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Hearing on the Patent Eligibility Restoration Act (PERA)
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Chairman Tillis, Ranking Member Schiff, and Members of the Subcommittee:

Thank you for the opportunity to appear before you to discuss the Patent Eligibility Restoration Act of 2025 ("PERA") and the urgent need to bring clarity to 35 U.S.C. § 101. It is an honor to return to this Committee and build on the testimony I provided last year.

I want to begin by commending Ranking Member Tillis and Senator Coons for their leadership in reintroducing PERA, Senators Blackburn and Hirono for co-sponsoring it, and this Subcommittee for once again taking up the critically important task of modernizing one of the most fundamental provisions of our patent laws. At its core, the question before you is whether Congress should restore a clear and reliable statutory standard for subject-matter eligibility. In my view, the answer is unequivocally yes. After more than a decade of confusion and inconsistent court rulings, only Congress can resolve the uncertainty that threatens investment, innovation, and America's competitive edge.

Section 101, first enacted in the Patent Act of 1793, has remained largely unchanged for more than two centuries. Yet the technologies that power today's economy were unimaginable when the statute was written. Courts and agencies have struggled to map 18th-century text onto 21st-century innovation, producing a patchwork of judge-made exclusions that Congress never enacted.

As Ranking Member Tillis emphasized in reintroducing PERA in this Congress, "clear, reliable, and predictable patent rights are imperative to enable investments in the broad array of innovative technologies … we cannot allow legal uncertainty to stall the next wave of American innovation."[2]

The urgency of reform is underscored by the fact that, in all twelve judges sitting on the *en banc* Federal Circuit lamented the state of eligibility law, describing it as incoherent and unworkable.[3]Their concerns have been echoed by witnesses and stakeholders from across industries, academia, and the innovation economy, who have testified to the chilling effect this uncertainty has on research, investment, and commercialization. Indeed, as Justice Clarence Thomas warned, "exclusionary principle[s]" espoused by the judiciary risk "swallow[ing] all of patent law."[4]

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[1] The views expressed herein are personal to me, and do not represent the views of Sullivan & Cromwell LLP or its clients.
[2] Office of U.S. Sen. Thom Tillis Press Release, *Tillis, Coons, Kiley, and Peters Reintroduce Landmark Legislation to Restore American Innovation* (May 1, 2025), *available at* https://www.tillis.senate.gov/2025/5/tillis-coons-kiley-and-peters-reintroduce-landmark-legislation-to-restore-american-innovation
[3] Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC, 927 F.3d 1333 (Fed. Cir. 2019) (en banc)
[4] *Alice Corp. v. CLS Bank Int'l,* 573 U.S. 208, 217 (2014).

That concern is not limited to the bench or industry. The current state of the law has even sown confusion among the expert ranks of the hardworking examiners at the United States Patent and Trademark Office ("USPTO"). In 2019, when I was the head of the agency, the USPTO issued revised guidelines that synthesized the case law, giving examiners and applicants a clearer framework. The results were measurable: according to the USPTO's Chief Economist, uncertainty in first-action eligibility determinations dropped by 44 percent in the year after their release. However, courts are not bound by USPTO guidance, and the gap between examination and litigation outcomes persists. But this USPTO-driven attempt to synthesize case law for the benefit of examiners provides a proof of principle—a better, more coherent framework that does indeed produce better, more consistent results. PERA would do the same, except that it would be binding on the USPTO and the courts; something that the Director's guidance cannot do.

