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Senate Committee on the Judiciary
Subcommittee on Intellectual Property
Hearing: "The Patent Eligibility Restoration Act – Restoring Clarity, Certainty, and Predictability to the U.S. Patent System" (Oct. 8, 2025)

Response to Questions from Subcommittee Chair Senator Tillis

Question 1: Is there a continuing need for Congress to step in with patent eligibility legislation? Please explain.

There remains a strong and continuing need for Congress to enact patent eligibility legislation and to provide continuing oversight. Despite changes in examination guidance from the USPTO[1] and numerous cases over the years, the underlying uncertainty created by the Supreme Court's Mayo, Myriad, and Alice decisions persists. These cases have produced a doctrine that is inconsistently applied, difficult for the USPTO to administer, and challenging for innovators and investors to navigate.

USPTO guidance, while helpful, cannot substitute for statutory clarity. Agency practice may change with administrations, and it cannot overturn judicial precedent. Patent ineligibility and its related instability may cause innovators and entrepreneurs to hesitate or decline from investing in patent eligibility dependent technologies, involving diagnostics, personalized medicine, artificial intelligence, and software-based technologies, which are critical to the U.S. economy and increasingly to our national security.

Over the past decade, China and the European Union have steadily broadened patent eligibility in similar technologies. China has made explicit policy choices to protect computer-implemented inventions, AI-related applications, and certain biotechnology subject matter, thereby aligning patent law with both its industrial priorities and evolving needs to address IP protection for fast developing emerging

[1] See US Patent & Trademark Office, *Subject Matter Eligibility* https://www.uspto.gov/patents/laws/examination-policy/subject-matter-eligibility. Note that all hyperlinks were reviewed as of October 25, 2025.

technologies. U.S. innovators, by contrast, increasingly face a disincentive to file or commercialize in their home market in many of these same technologies. Congressional action and oversight are therefore essential to restore predictability, ensure the USPTO can operate under clear statutory guidance, and maintain U.S. competitiveness in these and other emerging technologies.

Question 2: Despite how broken the current situation is regarding patent eligibility, is it in the interest of some parties to maintain the broken status quo? Why is this?

Yes. Some parties benefit from the current uncertainty. The ambiguity surrounding §101 allows defendants to dispose of infringement suits at an early stage, before costly discovery or claim construction. This procedural advantage can favor large incumbents and downstream implementers over smaller innovators or universities that rely on enforceable patents to protect their investments in R&D and attract additional capital.[2]

Others may also use the uncertainty strategically in global licensing negotiations, arguing that U.S. patents—especially those on diagnostics, AI, or software—are "weak" or unenforceable. This weakens the bargaining position of American rights holders, including those competing against foreign firms supported by more predictable legal frameworks. The lack of clarity may thereby also distort incentives to develop new technologies in the United States.

Question 3. The technologies that the U.S. most needs to develop to compete with China's growth, including advanced computing, AI, and biotechnology, are often those that fall outside current patent eligibility standards.

How will PERA help the U.S. maintain global leadership in competitive sectors? What does failure to enact such legislation mean to our global competitiveness?

PERA directly supports U.S. global competitiveness by restoring eligibility to the technologies that will define the next generation of economic and strategic leadership: advanced computing, artificial intelligence, quantum technologies, biotechnology, and clean energy. These are precisely the sectors where China's industrial policies, such as "Made in China 2025," seek dominance. They are also

[2] U.S. Patent & Trademark Office, *Study of Patent Eligibility Jurisprudence* (Oct. 2022) ("USPTO Study"), at pp. 23-25, 51, and fns. 207, 208, and 229, https://www.uspto.gov/sites/default/files/documents/USPTO-SubjectMatterEligibility-PublicViews.pdf .

areas where Chinese patent filings have surged.

Without legislative reform, the United States risks ceding leadership in these high-technology sectors to jurisdictions that offer clearer, more predictable protection. Firms will increasingly file patents, fund R&D and locate investment in those countries, eroding U.S. technological advantages, as well as its manufacturing, investment, and employment.

