Questions from Senator Tillis for Andrei Iancu
Witness for the 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"

1. **The first set of hearings on patent eligibility were held in 2019, with 45 witnesses over multiple days. In 2024, another hearing was held consisting of 8 witnesses. Since then, there has been guidance from the USPTO and additional court cases. Is there a continuing need for Congress to step in with patent eligibility legislation? Please explain.**

RESPONSE: Thank you, Chairman Tillis and members of the Subcommittee, for your continued commitment to restoring clarity and balance to Section 101 of the Patent Act. The Committee has devoted significant effort to this issue, and that persistence underscores both the complexity and the urgency of the problem.

As Chairman Tillis observed in his opening remarks, "the long overdue need for patent eligibility reform is one that if left unaddressed will cede America's well-earned title as the global innovation and intellectual property leader." I agree with that assessment.

After more than a decade of confusion and inconsistent judicial rulings, there remains an urgent need for Congress to act. The courts and the USPTO have struggled to apply eighteenth-century statutory language to twenty-first-century technologies. The result is a patchwork of exclusions that Congress never intended, where critical fields such as diagnostics, biotechnology, artificial intelligence, and advanced computing are left in legal limbo. Innovators and investors no longer know whether certain transformative discoveries can be protected under U.S. law, and this uncertainty is already driving research and capital abroad.

As I stated during the hearing, only Congress can reestablish clear statutory boundaries for patent eligibility. The USPTO's guidance has been helpful, but it cannot override judicial precedent. The Supreme Court has declined to revisit the issue, and lower courts continue to diverge. Legislation is the only way to restore a uniform national standard. Clarity in the law is not an abstract ideal; it is the foundation upon which our innovation economy rests. Without it, America's ability to compete and lead globally will erode.

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?**

RESPONSE: There is no question that some parties have grown comfortable with the current system, even as it continues to fail innovators and the broader economy. For some, uncertainty can serve as a competitive advantage. When the boundaries of patent eligibility are unclear, however, inventors face greater difficulty securing and defending patents. Those who already

dominate their markets can perhaps afford to operate without strong, predictable intellectual property protection, while emerging innovators cannot.

Uncertainty also encourages litigation and strategic behavior rather than invention. Some businesses rely on ambiguity to avoid competition or to weaken competitors' portfolios through protracted legal challenges. The result is a system that rewards size and legal resources instead of creativity and technical merit.

As I testified during the hearing, this is the opposite of what the framers of our Constitution intended. The patent system was designed to democratize innovation and to ensure that any individual with a new and useful idea could secure protection, disclose it to the public, and compete on merit. The current confusion under Section 101 undermines that principle. It favors the few who can navigate complexity at the expense of the many who depend on clear and reliable rules. Unless Congress clarifies this critical area of law, among other important initiatives, the United States will lose its competitive edge.

Ultimately, maintaining the broken status quo hurts the growth and prosperity of the United States. A strong and predictable patent system—for which, passage of PERA is critical—levels the playing field, fuels investment in research and development, and ensures that the United States remains the most dynamic and innovative economy in the world.

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 these competitive sectors? What does a failure to enact such legislation mean to our global competitiveness in general?**

RESPONSE: The United States cannot afford to fall behind in the technologies that will determine economic and strategic leadership in the twenty-first century, including artificial intelligence, quantum computing, biotechnology, advanced materials, and clean energy. These are precisely the fields where uncertainty in patent eligibility has created the greatest risk for innovators and investors.

As Chairman Tillis warned during the hearing, "If we do not act, we will cede our innovation advantage to China and other countries that are actively clarifying and strengthening their intellectual property systems."

PERA restores clarity to the law and ensures that the patent system functions as Congress originally intended. By clearly defining what is eligible for protection and what is not, PERA allows inventors and businesses to make confident decisions about research, development, and commercialization. It draws the correct line between abstract ideas and laws of nature as such, which remain ineligible, and practical technological applications, which advance innovation and should be protected.

When the rules are predictable, capital flows towards new technologies. When they are uncertain, investment stalls or moves to jurisdictions that provide clearer incentives. China and the European Union have recognized this reality and acted accordingly. China, in particular, has used intellectual property policy as a deliberate tool of economic strategy. Its patent office, for example, has clarified eligibility standards for software, AI, and biotechnology. Overall, China has experienced a surge in patent filings and investment in those sectors.

If Congress does not act, the United States will continue to lose ground. Innovators will increasingly choose to patent and commercialize their technologies elsewhere, and the industries that should be based in America will take root abroad. Our ability to shape international norms and protect the integrity of our innovation ecosystem will diminish.