While the Director's authority is limited, I am heartened that newly-confirmed USPTO Director Squires recognizes the urgency of the state of the law, identifying "reducing uncertainty under Section 101" as one of his top priorities. As he testified during his confirmation hearing, the law of patent eligibility "suffers from clarity of precedent and sows confusion and uncertainty into our patent system. This uncertainty clouds patents, erodes confidence in our system, and is leading to a lack of American competitiveness, particularly in AI and critical emerging technologies."[5]

He further cautioned that "the lack of clarity is compromising our world standing and threatens our national security." Director Squires has pledged to work with Congress and this Committee to ensure that our patent laws "meet the moment and serve both inventors and the Nation at large."[6] And Director Squires has not wasted time in ensuring that, to the best of his authority under existing precedent, patent eligibility is available to important areas of technology. Just two weeks ago, he joined an agency decision overturning a decision to deny the eligibility of a patent claiming an improvement in AI technology, stating, "[c]ategorically excluding AI innovations from patent protection in the United States jeopardizes America's leadership in this critical emerging technology."[7] Yet, there remains guidance that was issued under the previous Administration specific to AI that does just that—another illustration of the confusion and incoherence of the current state of the law.[8]

I congratulate Director Squires on his recent confirmation and welcome his attention to, and leadership on this issue. Yet, to reiterate, his statements underscore what this Committee has long recognized: even with

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[5] Nomination of John A. Squires To Be Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office — Questions for the Record (May 28, 2025), available at https://www.judiciary.senate.gov/imo/media/doc/2025-05-21_qfrresponses_squires.pdf

[6] Nomination of John A. Squires To Be Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office — Questions for the Record (May 28, 2025), available at https://www.judiciary.senate.gov/imo/media/doc/2025-05-21_qfrresponses_squires.pdf

[7] Appeals Review Panel of the Patent Trial and Appeal Board, Ex parte Guillaume Desjardins et al., Appeal No. 2024-000567, Decision on Request for Rehearing (Sept. 26, 2025), at 9, available at https://www.uspto.gov/sites/default/files/documents/202400567-arp-rehearing-decision-20250926.pdf

[8] Guidance: 2024 Update on Patent Subject Matter Eligibility, Including on Artificial Intelligence, 89 Fed. Reg. 58,128 (July 17, 2024), available at https://www.federalregister.gov/documents/2024/07/17/2024-15377/2024-guidance-update-on-patent-subject-matter-eligibility-including-on-artificial-intelligence

strong leadership at the USPTO, only Congress can deliver the statutory clarity that American innovation demands.

PERA provides that clarity. By defining in statute which categories of invention are in and which are out, and by eliminating the extra-statutory judicial exceptions that have sown confusion for more than a decade, PERA offers the reliable foundation our patent system urgently needs.

I. The U.S. Patent Code

Like much of American law, our patent system grew out of English common law traditions. Before the Revolution, patents were granted piecemeal by colonial judges or governors, often resulting in overlapping rights and disputes among the colonies. Recognizing the chaos and inconsistency of that system, the Framers wrote into the Constitution the Patent and Copyright Clause, empowering Congress "[t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries."[9] With that clause, the federal patent system was born.

James Madison, one of the principal architects of the Constitution, made the case plainly: "the utility" of this Congressional power "will scarcely be questioned" because "the public good fully coincides . . . with the claims of individuals."[10] In other words, when inventors are rewarded, society benefits as a whole.

One of the very first acts of the new Congress was the Patent Act of 1790. It was soon amended in 1793, and in that statute Congress articulated for the first time the categories of invention eligible for patent: "any new and useful art, machine, manufacture, or composition of matter, or any new and useful improvement thereof."[11] That formulation—broad and technology-neutral—remains, almost verbatim, in Section 101 today.

However, the early system struggled. By the 1830s, a significant portion of patents were "worthless and void," conflicting with each other or with public rights, and clogging the courts with lawsuits.[12] Congress responded with the Patent Act of 1836, which created the Patent Office and established professional examination of applications. That reform was essential: it provided inventors and the public with an orderly process for determining rights and avoiding the chaos of overlapping patent claims.

Over the next century, courts refined the doctrines that still define our system: nonobviousness, written description, limitations on subject matter, and the doctrine of equivalents. However, by the mid-20th century, Congress again recognized the need to codify and rationalize patent law. The Patent Act of 1952 created Title 35 of the U.S. Code and carefully organized the different requirements for patentability. Most important, it established four distinct provisions, each with a separate role:

- **Section 101**: a broad, categorical threshold—what types of inventions are eligible.
- **Section 102**: the requirement of novelty.