PERA ensures that U.S. law reflects Congress's intent that patent protection should extend to critical, new applied technologies and that patent protection should not extent to abstract ideas or natural phenomena. By reaffirming the statutory baseline of "any new and useful process, machine, manufacture, or composition of matter," the bill helps secure the innovation infrastructure that underpins U.S. economic and national security.

Question 4. PERA 225 has several changes this year compared to PERA from the prior Congress. Do you believe that these were good changes to the bill? Why or why not?

The 2025 refinements of PERA strengthen the bill. Clarifying exclusions for laws of nature, mental processes, and purely human activity addresses concerns that eligibility reform might unduly expand patentable subject matter. At the same time, the updated language reinforces that applied technologies may be patent-eligible even when they incorporate natural laws or abstract reasoning. This is consistent with prior precedents such as *Diamond v. Diehr*, 450 U.S. 175 (1981).

The bill's reaffirmation that questions of novelty, obviousness, and written description remain separate and fully applicable preserves patent quality. This is also essential to the separation of eligibility from other patentability doctrines.

More specifically, the bill narrows the exclusion for human genes and natural materials and clarifies the exclusion for business/economic methods unless they are impracticable without machine implementation. Eligibility is also recast in positive terms, rather than by referring to abrogation of judicial exceptions. Of course, the key accomplishment is that the bill maintains the legislative objective of clarifying and expanding patent-eligible subject matter in critical technologies.

Question 5. We are all concerned about the cost of prescription medication. Some have argued that the enactment of this bill would lead to higher drug prices for consumers.

What do you say to that?

Concerns that PERA would lead to higher drug prices may misapprehend both how patents function in the pharmaceutical sector and what PERA does. PERA does not change the standards for novelty, non-obviousness, written description, regulatory exclusivity, or market competition from generics and biosimilars. It clarifies what categories of technology may be considered for patent protection. Drug prices are ultimately governed by such factors as FDA practices including, exclusivity periods, market dynamics (including the role of generics and biosimilars), insurance and reimbursement structure, and not by patent eligibility doctrine.

PERA also promotes lower costs and greater competition by encouraging innovation in drug discovery tools and diagnostics by removing uncertainty that has chilled investments diagnostics and AI-driven drug discovery platforms. These technologies make therapies more targeted, reduce waste, and improve clinical outcomes.

Question 6. Some argue that medical diagnostics will continue to be invented and developed notwithstanding the change in subject matter eligibility from the Supreme Court, because of other factors promoting or protecting innovation – such as the incentives to "publish or perish" in academia, or the ability to protect innovation through other means like trade secrets.

Do you agree? Why or why not?

While "publish or perish" incentives spur certain types of innovation and trade secrets can protect certain forms of innovation, they are inadequate substitutes for patents in diagnostics and many other research-intensive sectors. Publications, by contrast, are most useful for the dissemination of scientific information. They do not protect commercial investments from misappropriation by others. Trade secrecy is also often incompatible with regulatory disclosure requirements or the need for reproducibility in medical practice.

Patents may also be readily used to encourage further collaboration through cross-licensing and other forms of cooperation. Without patent protection, companies that are not burdened with research and development costs will also have a competitive advantage if a new product can be easily reverse engineered, especially when compared to a company that has carried all of these research and development costs

forward.

The decline in U.S. diagnostic patent filings following *Mayo* demonstrates that innovators respond to legal incentives. Academic researchers and startups alike face reduced opportunities for commercialization, venture capital investment, and public-private collaboration. PERA restores the balance by allowing discoveries that are applied through concrete, technical processes to be patented while leaving fundamental scientific knowledge in the public domain.

Question 7
(a) If we don't fix current patent eligibility law, who stands to benefit? (b) In other words, in terms of our geopolitical competitors, who stands to gain from the innovation void that our current law is creating? (c) What are the national security implications and how does PERA factor into this discussion?

