adeia

April 29, 2025

Senator Thom Tillis
Chairman
Senate Judiciary Committee Subcommittee on Intellectual Property

Senator Chris Coons
Ranking Member
Senate Judiciary Committee Subcommittee on Intellectual Property

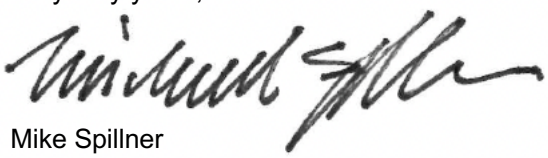
Dear Senator Tillis and Senator Coons:

I am writing on behalf of Adeia Inc., a publicly-traded U.S research and development (R&D) company (NASDAQ: ADEA) that invents and develops next-generation technologies for the media and semiconductor industries. Adeia is among the most innovative companies in America, ranking in the Top 75 of all organizations worldwide that were granted the most patents by the U.S. Patent and Trademark Office (USPTO) in 2024.[1]

Adeia strongly supports the Patent Eligibility Restoration Act (PERA) and the Promoting and Respecting Economically Vital American Innovation Leadership Act (PREVAIL). PERA and PREVAIL, if enacted, will strengthen and restore intellectual property protections for U.S. inventors, fueling American economic growth, technological progress, and global competitiveness. The bills make critical improvements to the U.S. patent system by clarifying patent eligibility standards and restoring much needed balance to administrative patent validity proceedings.

Adeia, much like other American R&D and growth tech companies, relies heavily on stable and reliable patent protection to support its business. A strong patent system is essential to incentivizing and protecting Adeia's investments in new, emerging technologies. For this reason, we commend you both for your leadership and unyielding commitment to the strengthening of the U.S. patent system through the re-introduction of PERA and PREVAIL.

Very truly yours,



Mike Spillner
Head of Government Affairs and Public Policy
Adeia Inc.

[1] https://ipo.org/wp-content/uploads/2025/01/2024-Top-300-Patent-Owners-List.pdf

Statement: PERA Act will Help Discoveries Move Beyond the Lab, Reach Patients

MAY 1, 2025

Today, Senators Thom Tillis (R-NC) and Chris Coons (D-DE) reintroduced the Patent Eligibility Restoration Act (PERA), a bipartisan effort to restore clarity and balance to the U.S. patent system by amending Section 101 of the Patent Act. Alliance for Aging Research President and CEO Sue Peschin, MHS, released the following statement:

The Alliance applauds Senators Tillis and Coons for reintroducing PERA. This bipartisan legislation is essential to ensuring that scientific discoveries can be developed into new diagnostic and medical technologies that improve the lives of patients, particularly older adults.

Accurate and early diagnosis is a foundation of effective health care, especially for older patients managing chronic diseases. Advanced diagnostic tools — built on decades of biomedical research — enable earlier detection, more targeted care, and better health outcomes. Yet uncertainty in Section 101 of the Patent Act has created barriers that slow the development and availability of these innovations.

PERA will restore much-needed clarity, helping ensure that new discoveries can move beyond the laboratory and reach patients. Strong and reliable intellectual property protections are vital to encouraging the continued advancement of medical technologies and supporting their translation into real-world solutions.

Older patients stand to benefit significantly from advances in diagnostics, which can lead to earlier interventions, improved quality of life, and reduced health care costs over time. By reinforcing the framework that supports innovation, PERA will help deliver better outcomes for patients and strengthen our health care system.

We thank Senators Tillis and Coons for their leadership and urge Congress to act swiftly to pass this important legislation.

STATEMENT FOR THE RECORD
Submitted by the Alliance of U.S. Startups and Inventors for Jobs (USIJ)

U.S. Senate Committee on the Judiciary
Hearing: "From Genes to Machines: The Patent Eligibility Debate"

July 14, 2026

The Honorable Chuck Grassley
Chairman
Committee on the Judiciary
United States Senate
Washington, DC 20510

The Honorable Dick Durbin
Ranking Member
Committee on the Judiciary
United States Senate
Washington, DC 20510

Dear Chairman Grassley and Ranking Member Durbin,

On behalf of the Alliance of U.S. Startups and Inventors for Jobs (USIJ), I write to submit this statement for the record in connection with the Committee's hearing, "From Genes to Machines: The Patent Eligibility Debate." USIJ appreciates the Committee's continued attention to patent subject matter eligibility and urges the Committee to advance the Patent Eligibility Restoration Act (PERA), S. 1546, sponsored by Senators Thom Tillis and Chris Coons.

USIJ is an association of inventors, startups, venture capital investors, and entrepreneurs whose ability to build new companies and bring new technologies to market depends on a reliable patent system. Our members work across biotechnology, medical devices, diagnostics, artificial intelligence, and other technology-driven fields where the current state of patent eligibility law has become a direct obstacle to investment.

The Eligibility Problem Is Well-Documented

Section 101's core language, drawn from the Patent Act of 1793, remained a workable, technology-neutral threshold for over two centuries.[1] The Patent Act of 1952 reinforced this by deliberately separating eligibility (§ 101) from the substantive conditions of patentability, novelty (§ 102), non-obviousness (§ 103), and disclosure (§ 112), so that each requirement would operate in its own lane.[2] Judge Giles Rich, one of the 1952 Act's principal drafters, warned courts not to commingle these categories.[3]

That warning went unheeded. 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 Supreme Court took narrow, judicially created exceptions to Section 101 and broadened them well beyond their original scope.[4] In Mayo, the Court held that a diagnostic method for optimizing drug dosages was an ineligible "law of nature," effectively rendering most diagnostic methods unpatentable and driving capital out of the sector.[5] In Myriad, the Court held that isolated human genetic sequences are not patent-eligible.[6] In Alice, the Court invalidated a computer-implemented financial settlement method as an "abstract idea," and lower courts have since applied that holding broadly to sweep in software, AI, and cybersecurity innovations, with outcomes often turning more on claim drafting than on the substance of the invention.[7]

By 2019, the Federal Circuit's own judges were sounding the alarm. In an 8-opinion, 7-5 split order denying rehearing en banc in Athena Diagnostics v. Mayo Collaborative Services, Judge Moore wrote that "since Mayo, we have held every single diagnostic claim in every case before us ineligible," and Judge Newman warned that the courts had "clouded the line" to exclude entire fields like precision medicine and advanced diagnostics.[8] Justice Clarence Thomas himself has warned that these judicially created exceptions risk "swallow[ing] all of patent law."[9] The USPTO's own 2019 examination guidelines, while helpful, illustrate the limits of administrative fixes: they reduced first-action eligibility uncertainty by 44 percent, but agency guidance cannot bind Article III courts, and the gap between examination outcomes and litigation outcomes persists.[10]

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[1] Patent Act of 1793, ch. 11, § 1, 1 Stat. 318 (1793); U.S. Const. art. I, § 8, cl. 8.
[2] Patent Act of 1952, ch. 950, 66 Stat. 797 (1952).
[3] *Application of Bergy*, 596 F.2d 952, 959 (C.C.P.A. 1979).
[4] *Bilski v. Kappos*, 561 U.S. 593, 601 (2010); *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 566 U.S. 66 (2012); *Association for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576, 580 (2013); *Alice Corp. v. CLS Bank International*, 573 U.S. 208 (2014).
[5] *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 566 U.S. 66, 77–79 (2012).
[6] *Association for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576, 580 (2013).
[7] *Alice Corp. Pty. Ltd. v. CLS Bank International*, 573 U.S. 208, 217 (2014).
[8] *Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC*, 927 F.3d 1333 (Fed. Cir. 2019) (order denying rehearing en banc); *id.* at 1352 (Moore, J., dissenting); *id.* at 1363 (Newman, J., dissenting).
[9] *Alice Corp. v. CLS Bank International*, 573 U.S. 208, 217 (2014).
[10] U.S. Patent and Trademark Office, Office of the Chief Economist, *Adjusting to Alice: USPTO Patent Examination Outcomes After Alice Corp. v. CLS Bank International*, IP Data Highlights No. 3 (Apr. 2020).

This is not an abstract debate confined to appellate opinions. Mark Deem, an Operating Partner at Lightstone Ventures who has co-founded roughly twenty medical device companies over three decades, testified before this Committee that current doctrine directly threatens investment in personalized medicine and AI-assisted diagnostics.[11] He described a high-resolution eye-tracking technology used to diagnose and develop treatment for conditions such as autism spectrum disorder, traumatic brain injury, and treatment-resistant depression that received a Section 101 rejection on the theory that the underlying steps could be performed by a human, despite its reliance on complex camera and computer systems. As the patent attorney handling that rejection told him, examiners "know that they sound crazy but are simply following orders," leaving inventors baffled and patent counsel "stuck in the middle." Deem testified that no investor can commit a decade of work and hundreds of millions of dollars to an invention that cannot be protected, a dynamic he tied directly to venture investment in medical devices being roughly flat in recent years, with deal volume at a multi-year low.

The costs are measurable. One estimate places diagnostic investment losses since Mayo at over $9.3 billion.[12] U.S. Patent & Trademark Office Director John Squires has also identified reducing Section 101 uncertainty as a top priority, testifying that current doctrine "clouds patents, erodes confidence in our system, and is leading to a lack of American competitiveness, particularly in AI and critical emerging technologies."[13]

Why This Matters for U.S. Competitiveness

The consequences of continued inaction extend beyond individual inventors. While the U.S. has spent the past decade litigating whether diagnostic methods, software-based innovations, and gene-based medicine are "abstract," other countries, China chief among them, have moved forward extending patent protection to these same categories of invention by focusing on the concrete features of the technology rather than getting caught in eligibility line-drawing.[14] Every year this uncertainty persists is a year in which the U.S. cedes ground in fields it should be leading, including AI-assisted diagnostics, precision medicine, and next-generation medical devices.

Startups and small companies are disproportionately harmed by this uncertainty. Unlike large incumbents with diversified patent portfolios and litigation budgets, emerging companies rely on a small number of core patents to attract the capital needed to survive years of product development before reaching market. When eligibility outcomes are

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[11] Statement of Mark Deem, Operating Partner, Lightstone Ventures, before the Senate Judiciary Committee, Subcommittee on Intellectual Property, Hearing on the Patent Eligibility Restoration Act — Restoring Clarity, Certainty, and Predictability to the U.S. Patent System (Jan. 23, 2024).
[12] 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).
[13] Statement of John A. Squires, USPTO Director-designate, before the Senate Judiciary Committee, Subcommittee on Intellectual Property, Confirmation Hearing (May 21, 2025) (responding to question from Sen. Tillis).
[14] See *supra* note 13.

unpredictable, that capital becomes harder to raise, and promising technologies go undeveloped.

PERA Provides a Clear, Workable Fix

PERA addresses this uncertainty directly. Rather than asking courts to continue refining an unworkable multi-factor test, PERA eliminates all judicial exceptions to eligibility and replaces them with a defined, limited set of statutory exclusions. Under the bill, an invention or discovery that can be claimed as a useful process, machine, manufacture, or composition of matter is eligible for patent protection, subject only to the following exclusions: unmodified human genes as they exist in the body, unmodified natural materials as they exist in nature, pure mathematical formulas standing alone, mental processes performed solely in the human mind, and processes that are substantially economic, financial, business, social, cultural, or artistic in nature and can be practically performed without a machine.

Critically, PERA preserves the existing patentability requirements under Sections 102, 103, and 112. Novelty, non-obviousness, and adequate disclosure remain fully intact as gatekeeping requirements. PERA does not lower the bar for what can be patented. It simply restores the separation Congress originally intended between the eligibility inquiry and those other statutory requirements, a separation the courts eroded starting with Alice and Mayo.

Conclusion

PERA reflects years of bipartisan, bicameral work to build consensus around a legislative fix to Section 101, and it has been substantively refined since it was first introduced to address concerns raised by stakeholders across the innovation ecosystem. USIJ urges the Committee to move forward with S. 1546 so that American inventors, startups, and investors can once again operate with confidence that their innovations, if novel, non-obvious, and adequately disclosed, will be eligible for patent protection.

We thank the Committee for the opportunity to submit this statement and welcome the chance to serve as a resource as this legislation moves forward.

Respectfully submitted,
Chris Israel
Executive Director
Alliance of U.S. Startups and Inventors for Jobs (USIJ)

American Chemical Society

ALBERT G. HORVATH
Chief Executive Officer

1155 SIXTEENTH STREET N.W.
WASHINGTON, D.C. 20036
Phone (202) 872-4534

July 14, 2025

The Honorable Thom Tillis, Chairman
Senate Subcommittee on Intellectual Property

The Honorable Christopher Coons
Senate Subcommittee on Intellectual Property

RE: American Chemical Society Support for the Patent Eligibility Restoration Act

Dear Senators Tillis and Coons,

On behalf of the American Chemical Society (ACS), I write to express our strong support for the Patent Eligibility Restoration Act of 2025 (PERA). If enacted, this legislation would bring much-needed clarity and predictability to the evaluation of subject matter eligibility under 35 U.S.C. § 101.

ACS is a federally chartered organization representing a community of more than 230,000 individuals around the world. The Society is committed to advancing chemistry through scientific research, education, and innovation—addressing critical challenges in health, energy, the environment, and beyond. Robust patent protection is essential to these efforts. Without it, scientific inventions and innovations are vulnerable to unauthorized use, weakening the incentive to invest in the research and development necessary to drive progress and advance the American economy.

ACS has long supported policies that strengthen U.S. innovation and ensure consistency and clarity in the implementation of patent law, both domestically and internationally—including with respect to subject matter eligible to be considered for patenting under § 101. The Society also advocates for the application of an objective, consistently applied test to determine patent eligibility. PERA meets both of these goals.