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[9] U.S. Constitution, *art. I, § 8, cl. 8 (the Patent and Copyright Clause).*
[10] *James Madison,* The Federalist No. 43 (1788).
[11] Patent Act of 1793, ch. 11, § 1, 1 Stat. 318 (1793).
[12] *Senate Report Accompanying Senate Bill No. 239,* 24th Cong., 1st Sess. (Apr. 28, 1836).

- **Section 103**: the requirement of non-obviousness.
- **Section 112**: the requirements of disclosure and claim specificity.

The 1952 Act deliberately separated eligibility (§ 101) from the substantive conditions of patentability (§§ 102, 103, and 112).[13] Each was meant to operate in its own lane. If an invention fit into one of the categories of § 101, it then had to satisfy the further conditions of novelty, non-obviousness, and adequate disclosure. If it failed at any of those later stages, the patent should not issue. Section 101 was never intended to carry the weight of those later inquiries.

As Judge Giles Rich, one of the principal drafters of the 1952 Act, later warned, courts must be vigilant not to "commingle" the categories of invention in § 101 with the conditions for patentability in §§ 102, 103, and 112.[14] Keeping those lanes distinct was one of the great achievements of the 1952 Act. It gave examiners and judges clarity, inventors predictability, and the system overall a coherence that fueled American innovation for decades.

II. The Breakdown of Section 101

Unfortunately, Judge Rich's warning has proven prophetic. Over the last fifteen years, the Supreme Court has steadily eroded the careful balance Congress established in the Patent Act of 1952. Beginning with *Bilski v. Kappos* in 2010 and continuing through *Mayo v. Prometheus* in 2012, *Association for Molecular Pathology v. Myriad Genetics* in 2013, and *Alice Corp. v. CLS Bank* in 2014, the Court took long-existing, but narrow, judicially-created exceptions to section 101—"abstract ideas," "laws of nature," and "natural phenomena"—and broadened them beyond recognition.

Each of these cases, considered individually, appeared to resolve narrow disputes. Together, however, and especially as applied by the lower courts, they have produced a doctrine that is unpredictable, unworkable, and harmful to innovation.

In *Bilski*, the Court invalidated claims to a method of hedging risk in commodities trading, deeming them an "abstract idea."[15] Yet the Court declined to say what kinds of business or software processes might still qualify as patentable "processes." The result was more uncertainty, not less.

In *Mayo*, the Court considered a diagnostic method that allowed doctors to optimize drug dosages by measuring metabolites in a patient's blood.[16] The Court held that the claims merely applied a "law of nature" with routine steps, and were therefore ineligible. However, whether steps are routine or conventional is precisely the type of question Congress assigned to sections 102 and 103, not section 101. The practical effect of *Mayo* was to render nearly all diagnostic methods unpatentable, driving capital out of the sector and leaving the United States dangerously reliant on foreign diagnostic technologies. During the COVID-19 pandemic, we saw the consequences firsthand.

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[13] *See* Patent Act of 1952, ch. 950, 66 Stat. 797 (1952).
[14] Application of Bergy, 596 F.2d 952, 959 (C.C.P.A. 1979)
[15] *Bilski v. Kappos,* 561 U.S. 593, 601 (2010).
[16] *Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC,* 915 F.3d 743, 746 (Fed. Cir. 2019).

In *Myriad*, the Court ruled that naturally occurring human genetic sequences are not patentable, even when isolated from the body for diagnostic or therapeutic purposes.[17] Whatever one thinks about the ultimate policy outcome, the decision again substituted judicial judgment for congressional debate, and upset longstanding doctrines governing patentability beyond genetics, discouraging investment in genetic therapies and other biotechnology.