Inaction on patent eligibility does not create a neutral status quo. It actively advantages large, entrenched implementers over startups, research-driven companies, and independent innovators. As set forth in my written testimony of October 8, 2025, empirical studies show that venture capital investment in diagnostics declined sharply after *Mayo Collaborative Services v. Prometheus Laboratories, Inc.* and *Alice Corp. v. CLS Bank International*, with one study documenting a nearly 9.3 billion dollar reduction in venture funding for diagnostics relative to other sectors.[3] Firms that depend on patents to attract investment and protect new technologies, such as early-stage biotechnology, diagnostics, and applied AI companies, have been disproportionately harmed by uncertainty under current § 101 jurisprudence. Large platform companies and implementers are also able to rely on distribution, user data, and standards adoption to remain comparatively insulated from the loss of patent protection. Independent inventors, startups and small businesses have borne a disproportionately higher burden of addressing the increased costs that have resulted from obtaining patents.[4]

This asymmetry has been exploited by foreign competitors. China has sought to position its patent regime as more innovation-friendly in fields now constrained under U.S. law. The Chinese State Council's *New Generation Artificial Intelligence Development Plan* (2017) explicitly directs agencies to "strengthen intellectual property protection in the field of artificial intelligence; improve the interactive

[3] A. Sasha Hoyt, *The Impact of Uncertainty Regarding Patent Eligible Subject Matter for Investment in U.S. Medical Diagnostic Technologies*, 79 WASH. & LEE L. REV. 397 (2022), at pp. 398, 446.
[4] USPTO Study, supra, at pp. 23-25, 51, and fns. 207, 208, and 229.

mechanisms linking technological innovation, patent protection, and standardization; and promote the transformation of AI innovation results into intellectual property" ("加强人工智能领域的知识产权保护，健全人工智能领域技术创、专利保护与标准化互动支撑机制，促进人工智能创新成果的知识产权化").[5] The State Council *Action Plan on Patent Commercialization (2023–2025)* likewise calls for "vigorously promoting the industrialization of patents and accelerating the conversion of innovation outcomes into practical productive capacity" ("大力推动专利产业化，加快创新成果向现实生产力转化").[6] These policies are aligned with China's civil–military fusion framework, which directs the integration of civilian technological innovation into defense applications to "promote mutual support and effective transformation of military and civilian technologies," and "strengthen military and civilian resource sharing and collaborative innovation"(" 促进军民技术相互支撑、有效转化" and "加强军民资源共享和协同创新").[7]

Europe has taken a similar approach to China of adopting predictable criteria for computer-implemented and AI-enabled inventions under its "technical effect" doctrine.[6] Failure to reform § 101 risks ceding the development and commercialization of foundational technologies and newly emerging technologies in AI, semiconductors, quantum computing, and biotechnology, to jurisdictions with more generous and stable legal environments. [8]

By enacting PERA, Congress would restore predictable patent eligibility, strengthen incentives for startups and research institutions, and signal to allies and competitors alike that the United States intends to lead through the rule of law in innovation. Far from expanding monopolies or raising drug prices, PERA would reinforce the innovation ecosystem that underpins both American economic vitality and national security. PERA is also not merely an economic measure. Properly determining patent eligibility is essential to America's national security and technological sovereignty.

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[5] State Council of the People's Republic of China, *New Generation Artificial Intelligence Development Plan* (国务院《新一代人工智能发展规划), Para. 4 (3) (July 8, 2017), https://www.gov.cn/zhengce/content/2017-07/20/content_5211996.htm.

[6] State Council, *Action Plan on Patent Commercialization (2023–2025)* (专利转化运用专项行动方案 (2023–2025 年)) (introductory paragraph) (June 18, 2024), https://www.cnipa.gov.cn/art/2024/6/18/art_3398_193173.html.

[7] State Council General Office, *Opinions on Deepening Civil–Military Fusion in the Defense Science and Technology Industry* (关于推动国防科技工业军民融合深度发展的意见), Paras. 2, 4 (Dec. 4, 2017).