By eliminating ambiguous judicial exceptions to patent eligibility, PERA establishes a clear statutory baseline: any useful process, machine, manufacture, composition of matter, or improvement thereof is eligible to be considered for patent protection, unless explicitly excluded. This shift enhances the legal foundation for scientific innovation and better aligns U.S. standards with those of other leading jurisdictions--including those where U.S. companies conduct business.

In fields such as biotechnology and diagnostics, PERA restores eligibility to important breakthroughs that were previously excluded under current case law. At the same time, it maintains appropriate boundaries by permitting protection for modified natural products while excluding unmodified substances as they exist in nature. This balance encourages innovation while respecting the fundamental boundaries of the patent system.

Importantly, PERA separates the eligibility analysis under § 101 from the distinct requirements for patentability under §§ 102, 103, and 112. This separation corrects the current confusion stemming from judicial interpretations that conflate eligibility with novelty and inventiveness. By treating eligibility as a distinct threshold inquiry, the Act enhances doctrinal clarity and legal predictability—

benefiting both inventors and investors. It also reinforces the role of § 101 as a gatekeeper that excludes only fundamental exceptions like abstract ideas and natural laws, without prematurely rejecting otherwise patentable inventions.

We appreciate your leadership on this important issue. ACS stands ready to provide further information or assistance as needed and would welcome the opportunity to engage in a more detailed dialogue on how targeted legislative reform can advance U.S. innovation. We remain committed to ensuring that the U.S. patent system continues to support scientific discovery and the advancement of the chemical enterprise that promote American business and our economy.

Sincerely,

Albert G. Horvath
Chief Executive Officer
American Chemical Society

AIPLA
American Intellectual Property Law Association

April 29, 2025

The Honorable Thom Tillis
Chair
U.S. Senate Judiciary Subcommittee
on Intellectual Property
U.S. Senate
113 Dirksen Senate Office Building
Washington, D.C. 20510

The Honorable Christopher Coons
Member
U.S. Senate Judiciary Subcommittee
on Intellectual Property
U.S. Senate
218 Russell Senate Office Building
Washington, D.C. 20510

RE: Patent Eligibility Restoration Act

Dear Chair Tillis and Member Coons:

The American Intellectual Property Law Association (AIPLA) is pleased to support the reintroduction of the Patent Eligibility Restoration Act (PERA), in the 119th Congress. This critical legislation addresses longstanding uncertainty in U.S. patent eligibility jurisprudence and provides necessary clarity to ensure our patent system continues to promote innovation and investment across all technological sectors.

AIPLA is a national bar association of approximately 7,000 members including professionals engaged in private or corporate practice, in government service, and in the academic community. AIPLA members represent a wide and diverse spectrum of individuals, companies, and institutions involved directly or indirectly in the practice of patent, trademark, copyright, trade secret, and unfair competition law, as well as other fields of law affecting intellectual property. Our members represent both owners and users of intellectual property. Our mission includes helping establish and maintain fair and effective laws and policies that stimulate and reward invention while balancing the public's interest in healthy competition, reasonable costs, and basic fairness.

PERA is crucial for restoring predictability to patent subject matter eligibility under 35 U.S.C. § 101. The bill eliminates vague judicial exceptions and reaffirms that any useful process, machine, manufacture, or composition of matter—or any improvement thereof—should be eligible for patent protection, subject only to clearly defined exclusions. By clarifying the statutory scope of eligibility, PERA strengthens incentives for R&D, particularly in emerging industries such as artificial intelligence, biotechnology, and medical diagnostics.

We commend the sponsors of this bill for their leadership in addressing the effects of recent jurisprudence that has led to inconsistent and often differing outcomes in the lower courts and before the U.S. Patent and Trademark Office. We believe this legislation will significantly enhance legal certainty for inventors, businesses, and investors, and help maintain the United States' leadership in global innovation.

AIPLA urges the Senate Judiciary Committee to quickly advance PERA. We appreciate your consideration of our views and look forward to supporting the Committee's work in modernizing and strengthening the U.S. patent system.

Sincerely,

Vincent E. Garlock
Executive Director
American Intellectual Property Law Association

CC: Members of the Senate Judiciary Committee

August 29, 2025

The Honorable Thom Tillis
United States Senate
113 Dirksen Building
Washington, DC 20510

The Honorable Adam Schiff
United States Senate
112 Hart Building
Washington, DC 20510

Dear Senators Tillis and Schiff:

We, the undersigned associations with a membership consisting of America's research universities, medical schools, and technology transfer offices, write to express our strong and unified support for S. 1546 the Patent Eligibility Restoration Act.

Creating clear and consistent rules about what inventions are patent eligible will catalyze research and innovation across our campuses and improve pathways of bringing breakthrough innovations to the marketplace. This bill provides clearer technology transfer guideposts for our member institutions, particularly in innovative fields like biotechnology, artificial intelligence, and medical diagnostics.

If we want American technologies to remain at the forefront of innovation and U.S. economic competitiveness, we need Congress to bring predictability back to the patent process.

We thank you for introducing this bill and we urge other senators on the Senate Judiciary Committee to support it as well.

Respectfully,

Barbara R. Snyder
AAU President

Waded Cruzado
APLU President

Stephen J. Susalka
AUTM CEO

STATEMENT BY STEPHEN SUSALKA
CEO, AUTM
ON INTRODUCTION PERA
MAY 1, 2025

“AUTM — the association representing technology transfer professionals — thanks Senators Tillis and Coons and others for their leadership in introducing PERA. This legislation is crucially needed to address the ambiguities that the courts have created about what is, and what is not, patent eligible. At a time when the U.S. is competing for innovation leadership, its patent system needs to clearly delineate this process so that it can move forward on numerous discoveries that otherwise would wither on the vine.”

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April 30, 2025

Senate Committee on the Judiciary
224 Dirksen Senate Office Building
Washington, DC 20510

Dear Senator:

On behalf of the Bayh-Dole Coalition, I would like to reaffirm our support for the bipartisan, bicameral ***Promoting and Respecting Economically Vital American Innovation Leadership (PREVAIL) Act*** **and the** ***Patent Eligibility Restoration Act (PERA)***. These bills would strengthen the U.S. patent system and uphold the principles of the Bayh-Dole Act, which provides the legal framework for turning federally funded research into real-world inventions.

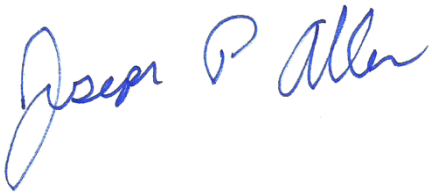
As you may recall from our previous letter, the Bayh-Dole Coalition is a group of innovation-oriented organizations and individuals committed to celebrating and protecting the Bayh-Dole Act, as well as informing policymakers and the public of its many benefits. Because the success of Bayh-Dole depends on a robust and stable patent system, the PREVAIL Act and PERA are essential to restoring clarity and fairness where it has eroded -- ensuring that publicly funded discoveries continue to attract investment, drive progress, and deliver value to the American people.

The PREVAIL Act addresses persistent issues at the Patent Trial and Appeal Board (PTAB), which currently permits repetitive challenges against innovators' patents. By restoring procedural fairness and limiting duplicative challenges, PREVAIL would provide critical protections for university inventors and other small entities, helping ensure that federally funded breakthroughs can progress from lab to market.

PERA addresses another foundational concern: the uncertainty around which types of inventions are eligible for patent protection. From life-saving diagnostic tools to AI-driven technologies, entire categories of cutting-edge innovation remain mired in ambiguity. PERA would restore much-needed clarity to eligibility standards, empowering researchers and investors to pursue breakthroughs that often originate in public research institutions and are vital to national competitiveness.

Together, these legislative efforts would reinforce the pillars of American innovation by ensuring that our patent system empowers, rather than obstructs, inventors. We commend the Committee's leadership in advancing these important reforms and urge you to preserve their core provisions, as the strength of our innovation economy depends on it.

Sincerely,



Joseph P. Allen
Executive Director
Bayh-Dole Coalition

Biocom California

June 16, 2025

Senator Thomas Tillis
United States Senate
113 Dirksen Senate Office Building
Washington, DC 20510

Senator Christopher Coons
United States Senate
218 Russell Senate Office Building
Washington, DC 20510

RE: Biocom California Support for S.1546 - Patent Eligibility Restoration Act of 2025

Dear Senators Tillis and Coons,

Biocom California writes to express our strong support for S.1546 - Patent Eligibility Restoration Act of 2025.

Biocom California is the largest, most experienced leader and advocate for California's life science sector, which includes biotechnology, pharmaceutical, medical device, genomics, and diagnostics companies of all sizes, as well as research universities and institutes, clinical research organizations, investors, and service providers. Biocom California drives public policy initiatives to positively influence the state's life science community in the research, development, and delivery of innovative products and technologies that improve health and quality of life. California's life sciences industry generates over $414 billion in annual economic output, supports 1.24 million jobs, and produces $128.6 billion in labor and sole proprietor income[1].

The bill would reform 35 U.S.C. § 101. to provide clearer guidelines on what constitutes patentable subject matter, thus restoring predictability to what qualifies for patent protection. By removing vague judicial exceptions and reaffirming what is eligible, the bill provides much-needed clarity to U.S. patent eligibility law. This strengthened framework will enhance incentives for research and development, especially in cutting-edge fields like artificial intelligence, biotechnology, and medical diagnostics, and will further help to ensure that our patent system continues to drive innovation and attract investment across all areas of technology.

With the clarity provided by PERA, innovators have a greater opportunity to help ensure that breakthroughs made in the lab can advance to benefit patients. Strong, reliable intellectual property protections are crucial for fostering continued medical progress and turning research into real-world solutions. This clarification would be particularly valuable for U.S.-based startups and early-stage innovators, by offering the clarity needed to secure investment for new ventures in critical fields like medical devices, diagnostics, and pharmaceutical manufacturing.

In our current climate, where the U.S. is striving to maintain its leadership in innovation, a clear and reliable patent system is essential to ensure promising discoveries aren't stalled or abandoned but instead have a clear path to development and impact.

We appreciate the opportunity to provide our support on behalf of our members and thank you for your consideration. Please contact Biocom California's Federal Advocacy Manager, Megan Kastner, at mkastner@biocom.org for additional information or questions. We look forward to continuing to work with you on this matter.

Sincerely,
Tim Scott

President & CEO
Biocom California

[1] Biocom California 2024 Economic Impact Report Databook. https://www.biocom.org/eir/

Biotechnology Innovation Organization
Statement for the Record
U.S. Senate Committee on the Judiciary
Hearing on "From Genes to Machines: The Patent Eligibility Debate"
July 14, 2026

The Biotechnology Innovation Organization (BIO) appreciates the opportunity to submit this statement for the record. We hope it will prove helpful, as the Committee works to restore clarity, predictability, and balance to U.S. patent eligibility law.

BIO is the world's largest trade association representing biotechnology companies, academic institutions, state biotechnology centers, and related organizations across the United States and in more than thirty other nations. BIO's members develop medical products and technologies to prevent, diagnose, treat, and cure disease, improving health outcomes for patients nationwide.

Few sectors depend more heavily on reliable patent protections than biotechnology. Strong patents enable small biotech companies to enforce their ownership of the innovations they create, enabling them to secure the investment and commercial partnerships needed to translate those innovations into useful products. Unfortunately, recent patent eligibility jurisprudence has weakened the ability of many innovators to secure the patent rights they rely on. This uncertainty has undermined investment and scientific progress in fields such as diagnostics, precision medicine, biomarker testing, and other areas that are crucial not only to America's public health but also to its global economic competitiveness.

BIO strongly supports the bipartisan Patent Eligibility Restoration Act (PERA), which would resolve current uncertainty by replacing judicial exceptions to patent eligibility with clearer statutory rules. This would strengthen investor confidence in the commercial viability of emerging biotech innovations and enable the U.S. biotechnology sector to maintain its global leadership for years to come.

Patent Eligibility Uncertainty Harms Small Biotechnology Companies

Small firms are responsible for originating a disproportionate share of biomedical innovation. More than half of the 363 new, U.S.-originated medicines approved by the FDA from 2011 to 2020 were created by small firms with less than $500 million in annual revenue.[1]

Small companies are particularly reliant on strong patent rights because of their business model. Many are pre-revenue, have no approved products, and are built around one or a small number of research and development programs. As such, they frequently depend on outside partners to fund research and development, conduct clinical trials, build manufacturing capacity, navigate global regulatory requirements, and help commercialize their products.

The ability to secure a patent on a new discovery is often the decisive factor in whether a small biotech company can attract the investment necessary to turn that discovery into a practical medicine. New medicines often require more than a decade of research and

[1] https://vitaltransformation.com/2022/12/the-us-ecosystem-for-medicines-how-new-drug-innovations-get-to-patients/

development, over $2 billion in capital, and extensive collaboration between publicly funded researchers, small companies, and larger commercial partners before they can reach patients.[2][3] By ensuring that innovators retain an exclusive right to the discoveries they make for a limited time, patents allow small companies to negotiate from a position of strength when partnering with larger firms, and give investors confidence that, if a high-risk program succeeds, the company will have a reasonable opportunity to recoup the cost of development.