Finally, in *Alice*, the Court addressed a computer-implemented method for financial settlement.[18] Although the claims involved specific machine-implemented steps, the Court invalidated them as nothing more than an "abstract idea" performed on a computer. Lower courts and the USPTO have since applied *Alice* broadly, sweeping in software, artificial intelligence, cybersecurity, and other genuine technological innovations. Outcomes often turn more on claim drafting than on the substance of the invention.

The problem with these cases is threefold. First, they commingle section 101 with sections 102, 103, and 112, importing novelty, obviousness, and disclosure concerns into a threshold inquiry that was never meant to bear that weight. Second, they exclude entire categories of invention from patent protection without congressional authorization, usurping a responsibility that the Constitution assigns to Congress. And third, they create uncertainty so pervasive—not knowing what is in or out of the patent system—that even the judges applying the law have acknowledged it cannot be administered with confidence.

By 2021, all twelve then-sitting Federal Circuit judges had publicly lamented the incoherence of eligibility jurisprudence. Judge Plager wrote that the law gives "little confidence" in its outcomes.[19] Chief Judge Moore observed that diagnostic claims face a de facto rule of ineligibility.[20] Judge Lourie has called for "higher intervention," and Judge Newman warned that the courts have "clouded the line" to exclude entire fields like precision medicine and advanced diagnostics.[21]

The practical effects are stark. Life-saving diagnostic methods are routinely invalidated as "laws of nature," no matter how specific their application. Software and AI breakthroughs are swept into the "abstract idea" category, with outcomes depending more on drafting style than technological substance. Even advanced manufacturing methods have been struck down on eligibility grounds when the real questions sounded in obviousness or enablement. Analysts estimate the U.S. has lost more than $9.3 billion in diagnostic investment since *Mayo*.[22] China now leads in 37 of 44 critical emerging technologies, and venture capital increasingly flows overseas.[23]

The USPTO has tried to bring order. In 2019, the Office issued revised eligibility guidelines, which reduced uncertainty in examination by 44 percent.[24] However, agency guidance is inherently reactive. It

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[17] *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.,* 569 U.S. 576, 580 (2013).
[18] *Alice Corp. Pty. Ltd. v. CLS Bank Int'l,* 573 U.S. 208, 217 (2014).
[19] *Interval Licensing LLC v. AOL, Inc.,* 896 F.3d 1335, 1348 (Fed. Cir. 2018) (Plager, J., concurring in part).
[20] *Berkheimer v. HP Inc.,* 890 F.3d 1369, 1376 (Fed. Cir. 2018) (Lourie, J., concurring
[21] *Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC,* 927 F.3d 1333, 1363 (Newman, J., dissenting)
[22] 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),
[23] *Reuters, China Leads U.S. in Global Competition for Key Emerging Technologies, Study Says* (Mar. 2, 2023), available at https://www.reuters.com/technology/china-leads-us-global-competition-key-emerging-technology-study-says-2023-03-02/
[24] *See 2019 Revised Patent Subject Matter Eligibility Guidance,* U.S. PATENT AND TRADEMARK OFFICE, 84 Fed. Reg. 50 (Jan. 7, 2019), available at https://www.govinfo.gov/content/pkg/FR2019-01-07/pdf/2018-28282.pdf.

cannot bind Article III courts, and it cannot repair the underlying doctrinal fault lines. The gulf between examination and litigation persists, leaving inventors and investors without the predictability they need.

The bottom line is clear: judicially created exceptions have destabilized patent law, chilled innovation, and eroded America's competitive edge. Only Congress can restore the clarity that American innovation requires.

II. Why Congressional Action Is Necessary

Courts and agencies no longer suffice as the architects of patent eligibility. Over the past decade, judicial decisions have extended limited exceptions into sweeping doctrines that Congress never authorized, producing jurisprudence so unstable that even federal judges admit it cannot be consistently applied. The USPTO's 2019 guidelines improved coherence in examination, but guidance cannot bind courts or resolve conflicting precedent. Inventors, examiners, and investors remain caught between two disconnected worlds—one for obtaining patents, and another for enforcing them.