[8] European Patent Office, Guidelines for Examination, Part G-II, 3.3.1 (Mar. 2024) (recognizing eligibility of computer-implemented inventions producing a "technical effect").

Note: These comments and my prior testimony were all submitted in my personal capacity.

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Responses To Questions for the Record from Senator Schmitt

Question 1. The Patent Eligibility Restoration Act (PERA) would widely broaden patent eligibility. What are the protections in the patent system to prevent patent trolls—especially foreign patent trolls like those from China—from using this law to supercharge their manipulation and abuse of the U.S. patent system?

PERA restores clarity under 35 U.S.C. § 101 but does not dilute any of the system's existing safeguards. Fundamental requirements of novelty (§ 102), non-obviousness (§ 103), and written description and enablement (§ 112) remain the core filters for patent quality. Post-grant procedures such as inter partes review and post-grant review (§§ 311–319, 321–329) will also provide efficient mechanisms to challenge weak patents. Procedural rules also protect against frivolous assertion. Following *eBay Inc. v. MercExchange, L.L.C.,* 547 U.S. 388 (2006), injunctions are not automatic, which prevents non-practicing entities from using the threat of injunctive threats to extract settlements. Under *Bell Atl. Corp. v. Twombly*, 550 U.S. 544 (2007), and *Ashcroft v. Iqbal*, 556 U.S. 662 (2009), plaintiffs must plead plausible claims of infringement. Under FRCP Rule 11 and 35 USC § 285 fee-shifting is permitted for exceptional cases. Venue restrictions from *TC Heartland LLC v. Kraft Foods Grp. Brands LLC*, 581 U.S. 258 (2017) limit forum shopping.

Based on Clarivate data, the immediate threat of Chinese NPEs in the courts is likely overstated. According to Clarivate, the top 10 NPE's in the United States which accounted for 50% of total NPE-initiated infringement cases, are all based in the United States, excepting one from Canada. In the EU, the top 10 NPEs, accounting

for 72% of NPE-initiated infringement cases, included eight U.S. based NPEs. These NPEs also account for 45% of NPE litigation in Europe.[1]

There are also very few examples of China-related funding of U.S. patent suits. One example involved Purplevine IP (Shenzhen), which funded four suits against Samsung in Delaware.[2] A solution to that problem would be to require disclosure of third-party funding, as some judges have already required, and as has been discussed by GAO and others.[3]

Overall, according to Clarivate, there was a 43% decrease in NPE cases during the period 2018-2023, with all infringement cases decreasing by 36%. Clarivate notes that "the decrease in NPE activities in the U.S. appears to almost align with the overall decrease in the number of infringement cases over the past six years." The data sharply contrasts with the increasing number of patent filings from China in the United States over the past several years, which, according to various data sources, has increased by over 500% from 2015 (9,004 filings) to 2023 (49,740 filings).[4]

In summary, these and other data reports all converge on the same point: foreign entities, including those from China, are not currently major users of the U.S. system to engage in patent-troll behavior, and the legal tools that prevent such abuse remain fully intact under PERA. Moreover, in the case of China, there has not been an increase in troll activity proportionate to China's increase in US patent filings.

Question 2. On balance, would PERA make it easier or harder for patent trolls to extort U.S. businesses and companies**?**

On balance, PERA would not make it easier for abusive entities to exploit the U.S. system. PERA instead reduces opportunities for gamesmanship by restoring a predictable eligibility baseline while leaving all other safeguards intact. Today's uncertainty arising from Supreme Court patent eligibility cases enables both sides to