Unfortunately, a series of Supreme Court decisions in the 2010s undermined the reliability of patent rights in the biotech industry. Whereas Section 101 of the Patent Act -- the section pertaining to patent eligibility -- had historically been interpreted as broadly allowing patents on inventions that are "new and useful," the Court's rulings advanced a different interpretation of the law, untethered from the statutory text, that carved out broad and unclearly defined exceptions for entire categories of inventions.[4]

- In *Mayo Collaborative Services v. Prometheus Laboratories, Inc.* (2012), the Court held that claims involving a method of optimizing drug dosing were patent-ineligible because they relied on an unpatentable "law of nature."[5]

- In *Association for Molecular Pathology v. Myriad Genetics, Inc.* (2013), the Court held that isolated DNA was patent-ineligible because it was a "product of nature."[6]

- In *Alice Corp. v. CLS Bank International* (2014), the Court ruled that certain computer-implemented inventions were patent-ineligible as "abstract ideas."[7]

The Federal Circuit has since applied these frameworks to invalidate patents on various biotechnology innovations.

- In *Ariosa Diagnostics, Inc. v. Sequenom, Inc.* (2015), the Federal Circuit invalidated patents covering a non-invasive prenatal test that detected fetal DNA in a maternal blood sample, treating the presence of cell-free fetal DNA as a natural phenomenon.[8]

- In *Roche Molecular Systems, Inc. v. Cepheid* (2018), the Federal Circuit invalidated claims covering methods for detecting Mycobacterium tuberculosis, treating the relationship between naturally occurring DNA sequences and the presence of the bacterium as a natural phenomenon.[9]

- In *Athena Diagnostics, Inc. v. Mayo Collaborative Services* (2019), the Federal Circuit invalidated claims covering a diagnostic method for myasthenia gravis, treating the correlation between certain autoantibodies and the disease as a natural law.[10] The case produced four dissenting opinions and four separate concurrences

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[2] https://www.mckinsey.com/industries/life-sciences/our-insights/fast-to-first-in-human-getting-new-medicines-to-patients-more-quickly

[3] https://www.deloitte.com/us/en/Industries/life-sciences-health-care/perspectives/navigating-the-glp-boom.html

[4] https://www.law.cornell.edu/uscode/text/35/101

[5] https://supreme.justia.com/cases/federal/us/566/66/

[6] https://supreme.justia.com/cases/federal/us/569/576/

[7] https://supreme.justia.com/cases/federal/us/573/208/

[8] https://law.justia.com/cases/federal/appellate-courts/cafc/14-1139/14-1139-2015-12-02.html

[9] https://law.justia.com/cases/federal/appellate-courts/cafc/17-1690/17-1690-2018-10-09.html

[10] https://law.justia.com/cases/federal/appellate-courts/cafc/17-2508/17-2508-2019-02-06.html

when rehearing was denied, underscoring the difficulty judges have had applying the current framework.

- In *CareDx, Inc. v. Natera, Inc.* (2022), the Federal Circuit invalidated claims covering methods for detecting organ transplant rejection by measuring donor-derived cell-free DNA in a transplant recipient's blood, treating the relationship between elevated donor-derived cell-free DNA and transplant rejection as a natural phenomenon.[11]

These precedents have created a dilemma for biotechnology innovators. Diagnostics often depend on identifying biological relationships and translating them into clinically useful tests. Precision medicine is predicated on naturally occurring biomarkers, genetic information, and treatment-selection methods. Data-driven tools are increasingly important for discovering, developing, and delivering new medicines and tests.

As changes in Section 101 doctrine have weakened patent protection on these types of innovations, it has harmed not only the innovators whose patents have been invalidated -- and the patients who stood to benefit from those inventions -- but also the broader investment environment. Companies making financing, licensing, and development decisions must account for the risk that future patents may be denied or revoked. It is difficult for them to do so when court precedent does not align with the statute and when courts routinely interpret the same patent-eligibility standard differently.

As a result, investors increasingly lack confidence that the patent protecting a given innovation will remain enforceable, leading them to withhold funding and hindering the development and commercialization of potentially lifesaving technologies.

Patent Eligibility Uncertainty Harms U.S. Competitiveness

The growing uncertainty surrounding patent eligibility has had measurable effects on biotechnology innovation, especially in the diagnostic sector. One study estimated that, in the four years following *Mayo*, investment in diagnostic technologies was approximately $9.3 billion lower than it would have been without the decision.[12]

There are also numerous examples of diagnostic innovations whose development was halted due to repeated and inconsistent Section 101 litigation. A series of case studies compiled by former Federal Circuit Chief Judge Paul Michel, former USPTO Director David Kappos, Corey Salsberg, and Matthew Dowd identified diagnostic technologies for lupus, Alzheimer's disease, major depressive disorder, metastatic melanoma, schizophrenia, cancer prognosis, and Noonan syndrome that were abandoned, narrowed to commercially weak claims, or left undeveloped after *Mayo* and *Myriad* made existing patents vulnerable and follow-on patent protection unavailable.[13] In several examples, universities had already licensed promising diagnostic technologies to commercial partners, only for those partners to terminate licenses, stop paying royalties, or decline further investment once Section 101 uncertainty undermined the value of the underlying patents.

Examples such as these have detrimental consequences for companies and patients alike. Companies are forced to spend significant time and resources working to commercialize

[11] https://law.justia.com/cases/federal/appellate-courts/cafc/22-1027/22-1027-2022-07-18.html

[12] https://scholarlycommons.law.wlu.edu/cgi/viewcontent.cgi?article=4762&context=wlulr

[13] https://ipwatchdog.com/2022/10/18/presenting-evidence-patent-eligibility-reform-part-iii-case-studies-litigation-data-highlight-additional-evidence-harm/

patents that may ultimately prove unenforceable. Patients lose out on new diagnostic technologies that showed real scientific promise but become commercially unviable because of legal uncertainty beyond the researchers' control.

These consequences also undermine U.S. economic competitiveness. While decisions such as *Mayo*, *Myriad*, and *Alice* have steadily curtailed patent eligibility in the United States, many other countries and regions maintain clearer and more predictable paths to eligibility. That creates a risk that biotechnology investment and research -- particularly in the most advanced biotechnology fields -- will shift to jurisdictions where innovators can more reliably protect and commercialize new inventions.

In Europe, for example, companies cannot patent medical acts performed directly on a patient, but they can patent diagnostic tools, testing technologies, substances, compositions, or other technical applications used to diagnose or treat disease. Japan excludes medical acts performed on the human body, but permits protection for related innovations such as pharmaceuticals, medical devices, manufacturing methods, laboratory analysis of patient samples, and certain biological inventions, so long as they satisfy ordinary patentability requirements. China excludes medical methods for diagnosing or treating disease, but it does not use the same broad U.S. rule that can block a diagnostic invention simply because the test relies on a naturally occurring signal in the body. In short, other countries frequently provide clearer paths to patent protection for the practical biotechnology tools that make modern diagnosis and treatment possible.

This imbalance has already had clear impacts on global patent filings. In 2017, patent law scholars Adam Mossoff and Kevin Madigan analyzed a dataset of 17,743 patent applications filed in the United States, Europe, and China.[14] They found that 1,694 of those applications for the same or similar inventions were granted in China or Europe, or both -- but rejected or abandoned in the United States. In 2019, Mossoff and Madigan published an updated analysis based on a refined version of the same dataset.[15] This update found that 1,310 applications were ultimately abandoned in the United States specifically because they were rejected on eligibility grounds, even though related patents were issued in China, Europe, or both.

Many of these patents pertained to the biotechnology industry. In Mossoff and Madigan's 2019 research, 618 of the 1,310 abandoned applications -- nearly half -- involved diagnosis or treatment of disease.[16] Of those healthcare-related applications, roughly a quarter were cancer-related. Among the applications rejected were claims for methods and compositions for diagnostic use in cancer patients; methods for detecting gynecologic cancer; methods for early determination of recurrence after therapy for prostate cancer; analyte testing methods and systems for diabetes-related complications; methods and kits for the prognosis of breast cancer; diagnosis of acute strokes; and methods for diagnosing and treating prostate and lung cancer.

As the Covid-19 pandemic demonstrated, America's ability to remain at the cutting edge of sectors such as medical diagnostics is a matter of economic and national security. During the pandemic, the United States faced severe shortages of testing supplies, including test kits, swabs, viral transport media, and reagents, and many hospitals waited a week or more for results.[17] Those delays limited physicians' ability to diagnose patients, manage hospital

[14] https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2943431

[15] https://ipwatchdog.com/2019/12/15/five-years-later-the-us-patent-system-is-still-turning-gold-to-lead/

[16] https://ipwatchdog.com/2019/12/15/five-years-later-the-us-patent-system-is-still-turning-gold-to-lead/

[17] https://pmc.ncbi.nlm.nih.gov/articles/PMC10358151/

capacity, and control the spread of disease. Lack of domestic diagnostic supply also made the United States heavily dependent on foreign suppliers, including China.

Of course, America's biotechnology industry also achieved significant successes during the pandemic. The extraordinarily rapid development of Covid-19 vaccines showed what U.S. biotechnology innovators can achieve when scientific breakthroughs are supported by a policy environment that enables investment, development, and commercialization. Given the stakes for U.S. competitiveness and security, it makes little sense to limit innovators' ability to pursue certain types of breakthroughs through an unusually narrow and unpredictable patent eligibility framework.

PERA Would Restore Clarity While Preserving Core Patent Safeguards

The Patent Eligibility Restoration Act, advanced by Senators Thom Tillis (R-NC), Chris Coons (D-DE), Marsha Blackburn (R-TN), and Mazie Hirono (D-HI), would resolve the patent eligibility uncertainty now affecting America's biotech sector and ensure that patent eligibility standards in the United States remain comparable to -- and competitive with -- those of our global rivals.[18]

PERA would bring greater certainty to patent eligibility by replacing the current patchwork of judicial exceptions with a more workable statutory framework. It would confirm that practical, human-made applications of scientific discoveries -- including diagnostics and other biotechnology inventions -- are eligible for patent protection, provided they satisfy the other requirements of the Patent Act.

Importantly, this would not make patents easier to obtain for inventions that lack merit. Under PERA, Section 101 would return to its intended purpose as a threshold eligibility test that asks whether an invention falls within one of the broad categories Congress identified: a process, machine, manufacture, composition of matter, or improvement thereof. While all inventions that meet this broad requirement would be therefore considered patent-eligible, that is distinct from the later question of whether the invention actually deserves a patent. To be granted, a patent would still need to satisfy Sections 102, 103, and 112, which require that the invention be new, non-obvious, adequately described, enabled, and claimed with sufficient clarity.[19][20][21] These requirements would remain fully in force under PERA.

PERA would also draw clear lines around what remains excluded from patent eligibility. It would not allow patents on natural materials themselves or abstract ideas untethered to practical application. The bill was also specifically revised to address concerns about gene patenting. It would not allow patents on an unmodified human gene as that gene exists in the human body.[22]

The net result of PERA would be a more predictable and balanced patent eligibility framework. Diagnostics, precision medicine technologies, and other biotechnology inventions would no longer be rejected at the outset simply because they involve biological relationships or natural materials. Instead, they would be evaluated under the full Patent

[18] https://www.congress.gov/bill/119th-congress/senate-bill/1546

[19] https://www.law.cornell.edu/uscode/text/35/102

[20] https://www.law.cornell.edu/uscode/text/35/103

[21] https://www.law.cornell.edu/uscode/text/35/112

[22] https://www.congress.gov/bill/119th-congress/senate-bill/1546/text#id7e2124adbdee47c99d574f0f4e0f3f6e

Act, where claims that are obvious, overbroad, insufficiently disclosed, or not truly new can still be rejected.

For biotechnology innovators, especially small and emerging companies, that clarity is essential. PERA would help restore confidence that patents can protect real-world applications of scientific discoveries, giving investors and commercial partners a stronger basis to support the costly work of development and commercialization. By doing so, it would accelerate American innovation and help ensure that the United States remains a global leader in biotechnology.

Conclusion

BIO thanks the Committee for holding this important hearing and for its continued work to support American innovation, patient access, and global competitiveness. The Patent Eligibility Restoration Act would address the documented shortcomings of the current framework while preserving the Patent Act's core safeguards.

BIO respectfully urges the Committee to favorably report the Patent Eligibility Restoration Act and stands ready to assist Congress in any way possible to advance this important reform.

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CFIF Reiterates Strong Support for the Patent Eligibility Restoration Act (PERA)

Print

Monday, July 13 2026

When it comes to American Exceptionalism and our nation's unrivaled legacy of invention, prosperity and power, no factor merits more credit than the fact that we value and **protect intellectual property (IP)** – patents, copyrights, trademarks and trade secrets – **more** than any other nation. Our Founding Fathers treasured IP so much that they explicitly protected it in the text of Article I of the Constitution, and the ensuing results speak for themselves.

For that reason, CFIF reiterates its strong support for the **Patent Eligibility Restoration Act (PERA)**, as the Senate Judiciary Committee holds a **hearing** this week on the bill entitled, "From Genes to Machines: the Patent Eligibility Debate."

PERA, which offers a rare point of bipartisan consensus in our otherwise divisive political environment, would restore greater fairness and legal certainty for America's innovators. That takes on greater importance each passing day, as China and other global rivals work tirelessly to catch the United States as the world's leader in innovation.

More specifically, **U.S. Supreme Court** and other decisions in recent years have created vague, judicially concocted exceptions that resulted in uncertainty across medical, tech and other innovation-intensive industries. That has in turn negatively impacted inventors and the investors who support them, who must rely upon the certainty that valuable breakthroughs will receive and retain patent protection.

Strong, predictable patents attract investment, reward risk and encourage commercialization. PERA would restore overdue correction by clarifying patent eligibility standards and reestablish Congress's proper authority over patent law while strengthening America's leadership. For that reason, CFIF strongly supports PERA, and urges Congress to pass it for President Trump's signature without any further needless delay.