Enacting PERA is not only about restoring fairness and predictability to patent law. It is about preserving America's position as the global leader in innovation, ensuring that the next generation of discoveries is made, protected, and built here at home.

4. **PERA 2025 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?**

RESPONSE: Yes, the refinements made this Congress reflect good-faith engagement with stakeholder feedback and strengthen the bill's precision.

The most substantive of the changes addresses the patent eligibility of human genes. While PERA from the last Congress did not allow for the patenting of human genes as they exist in the human body, PERA of 2025 expands on this point to disallow the eligibility of human genes, even if they are isolated from the human body. In this manner, PERA of 2025 now effectively codifies the narrow holding of the *Association of Molecular Pathology v. Myriad*. However, the bill would still undo the harmful follow-on decisions that have relied on the logic of the *Myriad* case to call into question the patent eligibility of other natural materials isolated from nature, such as new active ingredients that might be isolated from a plant.

The bill also contains several changes that are designed to underscore how operative language that was already present in the bill would not allow for the patentability of otherwise ineligible subjects simply because they are "done on a computer." The new rule of construction added under Section 4(b) of the bill, for example, further details how the operative language should not be understood to allow such insignificant pre- or post-solution activity to allow for the patent eligibility of a process that the bill identifies earlier as an area beyond the patent system's scope.

Finally, another rule of construction added by the bill clarifies that the PERA is not intended to affect the judicial doctrine of obviousness-type double patenting (OTDP). This rule of construction addresses apparent confusion that some have perpetrated suggesting that the bill would *sub silencio* affect this wholly separate doctrine. This rule of construction addresses that confusion. Contrary to what others have suggested, I do not believe that this rule of construction represents a *sub silencio* endorsement of the OTDP, either; it simply preserves Congress's ability to review and consider the appropriateness of OTDP in the future if it wishes to do so.

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?**

RESPONSE: There is no credible evidence linking clearer patent eligibility to higher drug prices. Pricing is determined by complex factors such as reimbursement systems, regulatory timelines, market competition, and various other factors, not by patent eligibility standards.

In fact, the opposite is true. Uncertainty in eligibility suppresses innovation. When patents are unavailable, companies invest less in risky biomedical research. Fewer innovations mean fewer competitors and fewer treatment options, which ultimately leads to higher, not lower, prices. The best way to promote affordability is to ensure robust competition through a steady pipeline of new, patented inventions.

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 academic, or the ability to protect innovation through other means like trade secrets. Do you agree? Why or why not?**

RESPONSE: I do not agree with the idea that medical diagnostics will continue to be developed at the same pace and scale without predictable and reliable patent protection. While academic research and publication will always continue to some extent, those activities alone do not bring new diagnostics to patients. Turning a scientific insight into a usable diagnostic test requires years of development, clinical validation, regulatory review, and manufacturing. Each of these steps demands significant investment, and that investment only occurs when innovators and investors can rely on clear and enforceable patent rights.

The incentives that drive academic research, such as the need to publish, are very different from those that drive commercialization. Publishing a paper contributes to knowledge, but it does not provide the resources required to transform a discovery into a safe and reliable diagnostic tool. Predictable patent protection is what enables researchers and companies to secure the financing necessary to take that step.

Trade secrets cannot fill this gap. They encourage secrecy rather than openness and prevent others from building upon prior work. The patent system, by contrast, promotes both innovation and transparency by requiring inventors to publicly disclose how their inventions work in exchange for limited exclusivity. That exchange has been central to the success of the American innovation economy for more than two centuries.

As I noted during the hearing, the current interpretation of Section 101 has left diagnostics and other critical technologies in "legal limbo," excluding entire categories of innovation from protection. Independent analyses following the Supreme Court's *Mayo* decision have shown that investment in U.S. diagnostics declined significantly compared to what would otherwise have

been expected.[1] At the same time, Europe and Asia, which continue to allow patent protection for diagnostic inventions, have gained a strong lead in the development and manufacture of at-home and personalized testing technologies.

Restoring clarity through PERA will not allow patents on natural phenomena or abstract ideas. It will simply ensure that genuine human-made diagnostic innovations that apply scientific discoveries to practical and technological uses can once again be evaluated within the patent system. That clarity is essential to attracting investment, advancing innovation, and ensuring that the next generation of diagnostic tools is developed and manufactured in the United States and transferred to the market where patients can benefit.