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[1] Clarivate, *2024 Non-Practicing Entity Global Litigation Report* (2024),
[2] Emily R. Siegel, *China Firm Funds U.S. Suits Amid Push to Disclose Foreign Ties (2)*, BLOOMBERG LAW (Nov. 6, 2023), at p. 15., https://news.bloomberglaw.com/business-and-practice/china-firm-funds-us-lawsuits-amid-push-to-disclose-foreign-ties?utm_source=chatgpt.com,
[3] Government Accountability Office, *Intellectual Property: Information on Third-Party Funding of Patent Litigation*, (Dec. 2024), https://www.gao.gov/assets/gao-25-107214.pdf .
[4] US Patent & Trademark Office, *Patent Counts by Country, State, and Year – All Patent Types* (December 2015), https://www.uspto.gov/web/offices/ac/ido/oeip/taf/cst_all.htm. Aaron Wininger, *2024 Annual China Filing Statistics Released: Utility Model Grants Continue to Drop While Utility Model Applications Continue to Increase*, CHINA IP LAW UPDATE (July 15, 2025), https://www.chinaiplawupdate.com/2025/07/2024-annual-china-filing-statistics-released-utility-model-grants-continue-to-drop-while-utility-model-applications-continue-to-increase/.

leverage § 101 motions in ways that do not always track the technical merits. PERA refocuses disputes on objective questions such as prior art (35 U.S.C. § 102), non-obviousness (§ 103), and disclosure (§ 112), while preserving fee shifting (35 U.S.C. § 285), Rule 11 sanctions, the *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388 (2006) injunction framework, PTAB review (35 U.S.C. §§ 311–319, 321–329), and venue limits under *TC Heartland*.

On balance, PERA reduces abuse by eliminating legal uncertainty and reinforcing examination standards that distinguish genuine innovation from litigation-driven patenting.

Question 3. How would expanding patent eligibility for AI processes under PERA impact the ability of businesses to implement those technologies?

Expanding eligibility for applied artificial intelligence process inventions will support investment, licensing, collaboration and standardization for inventions on concrete technological processes that improve computer functionalities or real-world outcomes, while still excluding disembodied laws of nature and algorithms. PERA aligns with the principle in *Diamond v. Diehr* 450 U.S. 175 (1981) that applying mathematics in a concrete, technological process is patent-eligible, while human mental steps and laws of nature remain unprotectable. This clarity lowers the cost of transacting (e.g., cross-licensing and supplier contracts), encourages patent disclosure instead of secrecy, facilitates patent-protected tech startups, supports domestic commercialization by reducing incentives to file first in overseas jurisdictions, and provides clearer rules to support filing first in the United States.

Question 4. What are examples of the types of AI innovations that are ineligible under current law but would be eligible under PERA?

There is no single secondary source that tracks specific patents of concern across jurisdictions. However, as addressed in my written testimony of October 8, 2025, there are scholarly commentaries on US practices and comparative analyses of EPO and CNIPA examination guidelines.[5] These consistently show that applied AI and

[5] See, e.g., Kevin Madigan & Adam Mossoff, *Turning Gold to Lead: How Patent Eligibility Doctrine is Undermining U.S. Leadership* (2018; updated references through 2019), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2943431; Liaoteng Wang et al., *A Comparative Look at Patent Subject Matter Eligibility Standards: China Versus the United States*, BERKELEY CENTER

software-based technological improvements are generally patent-eligible in Europe and China under their "technical effect" or "technical solution" frameworks. By contrast, U.S. §101 jurisprudence has frequently classified similar innovations as "abstract ideas." In his prior testimony before this committee, Prof. Mossoff has also identified several examples of inventions that were not permitted to be patented.[6] These analyses and case studies, as well as a review of patent examination practices in other countries, underscore that the United States has become an international outlier in excluding such technologies from patent protection.