Last year, CFIF produced a **web video** in large part urging Congress to pass PERA. The video features leading experts who've appeared on CFIF's ***IP Protection Matters*** podcast explaining how the bill will clarify patent eligibility. Those experts include: The Honorable Paul R. Michel, former Chief Judge on the U.S. Court of Appeals for the Federal Circuit; Alden Abbott, Senior Research Fellow at Mercatus Center and former General Counsel at the Federal Trade Commission; Chris Israel, Executive Director of Alliance of U.S. Startups and Inventors for Jobs; James Edwards, Founder and Executive Director of Conservatives for Property Rights; and Karen Kerrigan, President & CEO of the Small Business & Entrepreneurship Council. Watch the video below.

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COALITION AGAINST SOCIALIZED MEDICINE
a Project of THE CONSERVATIVE POLITICAL ACTION COALITION

Coalition Against Socialized Medicine Applauds the Introduction of the Promoting and Respecting Economically Vital American Innovation Leadership (PREVAIL) Act and the Patent Eligibility Restoration Act (PERA).

May 1, 2025

ALEXANDRIA, VA, May 1, 2025 – The Coalition Against Socialized Medicine (CASM), a broad coalition of leading conservative groups, including the Conservative Political Action Coalition (CPAC), Heritage Action, the National Taxpayers Union, Club for Growth, Citizens Against Government Waste, and American Commitment, has issued the following statement on the Promoting and Respecting Economically Vital American Innovation Leadership (PREVAIL) Act and the Patent Eligibility Restoration Act (PERA).

“The Coalition Against Socialized Medicine (CASM) is thrilled to see the introduction of the Promoting and Respecting Economically Vital American Innovation Leadership (PREVAIL) Act and the Patent Eligibility Restoration Act (PERA). As a coalition comprised of conservative, pro-competition organizations, CASM is thankful that our lawmakers are working to preserve the intellectual property (IP) protections that enable a functioning free market and promote American research and development.

“PREVAIL and PERA would work to strengthen and clarify IP rights and reinforce legal protections for innovation. Previous policies have empowered outside actors to disrupt innovation and investment, impeding advancement in the vital healthcare industry. Fortunately, PREVAIL and PERA will help preserve the patent system, restoring momentum to our country’s innovation pipeline.

“A pillar of freedom and innovation, IP protections promote competition while ensuring innovators can safely invest their time and money in new products. Patents are vital to fueling our free-market economy and medical sector, and both bills work to reinforce and uphold IP rights, promising continued innovation and progress.

“We urge Congress to act swiftly to pass the PREVAIL and PERA Acts, prioritizing the values that keep the U.S. the global leader of pharmaceutical innovation.”

21C Reaffirms Support for PERA as Senate Judiciary Committee Examines Patent Eligibility Reform

Washington, D.C. – The Coalition for 21st Century Patent Reform ("21C") is pleased to renew its endorsement of the bipartisan *Patent Eligibility Restoration Act of 2025* (PERA; S. 1546) in advance of the Senate Judiciary Committee's hearing titled, "From Genes to Machines: the Patent Eligibility Debate" on July 14, 2026. In 21C's view, this legislation represents a significant step forward in establishing clear and predictable patent-eligibility rules in the United States, providing long-overdue certainty for innovators and strengthening America's capacity to invest, invent, and compete.

21C is a diverse coalition of the nation's leading researchers and manufacturers who, like all inventors, rely on a robust patent system to protect their inventions and drive breakthrough, societally beneficial innovations. In that capacity, 21C advocates for federal policies that protect and modernize the United States patent system, recognizing that a strong and reliable patent framework is essential to supporting American innovation and technological leadership.

Over the past decade, Supreme Court decisions interpreting Section 101 of the Patent Act have left the scope of patent-eligible subject matter unsettled, creating uncertainty in the courts, at the U.S. Patent and Trademark Office, and across the broader innovation ecosystem. This uncertainty undermines the predictability that independent inventors, start-ups, universities, and corporations rely upon when making long-term investment decisions and funding research and development. Yet the current framework has led to the exclusion of many otherwise patent-eligible inventions from patent protection under Section 101, with consequences across critical U.S. sectors, including medical diagnostics and lifesaving treatments, advanced manufacturing, software development, and emerging technologies such as artificial intelligence and quantum computing.

Section 101 is intended to serve as the coarse filter for determining whether a category of invention is eligible for consideration, rather than a patentability test. Consistent with that purpose, PERA would restore clarity to the patent eligibility framework while preserving important guardrails against overreach. The legislation would continue to exclude from patent protection fundamental concepts that do not result from human ingenuity, including mathematical formulas, certain economic and social processes, genes as they exist in the human body, and natural materials as they exist in nature.

We would like to thank Senator Grassley (R-IA) and Senator Durbin (D-IL) for agreeing to hold this important hearing. Moreover, Senators Thom Tillis (R-NC) and Chris Coons (D-DE) have been stalwart champions for more certainty and reliability in our patent system, and we thank them for their continued leadership on PERA in Congress. 21C looks forward to continuing to work with all stakeholders to pass this important legislation. It is crucial for Congress to restore clarity and predictability to the nation's patent system to encourage U.S. innovation, attract investment, and strengthen American competitiveness.

For more information, visit http://www.patentsmatter.com

June 18, 2025

Dear Republican Senator/Representative:

The signatories below, comprised of public policy, grassroots, and free enterprise organizations, write to express our support for the Promoting and Respecting Economically Vital American Innovation Leadership (PREVAIL) Act (S. 1553, H.R. 3160), the Patent Eligibility Restoration Act (PERA; S. 1546, H.R. 3152), and the RESTORE Patent Rights Act (S. 708, H.R. 1574). We urge your support for this legislation.

The PREVAIL Act would secure private property rights to inventions and give quiet title, which is crucial for commercialization of and investment in patented innovations. That will boost the United States's competitive edge, especially in emerging and standardized technologies important to our economic and national security. PREVAIL would reform the Patent Trial and Appeal Board (PTAB) by adding procedural and due-process guardrails to reduce abuses of the administrative patent challenge system. These changes would protect patent owners from infringers' ability to game the PTAB system through repeated challenges, even when a court of law has already upheld that patent's validity, and inordinate PTAB discretion to tilt the process.

PREVAIL would help alleviate the damage to our patent system, to inventors (such as those who have testified before the Senate and House Judiciary Intellectual Property Subcommittees in recent years) who face the prospect of lost commercial traction during what is supposed to be their exclusive ownership and use of their invention, and from the erosion of property rights in the patent arena. Further, the legislation would mitigate the public's misgivings regarding this administrative body.

The PERA Act would fully eliminate judicially created exceptions to patent eligibility. It would restore the congressionally intentional breadth of the section 101 threshold question as to what is patent-eligible subject matter, including of a "useful process." This bill would prohibit examiners, courts, the Patent Trial and Appeal Board, or others from considering substantive patentability requirements (sections 102, 103, and 112) or from fixating on a patent claim apart from the invention as a whole in a 101 threshold determination regarding a specific invention or discovery. PERA would settle the current disquiet of uncertain patent eligibility among courts.

The RESTORE Patent Rights Act would result in courts again enjoining ongoing patent infringement after a patent is proven valid and being infringed. This would remedy the adverse way in which federal courts have applied the U.S. Supreme Court's 2006 *eBay v. MercExchange* case. Over the past two decades, courts have created a categorical rule of denying permanent injunctions against proven infringers. This development denies the wronged party justice. It also stands diametrically opposite two centuries of historical precedent and practice. In short, RESTORE would provide patent owners the

same equitable relief available in cases involving all other forms of property, including other forms of intellectual property.

These three bills would bolster the reliability, certainty, and strength of American patents. They would clarify and refine elements of the patenting process, making it easier for legitimate patent claims to reach fruition and withstand what would become fairer, more consistent, impartial scrutiny once granted.

We strongly urge your support by cosponsoring the bipartisan, bicameral PREVAIL, PERA, and the RESTORE Patent Rights Acts. We look forward to working with you to advance this legislation to enactment.

Respectfully,

James Edwards
Executive Director
Conservatives for Property Rights

Steve Chartan
Vice President of Government Relations
Heritage Action for America

Jenny Beth Martin
Honorary Chairman
Tea Party Patriots Action

Seton Motley
President
Less Government

Jeffrey Mazzella
President
Center for Individual Freedom

George Landrith
President
Frontiers of Freedom

Dee Stewart
President
Americans for a Balanced Budget

Ryan Ellis
President
Center for a Free Economy

Karen Kerrigan
President & CEO
Small Business & Entrepreneurship Council

Kevin L. Kearns
President
U.S. Business and Industry Council

Hon. J. Kenneth Blackwell
Chairman
Conservative Action Project

C. Preston Noell III
President
Tradition, Family, Property, Inc.

Charles Sauer
President
Market Institute

Anthony Zagotta
President
Center for American Principles

Ashley Baker
Executive Director
The Committee for Justice

Tom DeWeese
President
American Policy Center

Dick Patten
President
American Business Defense Council

Paul Caprio
Director
Family PAC Federal

Saulius “Saul” Anuzis
President
The American Association of Senior Citizens

Gerard Scimeca
Chairman
Consumer Action for a Strong Economy

Colin Hanna
President
Let Freedom Ring

Bob Carlstrom
Executive Director
Prosperity for US Foundation

Tom Giovanetti
President
Americans for a Strong Economy

Martha Boneta Fain
President
Victory Coalition Strategies
Vote America First

James L. Martin
Founder/Chairman
60 Plus Association

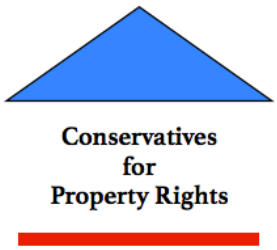
Matthew Kandrach
President
Consumer Action for a Strong Economy

Curt Levey
President
The Committee for Justice

Daniel Perrin
President
HSA Coalition

David Williams
President
Taxpayers Protection Alliance

Phil Kerpen
President
American Commitment



For immediate release
July 13, 2026

Contact: Ryan Moy
rmoy@crcadvisors.com

Statement on the Senate Judiciary Committee PERA Hearing

This statement on the full Senate Judiciary Committee's hearing on the Patent Eligibility Restoration Act (PERA) may be attributed to James Edwards, Executive Director, Conservatives for Property Rights:

"The Patent Eligibility Restoration Act is desperately needed to fix one of the key weaknesses in the U.S. patent system: grossly unsettled, judicially created exception-riddled rules for patent eligible subject matter. CPR commends the U.S. Senate Judiciary Committee for calling a full committee hearing on this vitally important legislation. PERA would ensure rationality, consistency and American innovation leadership in critical technological fields, including AI and medical diagnostics, in which China and other foreign competitors are making gains at America's expense.

"The Supreme Court and lower courts have butchered the bright lines of the patent statute's section 101 with nonsensical, inconsistent, judicially created exceptions, causing extensive turmoil and uncertainty as to the basic question of whether certain subject matter is patent-eligible. This uncertainty, unpredictability and inconsistency advantage our foreign competitors whose laws recognize patent eligibility for cutting-edge categories that formerly were or ought to be recognized in the United States.

"The need for legislation is clear. Senate Judiciary subcommittee hearings in 2019 brought forth overwhelming evidence from more than 40 witnesses of the section 101 problem and the nature of the solution. Since that time, the situation has only worsened. The Supreme Court has repeatedly declined to take patent eligibility cases. Last fall, though, the Senate IP Subcommittee held an important hearing on PERA.

"Conservatives for Property Rights heartily thanks PERA's sponsors, Senators Thom Tillis and Chris Coons and Representatives Kevin Kiley and Scott Peters, for their bipartisan leadership on this desperately needed correction. CPR calls on the Senate to advance PERA now."

# # #

CPR Letter: Patent Eligibility Restoration Act (S. 1546/H.R. 3152)

Coalition Letter: PREVAIL, PERA, and RESTORE Acts

Coalition Letter: PERA and PREVAIL Acts

Op-ed: "SCOTUS Let Us Down Again, So Congress Should Move PERA," IP Watchdog

May 1, 2025

The Honorable Thom Tillis
113 Dirksen Senate Office Building
Washington, D.C. 20510

The Honorable Chris Coons
218 Russell Senate Office Building
Washington, D.C. 20510

Dear Senators Tillis and Coons:

I am writing on behalf of the Council for Innovation Promotion (C4IP), a bipartisan coalition dedicated to promoting strong and effective intellectual property (IP) rights that drive innovation, enhance American economic competitiveness, and improve lives everywhere. C4IP is chaired by two former Directors of the U.S. Patent and Trademark Office (USPTO), Andrei Iancu and David Kappos, who served under Presidents Trump and Obama, respectively. Our board also includes two retired judges from the U.S. Court of Appeals for the Federal Circuit, former Chief Judge Paul Michel and Judge Kathleen O'Malley.

We write today to express C4IP's strong support for the reintroduction of the Patent Eligibility Restoration Act (PERA) and the Promoting and Respecting Economically Vital American Innovation Leadership (PREVAIL) Act. We thank Senators Thom Tillis, Chris Coons, Dick Durbin, and Mazie Hirono as well as Representatives Deborah Ross, Nathaniel Moran, Kevin Kiley, and Scott Peters for their continued leadership on these issues.

Together, these bipartisan bills would restore clarity, fairness, and predictability to the U.S. patent system. Because the patent system provides the foundation for our country's innovation engine, the improvements that these bills would make would directly support innovators — ensuring that they have the confidence and incentives needed to invest in research and development, leading to strengthened economic growth and sustained American leadership in innovation.

