,694 patent applications—the number of U.S. patent applications that fell victim to the *Alice-Mayo* inquiry, while these patents were ultimately granted in foreign jurisdictions like China, is significant.

¹⁵ See Kevin Madigan & Adam Mossoff, *Turning Gold to Lead: How Patent Eligibility Doctrine is Undermining U.S. Leadership in Innovation*, 24 GEO. MASON L. REV. 939 (2017).

¹⁶ See Kevin Madigan & Adam Mossoff, *Five Years Later, the U.S. Patent System is Still Turning Gold to Lead*, IPWATCHDOG (Dec. 15, 2019), <https://www.ipwatchdog.com/2019/12/15/five-years-later-the-us-patent-system-is-still-turning-gold-to-lead/id=116984/>.

The U.S. has long been a global leader in technological innovation, but this leadership is threatened by the indeterminacy and lack of protection provided under U.S. patent law for a whole range of inventions—from classic industrial inventions to today’s biotech and high-tech inventions. This is confirmed by data on the number of patent applications in recent years in the U.S., China, Europe, and other jurisdictions published by the World Intellectual Property Organization (WIPO). Consistent with predictions about the negative impact of the *Mayo-Alice* framework, WIPO reported a 1.6% drop in U.S. patent applications in 2018.¹⁷ This was the first decline in patent applications since 2009, when the U.S. was in the midst of the Great Recession, and the 2018 decline in patent applications was the first decline not associated with an economic recession or war. U.S. patent applications again decreased in 2020 and 2021, and had the USPTO had only a small 0.5% increase in 2022 (the last year for which we have published numbers on patent applications).¹⁸ The decline in U.S. patent applications during the COVID pandemic years of 2020 and 2021 was not matched by other jurisdictions, as patent applications *increased* in Europe, South Korea, and China in 2021 while the U.S. suffered another *decrease* in patent applications that same year.¹⁹ The 0.5% increase in USPTO patent applications in 2022 likely masks a comparative disadvantage given the significant increase in patent applications by China-based inventors in the USPTO. Thus, if one removes the patent applications from China-based inventors from the total 2022 numbers, it is likely that there was another drop in U.S. patent applications for 2022. This is evidence of a continuing, if not worsening, problem in U.S.-based innovation losing its leading edge compared to global competitors like China, where the government has expressly announced a policy of investing in and developing technologies to become the new leader in the global innovation economy.

PERA directly addresses this problem by abrogating the *Mayo-Alice* inquiry and confirming other substantive and procedural protections for innovators under § 101 that have long existed in U.S. patent law, such as mandating the assessment of the claimed invention as a whole. It returns patent eligibility doctrine to its status prior to the *Mayo-Alice* inquiry as only a “threshold test” relative to the distinct and separate patentability requirements of novelty (§ 102), nonobviousness (§ 103), and disclosure (§ 112).²⁰ Historically, courts very rarely used patent eligibility doctrine relative to the patentability requirements of novelty, nonobviousness, and disclosure, and PERA essentially reestablishes this earlier doctrinal approach. For example, it prohibits the USPTO or courts wrongly intermingling the patent eligibility analysis and the nonobviousness analysis, which the Supreme Court expressly authorized the USPTO

¹⁷ See WIPO, WORLD INTELLECTUAL PROPERTY INDICATORS 7 (2019), https://www.wipo.int/edocs/pubdocs/en/wipo_pub_941_2019.pdf.

¹⁸ See WIPO, WORLD INTELLECTUAL PROPERTY INDICATORS 7 (2023), <https://www.wipo.int/edocs/pubdocs/en/wipo-pub-941-2023-en-world-intellectual-property-indicators-2023.pdf>; see also WIPO, WORLD INTELLECTUAL PROPERTY INDICATORS 7 (2021), https://www.wipo.int/edocs/pubdocs/en/wipo_pub_941_2021.pdf (identifying a 3.9% decline in U.S. patent applications in 2020); WIPO, WORLD INTELLECTUAL PROPERTY INDICATORS 7 (2022), <https://www.wipo.int/edocs/pubdocs/en/wipo-pub-941-2022-en-world-intellectual-property-indicators-2022.pdf> (identifying a 1.0% decline in U.S. patent applications in 2020).