7. **During your time at the USPTO, you issued guidance to clarify the state of Section 101 law. This guidance did a lot of good, but as you have said before this guidance is not enough. As someone who has been on the forefront of IP policy in our country, why do you think Congress needs to legislate today?**

RESPONSE: Congress needs to legislate in order to codify a clear, predictable and stable system of laws in this critically important area of America's innovation economy. The guidance that the USPTO put in place while I was Director helped provide more certainty and clarity for examiners and patent applicants, but it necessarily had to operate within the bounds of the Supreme Court and Federal Circuit's case law. The USPTO cannot change the law nor bind the courts; it can only apply the law as interpreted by the courts.

It is ultimately this case law that needs to be addressed, and in my opinion, fixed, by Congress through legislation such as PERA. The courts have acknowledged the confusion surrounding patent eligibility but have also made clear that only Congress can resolve it. Legislation is therefore the only way to restore clarity and predictability across all areas of technology and in all tribunals in the United States.

PERA provides Congress with an opportunity to fix this area of law. By setting clear and technology-neutral statutory standards, Congress can restore uniformity to the law and reaffirm the United States as the global leader in innovation and intellectual property.

8. **PERA relies on language that some have suggested is undefined or that should not be left to the courts to weigh in on. For example, terms such as "substantially" and "practically." What are your thoughts on this?**

RESPONSE: The inclusion of terms such as "substantially" and "practically" in PERA is both necessary and appropriate. Patent law has always relied on standards that require interpretation and professional judgment. Concepts such as "novel," "non-obvious," and "useful" are likewise qualitative terms that have guided examiners and courts for more than two centuries.

[1] Sasha Hoyt, *The Impact of Uncertainty Regarding Patent Eligible Subject Matter for Investment in U.S. Medical Diagnostic Technologies*, 75 WASH. & LEE L. REV. 412, 414 (2018).

These words help ensure that the statute can be applied sensibly to a wide range of technologies. Innovation evolves constantly, and the law must be adaptable enough to address new developments without becoming rigid or outdated. Terms like "substantially" and "practically" provide that needed flexibility while maintaining clear limits on what can and cannot be patented.

Far from introducing confusion, this language helps draw the correct line between pure abstractions and laws of nature as such, which remain ineligible, and genuine technological applications, which advance human progress and deserve protection. The courts and the USPTO have extensive experience interpreting and applying such language consistently across the Patent Act, and there is no reason to believe they cannot do so here.

Properly understood, these terms strengthen the statute by allowing it to operate effectively across both current and future technologies while preserving the essential boundary between human innovation and the fundamental tools of science and nature.

9. **Do you think that PERA protects against eligibility for ineligible claims that have phrases like "do it on a computer" added to them?**

RESPONSE: It is a misconception that PERA would make abstract ideas patentable simply because they are performed on a computer. The legislation was written specifically to prevent that result. Under PERA, processes that are purely economic, financial, business, social, or cultural in nature remain ineligible for patent protection even if they include a computer or software reference. Merely adding a computer to such a category does not transform it into a technological invention.

PERA draws this distinction clearly in its operative language. A process that contains only a nonessential reference to a computer is not patent eligible. To qualify, an invention must involve a genuine technological implementation that cannot be performed without a machine or manufacture. This ensures that abstract concepts remain outside the patent system while real technological innovations that improve the operation of computers, machines, or processes are eligible for protection.

The newly added rule of construction in Section 4(b) further underscores that this is how the operative language of the bill should be understood to work. Likewise, Section 5(e) of the findings of the bill directly explains that doing something like a "marriage proposal" on a computer is not patent-eligible under the operative language of the bill.

10. **Compared to where "business method" claims currently stand in terms of patent eligibility, how would PERA change this, if at all? Please explain.**

RESPONSE: Under PERA, processes that are substantially economic, financial, or business in nature remain excluded from patenting, even when they reference a computer or other machine.

The intent of the legislation is to prevent patents on abstract commercial concepts while restoring predictability for genuine technological inventions.

What PERA changes is the clarity of that boundary. The current case law has blurred the line between abstract ideas and technological applications, often invalidating legitimate innovations along with improper claims. PERA codifies that business practices performed as matters of human activity remain ineligible, but that inventions providing true technological improvements to machines, systems, or manufacturing processes are eligible.

Senator Eric Schmitt
Senate Judiciary Subcommittee on Intellectual Property
Written Questions for the Honorable Andrei Iancu
Hearing on "The Patent Eligibility Restoration Act – Restoring Clarity, Certainty, and Predictability to the U.S. Patent System"
Wednesday, October 8th, 2025

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?**

RESPONSE: Restoring patent eligibility to the scope it had at the country's founding through the initial patent laws of 1790 and 1793 until just this last decade would erase arbitrary constraints that threaten to choke the advancement of American innovation simply because of the unpredictable nature of how patent eligibility case law is applied. This hurts American innovation first and foremost: China does not impose these arbitrary constraints on its own inventors in its national patent system, nor does Europe or any of our other main economic competitors.