For over a decade, U.S. innovators have faced profound uncertainty regarding what types of inventions qualify for patent protection under Section 101 of the Patent Act. Judicial decisions have introduced vague, subjective, and unpredictable eligibility tests. As a result, inventors, research institutions, and investors are often left unsure whether critical advances — particularly in cutting-edge fields like medical diagnostics, biotechnology, artificial intelligence, and computer-implemented technologies — can be protected.

This uncertainty has chilled investment, slowing the commercialization of groundbreaking discoveries and weakening America's competitiveness in sectors vital to public health, national security, and economic growth. Notably, U.S. patent eligibility doctrine has become unusually uncertain and restrictive compared to other advanced economies — leaving American innovators at a disadvantage as foreign competitors provide clearer, more reliable protections for emerging technologies.

PERA would restore clarity, certainty, and predictability by establishing straightforward, objective, and administrable standards rooted in statutory text. The bill would eliminate vague, judicially created exceptions like "abstract ideas" and "laws of nature," replacing them with understandable rules for what is eligible. It would ensure that genuine technological innovations, including diagnostics, biotechnology, and computer-implemented inventions, remain eligible for protection. By replacing subjective judicial tests with clear statutory guidance, PERA would revitalize investment, encourage research in critical fields, and restore Section 101 to its intended role of promoting innovation and economic growth in the 21st century.

While PERA addresses substantive eligibility standards, the PREVAIL Act would strengthen procedural fairness at the Patent Trial and Appeal Board (PTAB) by implementing targeted, commonsense reforms that promote fairness, efficiency, and consistency. The legislation would eliminate duplicative litigation by requiring challengers to choose their forum — either continuing a case in district court or proceeding before the PTAB — once the PTAB institutes a trial. It would also harmonize legal standards by requiring the PTAB to apply a clear and convincing evidence standard to invalidate patents and use the same claim construction standard applied in federal courts. In addition, PREVAIL would strengthen estoppel protections to prevent repetitive challenges across venues and ensure that only real parties in interest with a substantial stake may pursue PTAB proceedings.

These reforms would reduce wasteful duplication, improve consistency across venues, and ensure that patent rights are adjudicated under fair and predictable rules. By curbing strategic abuse of the PTAB process and reducing duplicative burdens on innovators, PREVAIL would make it easier for inventors to defend their patents without facing costly, repetitive, and burdensome proceedings. Strengthening procedural protections at the PTAB is essential to restoring balance to the U.S. patent system and supporting robust innovation and legitimate competition.

For America's innovative businesses, these improvements are especially critical. Today, large, well-resourced corporations can exploit procedural gaps by launching parallel, duplicative attacks on the same patent in multiple venues, forcing innovators to endure unsustainable litigation costs, prolonged uncertainty, and pressure to settle or abandon their rights. PREVAIL would restore fairness to the system by curbing these abusive tactics and ensuring that innovators have a meaningful opportunity to protect and enforce their IP rights.

Together, PERA and PREVAIL represent thoughtful, bipartisan solutions to restore confidence in America's patent system. Strong, reliable IP rights do not stifle competition — they drive it by fostering the incentives necessary for sustained innovation, dynamic economic growth, and American technological leadership. Without these critical reforms, the United States risks losing its innovation advantage to foreign competitors that offer more consistent and predictable protections for inventors.

We value your leadership in championing these critical reforms and urge Congress to prioritize the swift passage of PERA and the PREVAIL Act. C4IP stands ready to assist in advancing policies that strengthen America's IP system and secure its future as the global leader in innovation.

Sincerely,

Frank Cullen
Executive Director
Council for Innovation Promotion (C4IP)

EAGLE FORUM®
EDUCATION & LEGAL DEFENSE FUND

Founded by Phyllis Schlafly in 1981

info@phyllisschlafly.com

April 30, 2025

The Honorable Chris Coons
218 Russell Senate Office Building
U.S. Senate
Washington, DC 20510

The Honorable Thom Tillis
113 Dirksen Senate Office Building
U.S. Senate
Washington, DC 20510

Dear Senators Tillis and Coons:

Eagle Forum Education & Legal Defense Fund, a nonprofit organization founded by Phyllis Schlafly in 1981, applauds your bipartisan leadership seeking to address disquieting jurisprudence concerning patent-eligible subject matter. Your diligent commitment and efforts have culminated with the **Patent Eligibility Restoration Act (PERA)**.

You are quite familiar with the source of this disrupted area of patent law. The U.S. Supreme Court has eviscerated 35 U.S.C. § 101, particularly concerning medical diagnostics and software. For example, in its *Mayo Collaborative Services v. Prometheus Laboratories* decision, the court conflated patent eligibility with novelty and nonobviousness in relation to method claims. In *Ass'n. for Molecular Pathology v. Myriad Genetics, Inc.*, the court confused composition of matter related to isolated DNA, despite section 101's explicit inclusion of materials and processes among patent-eligible subject matter and the Constitution's use of the word "discoveries" and 101's use of "discovers" in relation to patent eligibility.

In *Alice Corp. v. CLS Bank*, the court virtually eliminated the patenting of software, which *Alice* essentially dismissed as an abstract idea. This continued down the wrong road of the Supreme Court's upholding of the Federal Circuit Court of Appeals' ruling in *Bilski v. Kappos*. In their respective upholding of a Patent Office denial of patent eligibility for a software-based business method patent, the courts effectively overturned the *State Street* machine-or-transformation test, adding complexity and uncertainty regarding business methods and software. In short, courts have ignored plain statutory language and substituted their legislating for Congress's. None of the victim classes of inventions and discoveries should have been rendered ineligible for patents.

The right road to restoring appropriate breadth to section 101 requires policies by which Congress overrules the judicial arrogation of legislative power in this area of the law. It requires returning 101 jurisprudence to the "anything under the sun that is made by man" as the patent-eligible standard. Further, it requires eliminating the many judicially created exceptions; prohibiting courts from creating future patent eligibility exceptions; ensuring that considerations relating to sections 102, 103, or 112 of Title 35 do not enter into 101 determinations; requiring that 101 decisions assess the invention as a whole, rather than specific claims; specifying applied mathematical formulas, computer-implemented inventions, and modified natural or genetic matter as being patent-eligible; drawing a distinction between those types of patent-eligible subject matter and patent-ineligible, naturally occurring human genes and natural matter, a mathematical formula in and of itself, and mental processes. Many of the policies included in PERA would address these issues.

In addition, Eagle Forum Education & Legal Defense Fund observes that certain provisions in PERA would allay concerns about the prospect of human genes being patent-eligible under restored 101. Some opponents of 101 restoration have fomented the claim that reforming 35 U.S.C. section 101 would allow human genes and naturally occurring material to be patented. The apparent intent is to alarm prolife groups and individuals in hopes of actuating them to oppose 101 reform.

As a prolife organization that also is a conservative leader on patent issues, Eagle Forum ELDF reassures fellow prolifers who may have reservations about 101 reform. Laws of nature and naturally occurring substances, including the genes in our bodies, would not be patentable, under current law or reforms such as those in PERA, because the genes do not meet threshold criteria of section 101. Even were there a threshold level of "useful improvement," human genes would fail to be patentable on grounds of novelty and obviousness.

Gene-based diagnostic tests, such as assays, constitute the practical application of a discovery of the correlation between the presence of a certain, isolated gene and the probability of certain disease. These may appropriately be considered for patenting. Such discoveries and inventions do not patent human genes. They do promote human life and are consistent with prolife principles.

In conclusion, Eagle Forum Education & Legal Defense Fund commends your proposals for fixing problems courts have caused by unduly limiting what is regarded as patent-eligible subject matter. Such policies would return 101 to its proper role as a threshold criterion.

Respectfully,

John Schlafly
Treasurer

Andrew L. Schlafly
Counsel

James Edwards
Patent Policy Advisor

Statement from Heritage Action Executive Vice President Ryan Walker

"Heritage Action proudly supports the Patent Eligibility Restoration Act (PERA) and the Promoting and Respecting Economically Vital American Innovation Leadership Act (PREVAIL Act) to strengthen America's patent system, drive innovation, and bolster our global competitiveness. Congress must act now to ensure the United States remains a global leader in technological advancement and secure a stronger, more competitive future for America."

22 April 2025

Senator Thom Tillis
Senate Committee on the Judiciary
224 Dirksen Senate Office Building
Washington, DC 20510

Senator Chris Coons
Senate Committee on the Judiciary
224 Dirksen Senate Office Building
Washington, DC 20510

In re: *Patent Eligibility Restoration Act (PERA)*

IEEE-USA fully supports the *Patent Eligibility Restoration Act (PERA).* Thousands of individual U.S.-based members of IEEE depend on reliable and effective patent rights to secure the benefits of their inventions and technological innovations. High-tech inventions have driven the U.S. economy since IEEE was founded by Thomas Edison, Alexander Graham Bell, and Nicola Tesla over a century ago. Like Edison, Bell, and Tesla, IEEE members rely on predictable and effective patent rights to license or otherwise commercialize their inventions in the innovation economy, growing jobs, and contributing to economic growth.

Decisions on subject matter eligible for patent protection – the kind and type of inventions to be protectable under U.S. patent laws – should be made under predictable rules. Categories of inventions that are eligible for patent protection are defined in 35 U.S.C. §101 ("any … process, machine, manufacture, or composition of matter, or any … improvement thereof").

However, judicial decisions have expressly created "exceptions" to the categories of subject matter defined by *35 U.S.C. §101* and promulgated various tests and criteria to determine when those exceptions apply. Those exceptions and criteria have narrowed the scope of innovations eligible for patenting and introduced uncertainty into what innovations are eligible for patent. The judicially created restrictions on patent eligibility put the United States at a competitive disadvantage as foreign governments seize on opportunities to expand the scope of eligible subject matter in their countries. Many inventions are patentable in China and Europe, but are ineligible in the U.S.

PERA eliminates the confusion created by courts as to what inventions are patent eligible and helps the U.S. regain a competitive edge in innovation. This legislation brings much-needed reform to subject matter eligibility, building into U.S. patent law the certainty as to which inventions are eligible for U.S. patent protection. PERA brings balance back to the patent system.

IEEE-USA thanks Senator Tillis and Senator Coons for sponsoring PERA and we ask that Congress pass this bill as soon as possible. Please do not hesitate to contact Erica Wissolik at e.wissolik@ieee.org or (202) 360-5023 if you wish to discuss the issue with us further.

Sincerely,

Nils Smith
IEEE-USA Vice President, Government Relations

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For Immediate Release
July 14, 2026

Innovation Alliance Statement on Senate Judiciary Committee Hearing on Patent Eligibility Restoration Act

PERA is Needed to Fix Broken Patent Eligibility Laws

Bipartisan Bill Would Restore Certainty and Predictability and Ensure U.S. Can Compete With China

WASHINGTON, D.C. – Innovation Alliance Executive Director Brian Pomper issued the following statement on the U.S. Senate Judiciary Committee's hearing on the bipartisan, bicameral Patent Eligibility Restoration Act (PERA) (S.1546/H.R.3152):

> "The Innovation Alliance applauds the Senate Judiciary Committee for holding a hearing on the bipartisan, bicameral Patent Eligibility Restoration Act (PERA). This legislation is needed to fix our nation's broken patent eligibility laws. It makes critical reforms that will help restore certainty and predictability to the U.S. patent system and ensure we can compete with China.
>
> "Historically, inventions in the United States were patented across broad categories of discovery. Starting in 2010, however, the Supreme Court issued a series of decisions that have upended longstanding settled law and narrowed the scope of patent-eligible subject matter. These decisions have created chaos in the patent world. Federal circuit judges and USPTO Directors have repeatedly noted that current interpretations of the law make it nearly 'impossible' to know whether certain inventions should be patent eligible and have urged Congress to pass legislation to provide clarity.
>
> "Meanwhile, our foreign competitors, including China, are granting patents on many inventions that are now unpatentable here. This not only undermines U.S. competitiveness and the ability of our nation to remain the global leader in innovation, but it creates a national security risk as other countries challenge U.S. leadership in developing key technologies.
>
> "PERA would solve this problem by clarifying categories of inventions that are eligible to receive patents, restoring needed certainty and predictability for American innovators and investors, and ensuring the United States avoids ceding leadership in key technologies to our foreign adversaries and competitors. We urge Congress to take up and pass this important legislation as soon as possible."

PERA was reintroduced last year in the Senate by IP Subcommittee Chair Thom Tillis (R-NC) and Senator Chris Coons (D-DE), and in the House by Representatives Kevin Kiley (R-CA) and

Scott Peters (D-CA). The legislation was drafted following years of study and deliberation with key stakeholders. For more information on PERA, click here.

###

ABOUT THE INNOVATION ALLIANCE
The Innovation Alliance represents innovators, patent owners and stakeholders from a diverse range of industries that believe in the critical importance of maintaining a strong patent system that supports innovative enterprises of all sizes. Innovation Alliance members can be found in large and small communities across the country, helping to fuel the innovation pipeline and drive the 21st century economy. Learn more at www.innovationalliance.net.

Contact: Cathleen Biegun
Cathleen@SevenLetter.com

February 17, 2026

The Honorable Charles Grassley
Chairman
Committee on the Judiciary
U.S. Senate
Washington, DC 20510

Dear Chairman Grassley:

Thank you for your leadership to ensure the Iowa innovation economy thrives. The undersigned represent Iowa inventors, startups, universities, accelerators, and intellectual property (IP) professionals. We write in strong support of three bipartisan patent bills that will strengthen the Iowa innovation economy: the PREVAIL Act (S.1553/H.R.3160), the Patent Eligibility Restoration Act (S.1546/H.R.3152), and the RESTORE Patent Rights Act (S.708/H.R.1574).