The costs of inaction are significant and mounting. Innovation thrives only when the rules are predictable and inventors and their investors can rely on the protections our system promises. When the law is unpredictable, investment dries up. The U.S. is losing its competitive edge in sectors where reliable patent protection matters most: diagnostics, artificial intelligence, biotech, and advanced manufacturing, among others. Investment capital is cautious when the legal foundation is murky. Diagnostic methods, once eligible, now face blanket invalidation under judicial doctrines; American innovators in AI see vital inventions rejected while their foreign counterparts navigate more predictable systems. Across advanced manufacturing, biotech, and emerging technologies, the uncertainty sends a signal: America can no longer guarantee that breakthrough work will be protected here. The result is talent and capital migrating to jurisdictions with firmer ground—and that erodes our global standing.

Now is the moment for Congress to step in. The Constitution entrusts Congress with the power to define intellectual property rules, and that authority cannot be ceded. For patent eligibility, however, the substance of the statutory language is largely unchanged since the Patent Act of 1793.

Congress has a unique opportunity, and responsibility, to restore clarity. By reaffirming that genuine human-made inventions can qualify for patent protection, while explicitly delineating boundaries for ineligible subject matter, a legislative solution can reestablish a technology-neutral eligibility framework that courts and agencies must follow. It can safeguard the separation intended by the 1952 Patent Act, by vesting eligibility as a threshold inquiry and reserving novelty, non-obviousness, and disclosure to their proper domains.

This is not simply a nuance in legal drafting; this is central to America's long-term competitiveness and security. Other nations are actively strengthening their IP regimes to attract the best ideas, entrepreneurs, and capital. If we do not act now, we risk ceding the future in fields such as AI, biotech, advanced manufacturing, and quantum science. Legislative clarity is essential—not just to restore confidence in our patent system, but to preserve America's capacity to lead in tomorrow's breakthroughs.

III. What PERA Does—and Why It Works

PERA is a targeted repair that restores § 101 to its proper, limited function while addressing modern realities. First, the bill reaffirms that any useful process, machine, manufacture, composition of matter, or improvement thereof is eligible, returning the statute to the technology-neutral breadth that has served the country well. “Technology-neutral” is critical—it keeps bureaucracy from second-guessing or incorrectly trying to predetermine the direction of technological innovation. Second, it replaces amorphous judicial carve-outs with short, explicit rules enacted by Congress. These rules provide clear guidelines for the outer boundaries of what the patent laws protect, specifying that the patent system is not meant to encompass claims to mathematical formulas “as such”; mental processes performed solely in the human mind; unmodified human genes as they exist in the body and unmodified natural materials as they exist in nature; and processes that are substantially economic, financial, business, social, cultural, or artistic.

Third, PERA adds practical guardrails for modern computing. It makes clear that “mere involvement of a computer” or other insignificant pre- or post-solution activity does not confer eligibility. At the same time, it recognizes that a process that cannot practically be performed without a machine—including a computer—is within the statute’s technological domain and should be judged on the merits under the traditional sections. This line respects the reality that software now drives physical systems, while preventing business methods from being smuggled into eligibility by the simple expedient of a computer reference.

Finally, PERA preserves the separation of gates Congress established in 1952 and clarifies what “useful” means in this context: a specific and practical application. Courts are instructed to assess eligibility without importing novelty, obviousness, or disclosure concerns into § 101. Those doctrines remain fully available—indeed, essential—to police claim scope and quality where they belong.

IV. How PERA Operates in Practice

The bill’s operation is best illustrated through examples that recur in today’s innovation economy. Consider a blood-based assay that detects a biomarker pattern indicative of early-stage pancreatic cancer. The correlation between the biomarker and disease risk is a natural phenomenon and, under PERA, remains outside the patent system if claimed as such. A human-made assay that applies that correlation through specified steps—defined sample preparation, detection chemistry, thresholds, and a corresponding clinical action—presents a specific and practical application. Under PERA, such a claim is eligible at the threshold and then must satisfy novelty, non-obviousness, enablement, and written description.