As for the question regarding patent "trolls," which I understand to refer to frivolous litigation, it is critical to appreciate that patent eligibility does not equate to patentability. Eligibility is the first step toward getting a patent granted, answering only the question of whether a technology falls within the scope of the patent system or falls outside of the patent realm, such as artistic creativity that is more suited for copyright protection. Once this question is answered, a patent applicant must still demonstrate that his or her invention is new, is non-obvious, and meets the disclosure requirements—all hurdles designed to maintain the quality of the patent system. There is a common misconception that the patent system routinely grants low-quality patents that contribute to a so-called patent troll problem, but this is incorrect, as recent studies show.[1] One such study, for example, shows that the Patent Office actually rejects more valid patent claims than it approves of invalid claims, to the detriment of businesses that need patent protection for their inventions to procure investment and fund their future R&D.

Frivolous litigation should indeed be prevented to the extent possible, whether it is patent litigation or any other type. It is helpful that the patent system already contains numerous safeguards against frivolous litigation, such as attorney fee-shifting (which is not a feature of most other areas of civil litigation), as well as state laws against harassing "demand letters." There are also several ways to challenge an issued patent's validity, including in district court, before the USPTO's Patent Trial and Appeal Board (PTAB) in *inter partes* reviews and post-grant reviews, and in *ex parte* reexamination requests to the USPTO. If more measures are needed to curb frivolous litigation, they should be explored separately. The substantive question of patent eligibility should not be over-extended in order to address this separate issue.

[1] ANI HARUTYUNYAN ET AL., SUNWATER INSTITUTE, PATENT QUALITY IN THE UNITED STATES: FINDINGS AND SUGGESTIONS FOR POLICYMAKERS 2, 8-10 (2024), https://sunwater.org/wp-content/uploads/2024/09/SWI-Policy-Report-Patent-9-23-2024.pdf.

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

RESPONSE: PERA would not have any effect. Patents that were improperly issued can be invalidated in many ways and in many fora, including, if applicable, under Section 101 as it would be rewritten under PERA. As described above, there are also many existing protections in the patent system against frivolous litigation.

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

REPONSE: A patent system that more clearly allows for AI inventions to be patent eligible would allow individuals and companies inventing in this space to obtain an appropriate scope of patent protection for their innovation with less risk of unpredictable court invalidations based on eligibility in the future. This certainty, in turn, would help secure investments into implementation of AI technology, particularly for companies or individuals who cannot rely on other competitive advantages to protect their innovation, such as market share. As in other areas of technology, a clear, stable, and predictable patent system results in more innovation, and this is also true with respect to AI technologies.

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

RESPONSE: The patent eligibility guidelines for AI issued by the last administration,[2] as well as some initial case law from the Court of Appeals for the Federal Circuit,[3] suggest that it will be difficult for inventors in the AI space to obtain patent protection for inventions where an analogy can be drawn between what a machine can be manipulated to do and what a human does on his or her own. In other words, by anthropomorphizing a machine to characterize its output as "like" what a human does when a human thinks, the sheer ingenuity that went into engineering a machine with this degree and type of computing ability is not necessarily patent eligible. This is a backward way to run a patent system, directly undercutting support for technological invention and progress. Unless clarified, this will result in less American innovation in this critical area of technology, precisely at a time when the United States needs to maximize its innovative output in order to remain competitive.

[2] 2024 Guidance Update on Patent Subject Matter Eligibility, Including on Artificial Intelligence, 89 Fed. Reg. 57892 (Jul. 17, 2024), https://www.govinfo.gov/content/pkg/FR-2024-07-17/pdf/2024-15377.pdf.
[3] Recentive Analytics, Inc. v. Fox Corp., No. 2023-2437, slip op. (Fed. Cir. Apr. 18, 2025), https://www.cafc.uscourts.gov/opinions-orders/23-2437.OPINION.4-18-2025_2500790.pdf.

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

RESPONSE: Congress should open the patent system doors to the critical technological innovation that constitutes AI to foster the best possible environment for AI to develop rapidly, from the full range of innovators including startups and small, medium and large businesses alike. Even more importantly, Congress should clarify the law, as predictability in the patent system is conducive to innovation and investment in that innovation. Enabling increased innovation makes it easier for disruptive innovators to get a foothold, and empowering such out-of-the-box thinkers and inventors has long been the key to the United States's competitive advantage.