Strong, predictable patent rights are crucial to the Iowa economy. Iowa holds $24.7 billion in IP,[1] and, according to the USPTO, IP-intensive industries support more than 30% of private-sector Iowa jobs.[2] Iowans have invented and patented thousands of new technologies in recent years, including cutting-edge innovations in agriculture and healthcare. In fact, Iowans regularly obtain more than 1,000 patents each year.[3] These patent-protected inventions help create new jobs and attract hundreds of millions of dollars in federal government grants and venture capital investment to the state.[4]

Together, the PREVAIL, Patent Eligibility Restoration, and RESTORE Patent Rights Acts will catalyze continued innovation, job creation, and economic growth in Iowa. By providing inventors greater clarity and certainty around their ability to obtain and enforce patents, these bills would ensure that inventors may confidently invest in the research and development needed to invent new technologies and power the Iowa innovation economy.

We believe it is imperative that Congress act on these bills now:

- **RESTORE**—For more than two centuries, a patent owner whose rights had been infringed could obtain a court order to stop continued IP theft. Injunctions were granted in almost 95% of cases where patents were found valid and infringed, but Iowa inventors

[1] U.S. Chamber of Commerce Global Innovation Policy Center, *From Innovation to Employment: IP's Role in Job Growth* (accessed Oct. 16, 2025), https://www.uschamber.com/assets/documents/maps/ipjobs/IPFactSheet_Iowa.pdf.
[2] Andrew A. Toole, Richard D. Miller & Nicholas Rada, *Intellectual Property and the U.S. Economy: Third Edition*, U.S. Patent and Trademark Office (Mar. 2022), https://www.uspto.gov/sites/default/files/documents/uspto-ip-us-economy-third-edition.pdf, at 20.
[3] U.S. Patent and Trademark Office, *Performance and Accountability Report: Fiscal Year 2021*, https://www.uspto.gov/sites/default/files/documents/USPTOFY21PAR.pdf, at 208.
[4] *See, e.g.*, Letter from Mark J. Braun, Iowa Board of Regents, to Iowa General Assembly (Nov. 11, 2024), https://www.legis.iowa.gov/docs/publications/DF/1463244.pdf.

lost that protection in 2006.[5] RESTORE would help Iowa inventors by reviving this right and stopping IP theft.

- **PREVAIL**—When Congress established the Patent Trial and Appeal Board (PTAB) as part of the 2011 America Invents Act, it intended to create a cost-effective alternative to federal court for patent challenges. However, large technology companies have instead exploited the PTAB since its inception, using it as an additional opportunity to attack patents of smaller competitors. PREVAIL would make commonsense changes to reduce PTAB abuse and return the tribunal to its core purpose. For example, PREVAIL would align the standard of proof for invalidating patents in the PTAB with the standard in federal court.
- **PERA**—The law is not clear on the rules around what technologies are eligible to be considered for a patent, especially in bioscience—a sector crucial to the Iowa economy. Uncertainty about patent eligibility discourages new innovation. PERA would clarify this area of patent law and provide Iowa inventors the certainty they need to confidently invest in new innovation.

Passing RESTORE, PREVAIL, and PERA will allow Iowa inventors to spend less time and resources in the courtroom protecting their inventions and more time and investment in the lab developing the next bioscience breakthrough.

We urge you to support these bills and to advance them through the Senate Judiciary Committee as soon as possible. Thank you for your attention to this matter.

Respectfully,

Gregory Lars Gunnerson, President, Iowa Intellectual Property Law Association

Jessica Hyland, Executive Director, Iowa Biotechnology Association

Marie Kerbeshian, Assistant Vice President and Executive Director, University of Iowa Research Foundation

[5] Kristina M.L. Acri Née Lybecker, *Injunctive Relief in Patent Cases: the Impact of eBay* (Colo. Coll., Working Paper No. 2024-01, 2024), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4866108.

Heidi Nebel, Partner, McKee, Voorhees & Sease, P.L.C.

James C. Register III, PhD, Interim President & CEO, BioConnect Iowa

July 9, 2026

The Honorable Charles Grassley
Chairman
Committee on the Judiciary
U.S. Senate
Washington, DC 20510

Dear Chairman Grassley:

We are Iowa inventors, and we write to ask you to support three bipartisan patent bills that will help us continue to innovate in our great state:

(1) The Promoting and Respecting Economically Vital American Innovation Leadership (PREVAIL) Act (S.1553/H.R.3160);
(2) The Patent Eligibility Restoration Act (PERA) (S.1546/H.R.3152); and
(3) The Realizing Engineering, Science, and Technology Opportunities by Restoring Exclusive (RESTORE) Patent Rights Act (S.708/H.R.1574).

From the gas-powered tractor to the vending machine to the trampoline, the ingenuity of Iowans has brought us many exciting and noteworthy inventions. In fact, Iowans regularly obtain more than 1,000 patents each year for their inventions.

As President Abraham Lincoln once said, patent rights "add[] the fuel of interest to the fire of genius." By giving inventors the exclusive right to their inventions for a limited time, patents incentivize us to invest in time-consuming, expensive, and risky research and development as we work to bring our ideas to life and ultimately to market.

However, in recent years, court decisions and other changes in U.S. patent law have made it much more difficult for inventors to obtain and enforce patent rights and therefore much less worthwhile for inventors to pursue their ideas. Three bipartisan bills—PREVAIL, PERA, and RESTORE—would help turn the tide back in favor of American innovation.

(1) **PREVAIL**—Congress established the Patent Trial and Appeal Board (PTAB) as part of the 2011 America Invents Act (AIA) to create a more efficient and cost-effective alternative to federal court for patent challenges. Unfortunately, the PTAB has instead been abused by Big Tech and other large companies that launch repeated, duplicative attacks on the patents of smaller competitors to drain inventors' limited resources, force inventors into unfavorable settlements, and stifle competition. PREVAIL would make commonsense changes to reduce PTAB abuse and make the process fairer for inventors.

(2) **PERA**—Court decisions have muddled the rules around what inventions are eligible to be considered for a patent. When it is unclear if inventions can be patented, inventors are less likely to pursue their ideas in the first place. PERA would clarify patent eligibility and give Iowa inventors confidence to invest in new innovations.

(3) **RESTORE**—For more than two centuries, an inventor could stop an infringer from unlawfully making, using, selling, or importing their patented invention by obtaining an injunction. Injunctions were granted in approximately 95% of these cases, but inventors lost this protection in 2006 when the Supreme Court made it much more difficult to obtain an injunction. Injunction rates for inventors that license their patents have plummeted by more than 90%. Meanwhile, courts in China continue to grant injunctions 95% of the time. Inventors in the United States deserve rights at least as strong as inventors in China. RESTORE would help Iowa inventors combat predatory infringement and vindicate our constitutional right to determine who can make, use, sell, or import our inventions.

Together, these bills will help Iowa inventors by giving us the confidence that when we have an idea, we will be able to protect and defend it. We urge you to support PREVAIL, PERA, and RESTORE and to advance these bills through your committee as soon as possible.

Respectfully,

Jon Bakas, Iowa City
Amy Jo Brogan, Cedar Rapids
Sharon Campbell, Walnut
Mathew Conroy, Waterloo
Denise Cronin, Red Oak
Christina Gillett, Walcott
Greg Gormley, Lenox
Barry Jones, Minden
Tom Maring, Marion
Jack Marovets, Cedar Rapids
Robert Mauro, Eagle Grove
Frank Morosky, Cedar Rapids
Monica Murphy, Des Moines
Danielle Natt, Elliott
Nathaniell Odle, Lowden
Bruce Richardson, Cedar Rapids
Tim Riley, Amana
Larry Schroeder, Iowa City
Melvin Spencer, Sioux City
Tom Swegle, Des Moines
James Trotter, Shell Rock
Jimmy Turnage, Farley
Linda Ugi, Evansdale
Everett Wade, Newton
Steve Waithe, Boxholm
Alicia Williams, Rockwell

Laura A. Coruzzi, Ph.D., J.D.
70 East 10th Street, Apt 15M
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May 11, 2025

The Honorable Thom Tillis
Chairman
Subcommittee on Intellectual Property
Committee on the Judiciary
United States Senate
Washington, D.C. 20510
Peter_Pappas@judiciary-rep.senate.gov

The Honorable Chris Coons
Minority Member
Subcommittee on Intellectual Property
Committee on the Judiciary
United State Senate
Washington, D.C. 20510
James_Barton@judiciary-dem.senate.gov

By email

Re: Patent Eligibility Restoration Act of 2025 ("PERA 2025")

Dear Senator Tillis and Senator Coons:

My heartfelt thanks and appreciation to you both for your efforts in drafting and re-introducing the Patent Eligibility Restoration Act, 2025 ("PERA 2025") on May 1st, Law Day! This bipartisan, bicameral legislation uses a balanced approach that will restore eligibility to many important inventions in the biotech sector. I am certain that it will spur investment in potentially life-changing genetic approaches to medicine. I have sent letters supporting the legislation to each member of the Subcommittee on Intellectual Property and hope it will be scheduled for mark up soon. I am prepared to continue to work with you and other stakeholders as the language is refined and, hopefully, adopted into law.

I am a patent attorney with a Ph.D. in biology and over 30 years' experience in the life sciences field: formerly a partner at the law firms of Pennie & Edmonds and Jones Day; most recently, Executive Vice President at REGENXBIO, a clinical stage biotech company that is developing gene therapies for serious life-threatening conditions; and currently its consultant.

Prior to entering the practice of law, I was a research scientist/postdoctoral fellow at Mt. Sinai School of Medicine in New York, where I witnessed the immense impact patents have on

securing the private sector investment universities need to translate their groundbreaking discoveries to the clinic for the benefit of patients. I saw first-hand how the lack of patent protection stymied drug development for patients with critical needs. Simply put, patents benefit patients.

As you both know, the controversial Supreme Court decisions denying patent eligibility for lifesaving innovations, such as *Mayo* and *Myriad*, and the ensuing series of confused decisions of lower courts have created substantial uncertainty over whether investment in potentially life changing gene-related discoveries will be protected by the U.S. patent system. They have had adverse impacts on our diagnostic and therapeutic industries putting the United States behind other nations, especially China. Here are links to articles I have published on the topic which I shared with the IP Subcommittee members and I hope you find useful to support the bill: *Nature Biotechnology*, August 9, 2022: https://rdcu.be/cTlEM, and the *Albany Law Journal of Science and Technology*, vol 33, issue 1, 2023: https://tinyurl.com/CoruzziALJST.

If Congress acts to restore balance, predictability, and fairness into Section 101 of the Patent Code, many biotechnology companies, academic medical research centers, life science inventors, and – most importantly, patient advocacy organizations and families facing the enormous challenges presented by untreatable diseases stand to benefit. The certainty PERA 2025 will restore to United States patent rights will help to incentivize the private sector to invest in biotech and biomedical innovation—especially critical now in view of the current economic challenges and cuts in federal funding for such important medical research. I hope and urge that the Judiciary Committee take expeditious action to mark up and favorably report the bill to the Senate Floor.

In closing, I note with appreciation that both of you have been well served by your respective staffs working with a diverse group of intellectual property lawyers (myself included) on this complex matter of patent law. Once again, thank you both for digging in, working across the aisle and developing this legislation. I and many others stand ready to work with you during the mark up process and beyond.

Yours truly,

Laura A Coruzzi

Laura A. Coruzzi, Ph.D., J.D.
Cell: 917-544-0683

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MDMA Statement of Support on Reintroduction of the Bipartisan "PREVAIL Act" and "PERA"

WASHINGTON, DC – The Medical Device Manufacturers Association's (MDMA) President and CEO Mark Leahey issued the following statement today applauding the bipartisan reintroduction of the "Promoting and Respecting Economically Vital American Innovation Leadership Act (PREVAIL Act)" and the "Patent Eligibility Restoration Act (PERA):"

"MDMA thanks Senators Thom Tillis (NC) and Chris Coons (DE) for the bipartisan reintroduction of the 'PREVAIL Act' and 'PERA.' These important bills would strengthen intellectual property rights, which ultimately results in new innovative cures, therapies and diagnostics to help address the needs of patients and providers. The United States cannot maintain and grow our leadership position in medical technology innovation without strong IP protections in place, and the 'PREVAIL Act' and 'PERA' would support this critical work to bolster our ecosystem."

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Statement of Chuck Hong, co-founder and CEO of Netlist CEO in Support of the Promoting and Respecting Economically Vital American Innovation Leadership (PREVAIL) Act and the Patent Eligibility Restoration Act (PERA)

April 30, 2025

As co-founder and CEO of Netlist, a small company that develops advanced memory technologies, I am writing to express our strong support for the Promoting and Respecting Economically Vital American Innovation Leadership (PREVAIL) Act and the Patent Eligibility Restoration Act (PERA). I applaud Senator Thom Tillis and Senator Chris Coons for reintroducing these important bills and urge the Senate to ensure their swift passage.

The Promoting and Respecting Economically Vital American Innovation Leadership (PREVAIL) Act provides a critical opportunity to restore predictability and balance to the U.S. patent system. By curbing serial abuse and preventing duplicative challenges, while still disincentivizing frivolous lawsuits by NPE's, this legislation will protect innovators like Netlist from being outspent and outmaneuvered by larger competitors seeking to avoid compensating smaller firms for their inventions. The PREVAIL Act's reforms are essential not only for fairness but for maintaining the integrity of our innovation ecosystem. We strongly support this legislation and urge Congress to pass the PREVAIL Act to protect America's inventors and ensure that innovation continues to thrive.

