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,
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