¹⁹ See WIPO, WORLD INTELLECTUAL PROPERTY INDICATORS 7 (2022), <https://www.wipo.int/edocs/pubdocs/en/wipo-pub-941-2022-en-world-intellectual-property-indicators-2022.pdf>.

²⁰ *Bilski v. Kappos*, 561 U.S. 593, 602 (2010).

and courts to do in its formulation of the *Mayo-Alice* inquiry.²¹ In our 2019 update to our dataset on rejected patent applications in the U.S., we confirmed this improper and indeterminate intermingling of distinct patent doctrines—patent eligibility and nonobviousness—in which we identified a significant overlap between UPSTO rejections of the patent applications in the dataset under both § 101 and § 103.²²

In sum, PERA effectively reestablishes the original function of patent eligibility doctrine that guided the UPSTO and courts for almost 200 years in which the U.S. first achieved and sustained its unprecedented global industrial and technological leadership.

6. **An article was published late last year analyzing a decade’s worth of patent eligibility decisions by the Federal Circuit, and they concluded that “under one of the most well-established metrics for measuring the predictability in the law, [Section] 101 proved to be *more predictable* than other areas of patent law over the past decade.” This is the opposite of what is claimed by many industry experts and even some current and former federal judges.**

How do you explain this disconnect?

As is common with many academic articles, the conclusion by Professors Nikola Datzov and Jason Rantanen only appears superficially to contradict the many complaints about the *Mayo-Alice* inquiry by Federal Circuit judges, lawyers, inventors, and representatives from companies that rely on patents in their business models. On closer inspection, the Datzov and Rantanen analysis *confirms* the legitimate calls for reform by these numerous judges, lawyers, industry stakeholders, and commentators. For example, Datzov and Rantanen state that “the rate at which the Federal Circuit reaches an ultimate outcome that the patent claims are not directed to eligible subject matter has fairly consistently remained around 90% since 2014.”²³ I and many other witnesses who testified at the hearing on January 23, 2024, as well as a majority of the witnesses who testified at the three days of hearings in 2019, reported the same number—because this excessive rate of patent invalidation under the *Mayo-Alice* inquiry is a problem. Economists and empirical researchers have long recognized in civil litigation that if appeals courts are reaching the same decision in 90% of the cases, this represents an unbalanced doctrine or legal decision-making institution that is not properly functioning according to normal operating conditions in a legal system.²⁴ In sum, something is out of whack institutionally, legally, or both; in this case, it is the *Mayo-Alice* inquiry.

²¹ See *Mayo*, 566 U.S. at 90 (“We recognize that, in evaluating the significance of additional steps, the § 101 patent-eligibility inquiry and, say, the § 102 novelty inquiry might sometimes overlap.”).

²² See Madigan & Mossoff, *supra* note 16 (identifying significant overlap in rejections of the same patent applications under both § 101 and § 103).

²³ Nikola L. Datzov and Jason Rantanen, *Predictable Unpredictability* (2023), at 22, <https://papers.ssrn.com/abstract=4380434>.

²⁴ See George L. Priest & Benjamin Klein, *The Selection of Disputes for Litigation*, 13 J. LEGAL STUD. 1, 20 (1984) (explaining the role of selection effects in why appellate court decisions have a “tendency toward 50 percent plaintiff victories” among cases litigated on appeal). This is now known as the famous “Priest-Klein hypothesis.”