Or consider a computer-implemented invention in cybersecurity. A team designs a new training architecture that reduces memory bandwidth and achieves provably faster convergence on commodity GPUs for intrusion detection at the network edge. Under current doctrine, such claims are often recast as “data analysis on a computer.” Under PERA, the question at § 101 is straightforward: can the claimed process be performed, in practical terms, without a machine? If not, the claim is within the statutory domain and should be adjudicated under §§ 102, 103, and 112, which will test whether it is genuinely new, non-obvious, definite and properly supported. By contrast, a scheduling or hedging method that merely appends a computer remains ineligible; business methods do not become technological inventions by virtue of a keyboard.

The same holds in traditional industries. A startup develops a process-control loop that stabilizes phase composition when printing superconducting tapes at scale. That is plainly technological work. Under PERA, the claim passes the eligibility threshold. Whether it is patentable ultimately turns on the familiar merits inquiries, not on metaphysical distinctions at § 101.

Finally, with respect to genes and natural materials, PERA is clear. An unmodified human gene, whether in situ or merely isolated, and unmodified natural materials as they exist in nature, are not patent-eligible. Engineered constructs and human-made applications of scientific discoveries, however, may be eligible and will be judged against the full range of statutory requirements. This draws a principled line that respects both science and ethics while preserving incentives for applied research.

V. Addressing Concerns

Some worry that eligibility reform will unleash abstract software or business-method patents. PERA directly addresses this by excluding processes that are substantially economic, financial, business, social, cultural, or artistic and by making explicit that merely saying "do it on a computer" is not enough. At the same time, the bill protects genuine, machine-implemented technology that cannot practically be performed without a computer. That is the right line in a world where software is integral to physical systems.

Others fear a return to patents on human genes or on laws of nature. PERA forecloses that outcome. The bill expressly excludes unmodified human genes, including those merely isolated, and unmodified natural materials. What it restores is protection for applications of scientific knowledge—the human-made inventions that translate discovery into diagnostics and therapies—subject to the robust guardrails of novelty, non-obviousness, and adequate disclosure.

Finally, some suggest that courts already have sufficient tools and that legislation is unnecessary. A decade of fractured case law proves otherwise. Although administrative guidance has helped examination, it cannot bind the courts or resolve the doctrinal conflicts. If the Nation is to rely on simple, durable rules at the eligibility threshold, those rules must come from Congress.

VI. Implementation and Oversight

If enacted, PERA should be implemented swiftly and transparently. The USPTO can promptly update the Manual of Patent Examining Procedure and examiner training materials to reflect the statute, including recent work clarifying practical application in AI-heavy arts. The Judicial Conference and Federal Judicial Center can provide educational materials to ensure district courts understand that eligibility is a limited, threshold inquiry distinct from the merits tests Congress enacted. The Patent Trial and Appeal Board can align its practice so that eligibility and novelty or obviousness proceed in their proper lanes, minimizing duplication and cost. And Congress can direct regular reporting from the USPTO and, as appropriate, the GAO on examination outcomes, appeal rates, pendency, and investment indicators in areas most affected by § 101 uncertainty, so that the Committee can monitor the statute's performance and make course corrections if needed.

VII. Conclusion

America's patent system is a growth engine when it is reliable and predictable. We have seen that careful administrative guidance can reduce uncertainty within the USPTO, however, courts remain bound by a doctrinal lattice that the Supreme Court has chosen not to revisit. Only Congress can restore a clear, modern statutory rule for patent eligibility. PERA does so—faithfully, narrowly, and with precision—protecting genuine technological advances while excluding claims that do not belong in the patent system. By returning § 101 to a true threshold inquiry and reaffirming the roles of §§ 102, 103, and 112, Congress will give American innovators the clarity they need to invest, to build, and to keep the next generation of breakthroughs here at home.

For these reasons, I respectfully urge the Committee to advance the Patent Eligibility Restoration Act of 2025.