Examples of the application of U.S. case law on patent eligibility to AI inventions rejected as abstract ideas include such technologies as real-time data analytics that monitor complex systems (*Electric Power Group L.L.C. v. Alstom S.A.*, 830 F.3d 1350, 1351-57 (Fed. Cir. 2016), advanced statistical/machine language computations which were viewed as "mathematical concepts" (*SAP Am., Inc. v. InvestPic, LLC*, 898 F3d 1161, 1163-68 (Fed. Circ. 2018), modeling that had real-word medical utility (*In re Bd. of Trs. Of the Leland Stanford Junior Univ.*, 991 F. 3d 1245, 1250-1258 (Fed. Cir. 2021), and AI-enabled signal and image processing (*Yu v Apple*, 1 F.4th 1040, 1044-1050 (Fed. Cir. 2021). These examples involve technologies which both Europe and China expressly recognize as patentable when they contribute to a technological process or improve system performance. In Europe, the foundational *VICOM* decision of the European Patent Office held that computer-implemented image processing is a patent-eligible "technical effect,"[7]and the EPO's Enlarged Board decision, *G 1/19*, affirmed that simulations and AI models directed to solving technical problems are patent-eligible even if the output is generated in a computer environment.[8] China's patent authority has adopted similar principles in its 2024–

FOR LAW & TECHNOLOGY, (2021), https://www.law.berkeley.edu/wp-content/uploads/2021/05/Comparative-Look.pdf; Liu Ruixian, *A Comparison of Chinese and U.S. Patent Eligibility Standards: A Case Study*, MANAGING IP (April15, 2025), Kangxin Partners, https://managingip.com/article/2eobmnlsl13g7aik124002/sponsored-content/comparison-of-chinese-and-us-patent-eligiblity-standards-a-case-study; Minnan Xie, *Strategies for Patenting Personalized Medicine and Companion Diagnostics in China*, MANAGING IP (Dec. 5, 2023), https://www.managingip.com/article/2cjlbohj8nh4v1hkwcagw/sponsored-content/strategies-for-patenting-personalised-medicine-and-companion-diagnostics-in-china; Christine M. Morgan, Hallie H. Wimberly, *SCOTUS Remains Silent on Fractured Approach to Patent Ineligibility*, REED SMITH CLIENT ALERT (July 7, 2022), https://www.reedsmith.com/en/perspectives/2022/07/scotus-remains-silent-on-fractured-approach.

[6] Adam Mossoff, *Senate Judiciary Responses to Questions for the Record* (Jan. 23, 2024) at question 2 "What specific types of inventions would become newly eligible for a patent under PERA, that are currently not patentable?", https://www.judiciary.senate.gov/download/2024-01-23-qfr-responses-mossoff?download=1.

[7] Decision T 208/84 (Computer-related invention/VICOM), 1987 O.J. EPO 14, 19 (Tech. Bd. App. 1986) ("image-processing method constitutes a technical process").

[8] Decision G 1/19 (Simulations/CONNOR), ECLI:EP:BA:2021:G000119.20210310, paras. 94, 120 (Enlarged Bd. App. Mar. 10, 2021).

2025 Examination Guidelines for Artificial Intelligence, which identify AI algorithms used in industrial control, imaging, medical devices, and engineering applications as patent-eligible "technical solutions."[9] The divergence between the United States and its major economic competitors reflects systematic doctrinal differences which merit Congressional intervention.

Question 5. Why should Congress—or why should Congress not—expand eligibility to such AI innovations?

Congress should expand eligibility to applied AI innovations because they can embody concrete technological improvements that drive advances in computing efficiency, medical accuracy, cybersecurity, robotics, and national competitiveness. These patents should be protected as engineering solutions that produce measurable and verifiable technical results.

With technology continuing to evolve rapidly, Congress should also plan to oversee how USPTO and the courts adjust to patentability issues in other newly emerging technologies as well. Such oversight should also continue to consider how other countries are also addressing these challenges.

Failing to restore existing eligibility harms the United States in three ways: First, without predictable patent protection, firms face uncertainty that deters private investment and reduces incentives for disclosure, leading to secrecy and/or offshore patenting. Second, when comparable technologies are patent protected overseas but not in the United States, these foreign jurisdictions may set the terms of commercialization, licensing, and standards development. Third, AI has been identified by Congress and the Executive Branch as strategic technology. Other technologies, such as medical diagnostics, can also have national security implications, as was the case during the recent global pandemic. Current U.S. eligibility doctrine disincentivizes domestic filing and risks ceding core AI infrastructure and other critical technologies to competing nations.