Beyond the blithe acceptance of a 90% invalidation rate for patent claims as representative of normal operating conditions in courts, there are several problems with the article by Professors Datzov and Rantanen. First, Professors Datzov and Rantanen conflate *legal* unpredictability and *commercial* unpredictability. As I have explained in numerous amicus briefs in patent eligibility cases over the past decade, the *Mayo-Alice* inquiry is indeterminate insofar as courts are using it to invalidate patents on inventions that have long been upheld by courts as patent eligible *before* the *Mayo-Alice* inquiry was created by the Supreme Court. I have also acknowledged in these amicus brief that the *Mayo-Alice* inquiry is predictable in a more narrow sense: courts almost always invalidate patents as ineligible when they apply this legal framework. This creates unpredictability for innovators in the biopharma and high-tech sectors who rely on the patent system to make long-term investments costing billions of dollars.²⁵ Innovators cannot reasonably predict that they will receive reliable and effective property rights to secure a return on their investments in creating and commercializing new innovations; in fact, their only safe prediction is that there is a 90% chance their patent will be invalidated by a court. Thus, a reasonable businessperson concludes not to make the investment in the new technology or drug, or to shift the investment overseas to a country in which they can be certain they will receive legal protection for their fruits of their inventive labors.

This is what one scholar has identified as “investment-killing uncertainty,” which he rightly recognizes as the primary form of uncertainty in a legal system that “creates a problem that must be addressed by policy makers and suggests appropriate action” in enacting reform.²⁶ Investment-killing uncertainty, which can be the result of a legal doctrine being applied consistently, is the unpredictability and indeterminacy that lawyers and economists speak about when they speak of the function of property rights in incentivizing investments and commercialization activities (as I explained above in my answer to Question 3(a)). Datzov and Rantanen agree with judges and others calling for reform when they find a 90% invalidation rate in the Federal Circuit’s application of the *Mayo-Alice* inquiry, and this agreement confirms there is an unbalanced, anti-patent bias inherent in the *Mayo-Alice* inquiry that must be reformed, just as nonobviousness doctrine required reform in the 1952 Patent Act given the high rates of invalidation of patents under the Supreme Court’s “flash of creative genius” test.

Datzov and Rantanen’s questionable decision to blithely accept massively lopsided decisions lacking dissents as evidence of investment-spurring predictability is further confirmed by their review of the Patent Trial and Appeal Board (PTAB) decisions. Datzov and Rantanen’s review of the Federal Circuit’s affirmance rate of the PTAB’s § 101 decisions is especially relevant given the PREVAIL Act, and the STRONGER Patents Act before this, introduced by members of this committee. The PREVAIL Act imposes important procedural and substantive reforms on an agency tribunal that many lawyers, judges, and stakeholders in the innovation economy have repeatedly identified as institutionally and legally unbalanced, and which the Federal Circuit has not reined in. Yet, Datzov and Rantanen find nothing wrong with a 100%

²⁵ See Daniel R. Cahoy, *Patently Uncertain*, 17 NW. J. TECH. & INTELL. PROP. 1 (2019), <https://scholarlycommons.law.northwestern.edu/njtip/vol17/iss1/1> (distinguishing between “investment-killing uncertainty” from other forms of legal uncertainty, such as uncertainty in formal reasoning or in remedies)

²⁶ *Id.*, at 6.

affirmance by the Federal Circuit of PTAB decisions *invalidating* patents under § 101 in nine years over a span of ten years (2012-2022)—there was only one year the rate dropped to 93.3% (2020). Datzov and Rantanen conclude that “PTAB judges have been doing a good job of correctly and predictably determining when the patent claims are ineligible.”²⁷ Given the extensive, necessary reforms of the PTAB in the PREVAIL Act, this is a surprising claim that further highlights the problematic nature of the study by these two academics.

There is much else that can be said about this study beyond its fundamental and improper equivocation between difference senses of predictability in the patent eligibility debates. For reform advocates supporting PERA, there is massive *commercial and investment unpredictability* created by a decade of decisions applying the *Mayo-Alice* inquiry to invalidate patents at rates of 90% or more. (Whether these inventions or discoveries would satisfy the patentability requirements for novelty, nonobviousness, and disclosure is a separate question, and one that the USPTO and a court would assess if they moved past the threshold legal inquiry of whether an invention is patent eligible.) For Datzov and Ratanen, a doctrine producing 90% patent invalidation rates—and 100% affirmance rates of § 101 invalidation decisions by the PTAB—are acceptable because they reflect *legal* predictability. But this is not predictable protection of property rights that secures investments and promotes the creation of new commercial business models in the innovation economy that drive economic growth.

²⁷ Datzov & Rantanen, *supra* note 23, at 77.