In addition to our support for the PREVAIL Act, Netlist also strongly endorses the Patent Eligibility Restoration Act (PERA). The current state of patent eligibility in the U.S. has become alarmingly uncertain, with vague standards making it difficult for inventors to determine whether their innovations qualify for patent protection. As a company that depends on the strength of its intellectual property, Netlist understands the frustration of navigating an unpredictable system that undermines investment in groundbreaking technologies and places U.S. firms at a competitive disadvantage on the global stage.

PERA addresses these issues by clearly defining what is and is not eligible for patenting, eliminating the arbitrary judicial exceptions that have confused and weakened patent eligibility. By providing a straightforward and predictable framework, PERA will ensure that truly novel and non-obvious inventions, like those developed by Netlist, can be patented without the risk of being dismissed as "abstract." This clarity is vital for fostering confidence among innovators and investors, empowering them to bring new technologies to market without fear of endless legal uncertainty.

Netlist urges Congress to pass both the PREVAIL Act and the Patent Eligibility Restoration Act. Together, these reforms will strengthen the U.S. patent system, protect inventors, and help ensure that America remains a global leader in innovation.

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May 12, 2025

The Honorable Thom Tillis
113 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Chris Coons
218 Russell Senate Office Building
Washington, DC 20510

John Kolakowski

Head of IP Regulatory Affairs North America

Nokia Technologies

Direct mobile: +1 202 468 4428

john.kolakowski@nokia.com

Dear Senators Tillis and Coons,

Nokia is a multinational telecommunications and information technology company founded in 1865. Our products and services focus on telecommunications infrastructure, including fixed and mobile networks, IP routing, optical networks, private networks, data centers and 5G solutions. We have played and continue to play a significant role in the development of wireless communication and other technology standards used around the world.

Nokia has a significant presence in the United States and is a key contributor to economic growth and vitality here. Nokia has approximately 7,500 U.S.-based employees across 17 U.S. office locations and two data centers. More than 40,000 indirect jobs have been created through Nokia's supplier ecosystem, and we have invested more than $374 million into U.S. startups via our venture capital arm, NGP. Notably, Nokia also is the first manufacturer to commit to and produce Build America/Buy America-compliant products for the U.S. Broadband Equity, Access, and Deployment (BEAD) program.

Nokia solutions are essential to the security of U.S. critical infrastructure. Nokia is leveraging 5G, IP, IoT, and new data center technologies to improve agility, resiliency, and situational awareness for the U.S. Department of Defense and other federal mission-critical networks aligned with a defense-in-depth approach to network security.

Nokia has four U.S.-based Research & Development (R&D) Innovation Centers including Nokia Bell Labs Murray Hill, Dallas, Naperville and Sunnyvale-Almanor, where its scientists, engineers, partners, and customers build and test communications solutions. We have invested about 150 billion euros in R&D since 2000, which has helped us develop one of the largest, most diverse, and most valuable patent portfolios in the world. We hold over 20,000 patent families, with more than 7,000 declared as essential to the 5G communication standard, and revenue

derived from licensing our inventions is crucial to our business model and our ability to continue developing the next generations of mobile technologies.

I write today to reaffirm that Nokia is supportive of the proposed Patent Eligibility Restoration Act that you have recently reintroduced in the Senate. We believe it will grow U.S. investment, create jobs, and save lives by promoting innovation in fields like medical diagnostics, artificial intelligence, and other critical and emerging technologies. It will allow the U.S. to compete with other countries where these innovations are already patent-eligible. It will return patent eligibility standards to sensibly providing a "coarse filter" that eliminates from patentability only a few specific and well-understood categories of subject matter. Then the patent office can focus on whether a purported invention is novel, nonobvious and sufficiently definite as required by Sections 102, 103 and 112 of the Patent Act.

We also reiterate our support for the recently reintroduced PREVAIL Act. It will strengthen the innovation economy and create jobs by ensuring fairness for inventors facing challenges to their patents before the Patent Trial and Appeal Board (PTAB) by companies that abuse the system. Nokia has been before the PTAB as both a patent holder and petitioner. We feel on balance that the changes proposed to PTAB procedures by the bill are sensible and warranted, particularly as they would bring IPR proceedings back to their original intended purpose of providing a cost-effective alternative to district court patent invalidation proceedings (rather than allowing duplicative proceedings putting undue burdens on patent holders and giving patent challengers a "second bite at the apple".

Best regards,

PO Box 14354, Research Triangle Park, NC 27709
919.281.8960

April 29, 2025

The Honorable Thom Tillis
US Senate
113 Dirksen Senate Office Building
Washington, DC 20510

Dear Senator Tillis,

On behalf of the North Carolina Life Sciences Organization, I want to thank you for reintroducing the Patent Eligibility Restoration Act and the Promoting and Respecting Economically Vital American Innovation Leadership Act. These two pieces of important legislation will bring much needed certainty and protection for patent holders, particularly those early innovators, crucial to American ingenuity.

PERA brings certainty and overdue clarity to Section 101 of the Patent Act. The existing uncertainty in the law has been a major impediment to the cutting-edge work of our innovators. In addition, this legislation would also afford US innovators the same protection now enjoyed by their foreign counterparts. At a time when the American people are demanding that critical industries be brought home, this equal treatment will be especially important.

The PREVAIL Act will empower startups and small businesses by realigning the Patent Trial and Appeals Board with Congress's original intent. Lawmakers had hoped the PTAB would provide a faster and cheaper alternative to costly federal court litigation. Instead, it has been abused to make it much harder and more expensive for small innovators to protect their patents. Promoting fair treatment for inventors, improving efficiency and ensuring the USPTO has adequate resources to administer the patent system will work to again incentivize American innovation and enable small entrepreneurial companies to compete.

As you know, NCLifeSci represents the life sciences industry in North Carolina with over 250 members, both large and small, the great majority of whom rely on intellectual property as the basis of their business and the lifeblood with which they can raise funds to advance their technology and hopefully provide treatments and cures for patients, food to feed the world and sustainable options for our climate.

NCLifeSci applauds your commitment to hearing from interested parties and we look forward to working with you and helping you to ensure passage of these important safeguards to our American patent system.

Sincerely,

Laura F. Gunter
President, NCLifeSci

July 13, 2026

The Honorable Chuck Grassley
Chairman
Senate Committee on the Judiciary
135 Hart Senate Office Building Washington, DC 20510

The Honorable Dick Durbin
Ranking Member
Senate Committee on the Judiciary
711 Hart Senate Office Building
Washington, DC 20510

The Honorable Thom Tillis
Chairman Intellectual Property Subcommittee
Senate Committee on the Judiciary
113 Dirksen Senate Office Building Washington,
DC 20510

The Honorable Adam Schiff
Ranking Member Intellectual Property Subcommittee
Senate Committee on the Judiciary
112 Hart Senate Office Building
Washington, DC 20510

Re: Letter of Patent Law and Innovation Scholars in Support of the Patent Eligibility Restoration Act (PERA)

Dear Chairman Grassley, Ranking Member Durbin, Chairman Tillis, and Ranking Member Schiff::

We write as academics who study patent law and innovation to encourage the Committee to advance the Patent Eligibility Restoration Act (PERA). PERA would strengthen U.S. competitiveness in high-tech industries by clarifying Section 101 of the Patent Act, which over time has been transformed from a simple filter for patent eligibility into a much broader test that Congress never intended.

Congress originally enacted Section 101 as a coarse screen to serve as a first test for patent eligibility. From the 1952 Patent Act until 2010, courts understood Section 101 to reach "anything under the sun that is made by man," and not surprisingly, American innovation flourished during that period.

However, in the 2010s, a quartet of Supreme Court decisions—*Bilski v. Kappos*, *Mayo Collaborative Services v. Prometheus Laboratories*, *Association for Molecular Pathology v. Myriad Genetics*, and *Alice Corp. v. CLS Bank*—effectively displaced the statutory text with judicially created exceptions to patent eligibility. These rulings turned Section 101 into a two-step test that appears nowhere in the statute and whose key terms—"abstract idea" and "inventive concept"—the Court has never defined.

Since then, lower courts and the USPTO have applied that test inconsistently, denying protection to diagnostic methods, computer-implemented inventions, and other long-patentable subject matter. Further, the Supreme Court has refused multiple opportunities to clarify, despite requests from the Federal Circuit and the Solicitor General under multiple administrations. The result is that inventors,

examiners, and investors can no longer reliably predict what is patent-eligible.[1] Even in cases where patent eligibility remains clear, it is often narrower in scope than recognized by America's global rivals.[2]

These developments have been bad for business and for innovation. In a survey of 475 venture capital and private equity investors, 74 percent said patent eligibility is an important consideration in investment decisions, and 62 percent said their firms are less likely to invest where patents are unavailable, with the sharpest effects in biotechnology and medical devices.[3] Between 2004 and 2017, patent-intensive industries' share of U.S. venture capital fell from over half to roughly 28 percent of total U.S. VC funding.[4]

Technologies critical to U.S. national competitiveness and national security have faced the most serious consequences. *Mayo* and *Myriad* cast doubt on protection for diagnostics, stunting research and development in biotechnology and genetic research.[5] In artificial intelligence, new empirical evidence shows that AI patents are significantly more likely to be invalidated than comparable patents, driven principally by Section 101.[6]

China, in the meantime, has broadened eligibility for AI and other computer-implemented inventions. Its AI patent filings nearly tripled between 2019 and 2024 while U.S. filings remained flat—a gap that bears directly on American competitiveness in a defining technology.[7]

The Patent Eligibility Restoration Act would strengthen American innovation and competitiveness in these critical areas. It would eliminate the vague exceptions and two-step test established by recent Supreme Court rulings, replacing them with clear statutory exclusions while keeping basic knowledge and unmodified natural materials free for all. It would leave intact the requirements of novelty, nonobviousness, and enablement/written description under Sections 102, 103, and 112.

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1 Kristen Jakobsen Osenga, *Restoring Predictability to Patent Eligibility* (IPPI: The IP Policy Institute, Mar. 2025); Kristen Jakobsen Osenga, *Fact Sheet: Patent Eligibility Restoration Act of 2025 (PERA)* (IPPI, updated Oct. 15, 2025). On the Court's refusals to take up the issue despite such requests, see *Athena Diagnostics, Inc. v. Mayo Collaborative Servs.*, 927 F.3d 1333 (Fed. Cir. 2019) (en banc denial with eight separate opinions urging clarification), and the Solicitor General's amicus briefs in *American Axle & Mfg., Inc. v. Neapco Holdings LLC*, No. 20-891 (May 2022), and *Hikma Pharms. USA Inc. v. Vanda Pharms. Inc.*, No. 18-817 (Dec. 2019).

2 Mark A. Cohen, Testimony Before the Subcomm. on Intellectual Property, S. Comm. on the Judiciary, Hearing on the Patent Eligibility Restoration Act, at 2–9 (Oct. 8, 2025) (contrasting China's broadening of eligibility for AI, software, and diagnostics-related inventions with U.S. narrowing; more than 1,300 U.S. applications abandoned after *Alice-Mayo* rejections had counterpart patents granted in China or Europe); 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), revised (2018). Kevin Madigan & Adam Mossoff, *The Value of Public Data: Update to Turning Gold to Lead*, (June 28, 2018).

3 David O. Taylor, *Patent Eligibility and Investment*, 41 Cardozo L. Rev. 2019 (2020).

4 Mark F. Schultz, *Declining Patent Reliability and Venture Capital Reallocation*, in Bringing Medicines to Life: How Intellectual Property Enables Innovation in the Life Sciences (Cambridge Univ. Press, forthcoming 2026).

5 Emily Michiko Morris, *A Response to 'Another Legislative Attempt to Revive Gene Patenting,'* Bill of Health, Petrie-Flom Center, Harvard Law School (Aug. 26, 2022); see also Schultz, supra note 4 (interview evidence on diagnostics and personalized medicine).

6 Amy Semet, *An Empirical Study of Artificial Intelligence Patent Litigation* (Univ. at Buffalo School of Law, working paper 2026).

7 Cohen, supra note 2, at 7–8, 11 (China's annual AI patent filings rose from 59,054 in 2019 to 188,757 in 2024; U.S. filings remained between 31,000 and 35,000).

PERA would not make everything patentable—but it would make eligibility predictable so that firms can again invest in cutting-edge innovation in the United States.[8] We urge the Committee to advance this critical bill.

Respectfully submitted,

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[8] See Osenga, *Restoring Predictability to Patent Eligibility*, supra note 1, at 3–4.

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May 7, 2025

The Honorable Thom Tillis
Chairman
Subcommittee on Intellectual Property
Committee on the Judiciary
United States Senate
Washington, D.C. 20510
Peter_Pappas@judiciary-rep.senate.gov

The Honorable Chris Coons
Ranking Minority Member
Subcommittee on Intellectual Property
Committee on the Judiciary
United State Senate
Washington, D.C. 20510
James_Barton@judiciary-dem.senate.gov

By E-mail

Re: Patent Eligibility Restoration Act of 2025 ("PERA 2025")

Dear Chairman Tillis and Ranking Minority Member Coons:

REGENXBIO commends you both for your efforts in drafting and re-introducing the Patent Eligibility Restoration Act, 2025 ("PERA 2025"). This bipartisan, bicameral legislation will confirm patent eligibility of many inventions in the biotech sector using a balanced approach to address legitimate concerns of skeptics. We have sent letters supporting the legislation to each member of the Subcommittee on Intellectual Property and hope it will be scheduled for mark up soon. We are prepared to work with you and other stakeholders as the language is refined and, as we hope, adopted into law.