Conversely, Congress should not refrain from expanding eligibility based on abstract fears of "overbroad software patents," because other jurisdictions effectively

[9] China Nat'l. Intellectual Prop. Admin., *Draft Examination Guidelines for Artificial Intelligence, Internet & Big Data (2024–2025) (Trial Implementation)* (2024). See also Aaron Wininger, *CNIPA Releases Draft Guidelines for Patent Applications for Artificial Intelligence-Related Inventions (人工智能相关发明专利申请指引(征求意见稿))* , CHINA IP LAW UPDATE (Dec. 6, 2024), https://www.chinaiplawupdate.com/2024/12/cnipa-releases-draft-guidelines-for-patent-applications-for-artificial-intelligence-related-inventions/.

safeguard against overreach through traditional patentability requirements such as novelty, inventive step (non-obviousness), enablement, and written description. Patent eligibility simply determines whether an innovation is the type of subject matter that is allowed to be examined, not whether it should ultimately be granted.

Restoring eligibility through legislation such as PERA would harmonize U.S. law with global norms, promote certainty for innovators, and ensure that the United States retains leadership in foundational AI technologies rather than making it only legally protectable overseas based on the protections afforded by foreign patent offices in their territory.

Question 6. Some argue that medical diagnostics will continue to be invented and developed notwithstanding the change in subject matter eligibility from the Supreme Court, because of other factors promoting or protecting innovation – such as the incentives to "publish or perish" in academia, or the ability to protect innovation through other means like trade secrets. Do you agree? Why or why not?

While "publish or perish" incentives and trade secrets can spur certain types of innovation, they are not adequate substitutes for obtaining utility patents in diagnostics and other research-intensive sectors. Publication does not protect investment in research and development, and trade secrecy is often incompatible with regulatory disclosure requirements or the need for reproducibility in medical practice. Trade secret protection can also be lost through trade secret theft, employee mobility or inadvertent disclosures. Patent examination also offers an opportunity for review by technical experts at a third-party government institution (a patent office) according to defined standards, and a broader on-line publication to the public by patent offices. Academic publications do not afford such disciplines or opportunities. Patents may also be used to cross-license technologies and encourage further collaboration and other forms of cooperation. Patents also provide a basis for fair competition. Without patent protection, companies that are not burdened with research and development costs but can reverse engineer an innovator's invention may also have a competitive advantage compared to the original innovator by not having borne the initial costs and risks of the original research and development.

The decline in U.S. diagnostic patent filings following *Mayo* demonstrates that innovators respond to legal incentives. Academic researchers and startups alike face reduced opportunities for commercialization, venture capital investment, and public-private collaboration. PERA restores the balance by allowing discoveries that

are applied through concrete, technical processes to be patented while leaving fundamental scientific knowledge in the public domain.

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b. In other words, in terms of our geopolitical competitors, who stands to gain from the innovation void that our current law is creating?

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Inaction on patent eligibility does not create a neutral status quo. It actively advantages large, entrenched implementers over startups, smaller research-driven companies, and independent innovators. Firms that depend on patents to secure investment and protect emerging technologies, including early-stage biotechnology, precision diagnostics, and applied artificial intelligence companies without large commercialization revenues, have been disproportionately harmed by uncertainty in U.S. patent eligibility law under § 101. This uncertainty inhibits investment, leads to abandonment of promising research, and incentivizes filing and commercialization in Europe and China, where eligibility standards are clearer and more predictable. Empirical studies show that venture capital investment in diagnostics declined sharply after *Mayo Collaborative Services v. Prometheus Laboratories, Inc.* and *Alice Corp. v. CLS Bank International*, with one study documenting a nearly 9.3 billion dollar reduction in venture funding for diagnostics.[10] Patent abandonment rates are also substantially higher for smaller entities in affected industries, while large platform companies and implementers are able to rely on such competitive factors as network effects, user data, branding and standards adoption to be comparatively insulated from the loss of patent protection. Commentators have also indicated that independent inventors, startups and small businesses have borne a disproportionately higher burden of the increased costs and risks of obtaining patents.[11]