REGENXBIO is a clinical stage biotech company headquartered in Rockville, Maryland that is developing gene therapies for serious life-threatening conditions. Our technology platform, originated at the University of Pennsylvania, is the foundation for gene therapies that we have translated to the clinic for the benefit of patients. Using a single treatment, our gene therapies

have the potential to correct disease allowing the body's natural mechanisms to work the way they were intended.

We are developing gene therapies for retinal, metabolic, and neurodegenerative diseases. In addition to our own clinical programs, REGENXBIO has partnered with others to enable the development of gene therapies based on our technology platform across a broad range of therapeutic areas and disease indications, including in an FDA-approved gene therapy for spinal muscular atrophy, a devastating, fatal genetic condition.

If Congress acts to restore balance, predictability, and fairness into Section 101 of the Patent Code, many biotechnology companies, academic medical research centers, life science inventors, and – most importantly, patient advocacy organizations and families facing the enormous challenges presented by untreatable diseases stand to benefit. PERA 2025 promises not only to facilitate the creation of next generation medical treatments but would also support America's continued world leadership in biomedical innovation and the employment opportunities for highly skilled U.S. workers that follow.

Because of the potential positive impact that the Section 101 reforms proposed in PERA 2025 could have on REGENXBIO and other biotech firms developing new treatments that may change the practice of medicine and the course of disease for literally millions of patients, we urge that the Judiciary Committee take expeditious action to mark up and favorably report the bill to the Senate Floor.

In closing, we note that both of you have been well served by your respective staffs working with a diverse group of intellectual property lawyers on this complex matter of patent law. Once again thank you both for working across the aisle and developing this legislation, and we assure you that we and many others stand ready to work with you during the mark up process and beyond.

Yours truly,

DocuSigned by:
Patrick Christmas
E8080778EE25459...

Patrick J. Christmas II, J.D.
Chief Legal Officer

Proposed reforms now being considered by Congress would remove damaging uncertainties and strengthen US patents at a time of major technological change

As the operator of patent pools related to 5G, Wi-Fi, IoT and video, Sisvel has a front-row seat to the creation and implementation of the technology standards that power growth and connectivity. Patent licensing plays a decisive role in determining how the economic benefits of these advances are distributed. Royalty flows are shaped by patent law and policy across the world's major economies.

Today, most of the influential legal decisions in this fast-developing area are being made by judges in the EU, the UK, India and China. That's partly because over the last 20 years the United States has walked away from its traditional role as a champion of strong patent rights. Other jurisdictions have stepped in to fill the void, so it is their courts that are now writing the rules of the road for the technologies of the future.

Three bipartisan bills pending in Congress would help to change this. By removing uncertainties and pitfalls unique to the US patent system, they would give innovators the confidence to once again make US patents central to their commercial and legal strategies:

- The **RESTORE Act** - introduced in the Senate by Sen. Chris Coons (D-DE) and Sen. Tom Cotton (R-AR), and in the House of Representatives by Rep. Nathaniel Moran (R-TX) Rep. Chip Roy (R-TX), Rep. Deborah Ross (D-NC), Rep. Henry C. Johnson (D-GA), Rep. Madeleine Dean (D-PA) and Rep. Scott H. Peters (D-CA) - would give patent owners the tools they need to stop infringement through the courts.
- The **Patent Eligibility Restoration Act (PERA)** - introduced in the Senate by Sen. Chris Coons (D-DE) and Sen. Thom Tillis (R-NC), and in the House of Representatives by Rep. Kevin Kiley (R-CA) and Rep. Scott Peters (D-CA) - would provide much-needed clarity on what kinds of inventions are eligible for patent protection.
- The **PREVAIL Act** - introduced in the Senate by Sen. Chris Coons (D-DE), Sen. Thom Tillis (R-NC), Sen. Dick Durbin (R-IL) and Sen. Mazie K. Hirono (D-HI), and in the House of Representatives by Rep. Ken Buck (R-CO) and Rep. Deborah Ross (D-NC), Rep. Nathanial Moran (R-TX) and Rep. Bill Posey (R-FL)- would place sensible limits on third-party attacks against granted patent rights.

Sisvel is a global business. The patent owners we work with come from every corner of the world. We support these commonsense, bipartisan bills because they will restore the strength to US patents they traditionally enjoyed.

RESTORE: Giving US patent owners tools to halt infringement

The core of the patent bargain is the disclosure of an invention in exchange for the time-limited right to exclude others from practising it. For most of US history, that meant patent owners that proved infringement were presumptively entitled to an injunction: a court order forcing the infringer to stop.

The 2006 *eBay* decision of the US Supreme Court did away with this presumption, replacing it with a four-factor test. In practice, this has drastically reduced the number of injunctions awarded to patent owners that have undertaken the difficult and expensive process of proving their claims in court.

Without the realistic prospect of injunctive relief, US patent holders have little leverage in negotiations with large companies that are using their inventions without permission, and which can hold out for years and years while reaping huge sums from the sale of infringing products.

Injunctions are much more readily obtained in other jurisdictions. This is one of the major reasons why so many important global patent cases are currently being decided outside the United States.

The RESTORE Act would effectively override the *eBay* decision, amending the patent statute with one simple, crucial paragraph:

If, in a case under this title, the court enters a final judgment finding infringement of a right secured by the patent, the patent owner shall be entitled to a rebuttable presumption that the court should grant a permanent injunction with respect to that infringing conduct.

Sisvel supports this bill which reinforces the private property rights inherent in the grant of a US patent and would restore to US courts a much more prominent role in global patent jurisprudence. We commend Senators Coons and Cotton, and Representatives Moran, Roy, Ross, Johnson, Dean and Peters for their initiative.

PERA: Providing clarity on what's patentable

PERA is an important step towards restoring predictability to the US patent system.

Over the past decade, the lack of clear guidance on patent eligibility has created significant uncertainty, particularly for cutting-edge technologies. A confusing and inconsistent body of judge-made law has proceeded from the Supreme Court's *Alice* (2012) and *Mayo* (2014) decisions, drawing criticism even from judges as they struggle to apply it.

PERA would sweep away the tangle of "judicial exceptions" to eligibility and instead re-affirm the plain language of 35 U.S. Code § 101 by clarifying that:

Any invention or discovery that can be claimed as a useful process, machine, manufacture, or composition of matter, or any useful improvement thereof, is eligible for patent protection.

However, the bill also sets out a list of bright-line, commonsense exceptions, excluding from patent eligibility:

1. A mathematical formula not part of a useful process, machine, manufacture, or composition of matter;
2. A mental process performed solely in the mind of a human being;
3. An unmodified gene, as that gene exists in the human body;
4. An unmodified natural material as that material exists in nature; and
5. A process that is substantially economic, financial, business, social, cultural, or artistic

Sisvel welcomes this clearer, simpler approach to subject matter eligibility, which will empower innovators to focus on creating transformative technologies without fear of arbitrary exclusions. We commend Senators Coons and Tillis, and Representatives Kiley and Peters for their initiative.

PREVAIL: Limiting third-party attacks on granted US patents

Another unique hazard for US patent holders is the Patent Trial and Appeals Board (PTAB), an administrative tribunal at the US Patent and Trademark Office (USPTO) established in 2012. Any party can use the PTAB to attack granted US patents while enjoying procedural advantages that would not be available in a court of law.

The PREVAIL Act would level the playing field by:

1. Requiring PTAB patent challengers to have standing;
2. Limiting serial petitions and duplicated arguments against the same patent;
3. Harmonising the PTAB's standards for claim interpretation and burden of proof with those of federal district courts; and
4. Streamlining disputes by forcing challengers to choose between challenging validity in the PTAB or in district court.

These measures strike an appropriate balance between maintaining stable and reliable patent rights while providing adequate opportunity to contest validity.

Sisvel supports this legislation, which would eliminate wasteful, duplicative disputes and curb opportunistic and abusive attacks on US patent rights. We commend Senators Coons, Tillis, Durbin and Hirono, and Representatives Buck, Ross, Moran and Posey for their initiative.

SBE Council Statement in Support of Bipartisan Bills to Strengthen U.S. Innovation and IP: PERA and PREVAIL Re-Introduced

For Immediate Release
May 1, 2025

Washington, D.C. – Today, bipartisan leaders in Congress who are spearheading efforts to protect and strengthen intellectual property (IP) are re-introducing the Patent Eligibility Restoration Act (PERA) and the Promoting and Respecting Economically Vital American Innovation Leadership (PREVAIL) Act. Small Business & Entrepreneurship Council (SBE Council) President & CEO Karen Kerrigan issued the following statement supporting the bipartisan measures, and noted their importance to startups, entrepreneurs, and small businesses:

"SBE Council is grateful for the bipartisan leadership of House and Senate members who are re-introducing the PERA and the PREVAIL Act. This is especially noteworthy given the small business community continues to celebrate and mark World IP Day and the renewed momentum behind Administration and congressional efforts to strengthen and protect U.S. intellectual property (IP)."

"Both PERA and PREVAIL offer important reforms that are especially important for startups and small businesses, as complex processes and systemic abuses within the patent system place IP protections in peril. This means creators, innovators, and entrepreneurs are challenged to bring their ideas to the market and raise the necessary capital to build their businesses and compete with larger entities. In the end, U.S. innovation suffers as does competitiveness, economic growth, market vibrancy, and job creation."

"PERA provides clear, predictable rules for what inventions are eligible for patents. A reform that will make the patent process less complex and costly for entrepreneurs and inventors. PREVAIL restores fairness to the U.S. patent system by addressing imbalances at the PTAB through a series of critical reforms. It closes procedural loopholes, limits duplicative attacks on the same patent, aligns the standards of review with those used in federal courts, and ensures that only parties with a legitimate interest can challenge a patent. Moreover, the bill includes provisions to make patent tools more accessible to smaller firms, along with a mandate for the Small Business Administration to study and report on how the system can better support innovative small businesses."

"These reforms are critical - MIT researchers found that startups with a patent are 87 times more likely to grow than those without one. American ingenuity is driven by inventors, creators and entrepreneurs who pursue their ideas with passion and take risks to the betterment of our economy and society. Legal frameworks and protections that support their efforts and protect

their IP is needed to fuel this innovation. PERA and PREVAIL are important reforms that will boost the innovative capacity of entrepreneurs and our nation."

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SBE Council is a nonpartisan advocacy, research and education organization dedicated to protecting small business and promoting entrepreneurship. For more than 30 years, SBE Council has advanced a range of private sector and public policy initiatives to strengthen the ecosystem for strong startup activity and small business growth.

Visit www.sbecouncil.org for additional information. X: @SBECouncil

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SurvivorsFor Solutions

May 6, 2025

The United States Senate Committee on the Judiciary
Subcommittee on Intellectual Property
224 Dirksen Senate Office Building
Washington, DC 20510

Dear Chairman Thom Tillis and Senator Chris Coons,

As a patient and the founder of Survivors for Solutions, an advocacy organization that works to protect the medical innovations that give people hope, I want to thank you for reintroducing the bipartisan Promoting and Respecting Economically Vital American Innovation Leadership Act (PREVAIL) and Patent Eligibility Restoration Act (PERA). These vital pieces of legislation will protect patients by enacting essential reforms to safeguard their continued access to future treatments and cures.

As a multiple sclerosis (MS) survivor who has been fortunate to have access to several breakthrough treatments in the more than three decades I've been living with my disease, I understand firsthand the impact of medical innovation. At the time of my diagnosis, there was not a single medication available to slow my disease's progression. I credit America's life sciences pipeline and the intellectual property rights that incentivize new development for my independence, career, and family. I speak for myself and for many other patients across the country when I say that any threats to patent protections and, therefore, medical innovation, are extremely discouraging and disheartening.

Unfortunately, such threats run rampant in our current system. Inefficiencies with the Patent Trial and Appeal Board (PTAB) have made it a breeding ground for the challenging of patents on drugs resulting from research and development programs. Duplicative intellectual property disputes threaten years of research into breakthrough treatments or medical devices that could have a ripple of negative effects on care delivery. Additionally, these threats create additional uncertainty that disincentivizes innovators from investing time and resources in future developments. Thankfully, the PREVAIL Act would implement reforms to protect intellectual property and ensure that our nation has a fair patent system that fosters innovation of life-changing medications and cures.

Furthermore, PERA would also protect the patent system by helping to clarify the law in light of various court decisions that make it more difficult for American innovators to invest in the critical research and development ventures from which so many patients are downstream. We cannot allow the uncertainty and restraints established by court decisions to run the risk of discouraging this innovation or, even worse, driving it to other countries more receptive to issuing patents on these innovations, putting these cures further out of reach for American patients. Instead, we must unleash the innovation flywheel, starting by ensuring researchers and inventors know the ecosystem exists in a policy framework that will protect the intellectual property (IP) of groundbreaking innovations and reward their contributions.

As I know from personal experience, the value of the hope that breakthrough treatments provide to patients cannot be overstated. Passing the PREVAIL and PERA Acts would restore this hope by halting unnecessary threats to medical innovation. As any patient, particularly one struggling with a rare, chronic, or life-threatening illness will tell you, there is nothing more powerful than the hope for the development of a cure for their condition. I urge you to continue your push to prioritize these patients

and their hope by protecting innovation and working with your colleagues to pass the PREVAIL and PERA Acts swiftly.

Please let me know if you have any questions. Thank you for your time.

Sincerely,
John Czwartacki
Founder and Chairman of Survivors for Solutions
www.survivorsforsolutions.org