[10] A. Sasha Hoyt, *The Impact of Uncertainty Regarding Patent Eligible Subject Matter for Investment in U.S. Medical Diagnostic Technologies*, 79 WASH. & LEE L. REV. 397, (2022), at pp. 398, 446.
[11] U.S. Patent & Trademark Office, *Study of Patent Eligibility Jurisprudence* (June 2022), at pp. 23 – 25, 41, including fns. 207, 208, and 229, https://www.uspto.gov/sites/default/files/documents/USPTO-SubjectMatterEligibility-PublicViews.pdf.

This asymmetry has been exploited by foreign competitors. China has sought to position its patent regime as more innovation-friendly in fields now constrained under U.S. law. The Chinese State Council's *New Generation Artificial Intelligence Development Plan* (2017) explicitly directs agencies to "strengthen intellectual property protection in the field of artificial intelligence; improve the interactive mechanisms linking technological innovation, patent protection, and standardization; and promote the transformation of AI innovation results into intellectual property" ("加强人工智能领域的知识产权保护、健全人工智能领域技术创新、专利保护与标准化互动支撑机制，促进人工智能创新成果的知识产权化").[12] The State Council *Action Plan on Patent Commercialization (2023–2025)* likewise calls for "vigorously promoting the industrialization of patents and accelerating the conversion of innovation outcomes into practical productive capacity" ("大力推动专利产业化，加快创新成果向现实生产力转化").[13] These policies are aligned with China's civil–military fusion framework, which directs the integration of civilian technological innovation into defense applications, to "promote mutual support and effective transformation of military and civilian technologies," and "strengthen military and civilian resource sharing and collaborative innovation" ("促进军民技术相互支撑、有效转化" and "加强军民资源共享和协同创新").[14]

Europe has taken a similar path, adopting predictable criteria for computer-implemented and AI-enabled inventions under its "technical effect" doctrine.[15] As a result, innovators increasingly file in Europe or China when U.S. eligibility law introduces uncertainty. Failure to reform § 101 risks ceding the development and commercialization of foundational technologies—AI, semiconductors, quantum computing, and biotechnology—to jurisdictions with more stable or welcoming legal environments.

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[12] State Council of the People's Republic of China, *New Generation Artificial Intelligence Development Plan* (国务院《新一代人工智能发展规划), Para. 4 (3) (July 8, 2017), https://www.gov.cn/zhengce/content/2017-07/20/content_5211996.htm.

[13] State Council, *Action Plan on Patent Commercialization (2023–2025)* (专利转化运用专项行动方案 (2023–2025 年)) (introductory paragraph) (June 18, 2024), https://www.cnipa.gov.cn/art/2024/6/18/art_3398_193173.html.

[14] State Council General Office, *Opinions on Deepening Civil–Military Fusion in the Defense Science and Technology Industry* (关于推动国防科技工业军民融合深度发展的意见), Paras. 2, 4 (Dec. 4, 2017).

[15] European Patent Office, *Guidelines for Examination*, Part G-II, 3.3.1 (Mar. 2024) (recognizing eligibility of computer-implemented inventions producing a "technical effect").

By enacting PERA, Congress would restore predictable patent eligibility, strengthen incentives for startups and research institutions, and signal to allies and competitors alike that the United States intends to lead through the rule of law in innovation. Far from expanding monopolies or raising drug prices, PERA would reinforce the innovation ecosystem that underpins both American economic vitality and national security. PERA is not merely an economic measure. It is essential to America's technological leadership and national security.

Note: These comments and my prior testimony were all submitted in my personal capacity.