Coalition for Innovative Laboratory Testing

October 8, 2025

The Honorable Thom Tillis
Chair, Subcommittee on Intellectual Property, Judiciary Committee
United States Senate
Washington, DC 20510

The Honorable Adam Schiff
Ranking Member, Subcommittee on Intellectual Property, Judiciary Committee
United States Senate
Washington, DC 20510

The Honorable Darrell Issa
Chair, Subcommittee on Courts, Intellectual Property, AI and the Internet
United States House of Representatives
Washington, DC 20515

The Honorable Henry Johnson
Ranking Member, Subcommittee on Courts, Intellectual Property, AI and the Internet, United States House of Representatives
Washington, DC 20515

CC: Hon. Chris Coons, United States Senator
Hon. Kevin Kiley, United States Representative
Hon. Scott Peters, United States Representative

Re: Patent Eligibility Restoration Act of 2025 & Diagnostics Innovation

Dear Senator Tillis, Senator Coons, Congressman Kiley and Congressman Peters:

The undersigned are representatives of companies that develop and/or commercialize innovative diagnostic tests, investors and firms that support those companies, and medical providers and organizations representing individuals who develop, use or benefit from these tests. We write to express our strong support for the Patent Eligibility Restoration Act of 2025 (PERA) S. 1546 / H.R. 3152.

With few exceptions, capital intensive, innovative technology-based industries rely on patent protection to facilitate growth, dynamism and a robust competitive landscape. Unfortunately, over the last 15 years, a series of four recent decisions by the U.S. Supreme Court, amplified by follow-on application of lower courts, have been highly destructive for the protection of diagnostic inventions, which have been particularly singled out for exclusion by judicial—rather than Congressional—action. As a result, investors tend to disfavor funding diagnostic R&D compared to other fields. This has discouraged entrepreneurs from undertaking the often-arduous, time-consuming and expensive process of developing, improving, validating and launching novel diagnostic tests, and

generating large amounts of evidence of clinical benefit, when they know that larger competitors can simply replicate their efforts without any recourse to secure equitable remuneration through a license.

This lack of patent eligibility is dampening innovation, reducing competition and almost certainly resulting in diseases being diagnosed incorrectly or too late. The consequence affects human health and well-being, as early diagnosis can be the key to successful treatment, and in the era of personalized medicine, precision diagnostics are critical to ensuring that the correct drugs are being administered to patients. We therefore call on Congress to remedy this situation by passing PERA.

The diagnostics sector plays a vital role in improving patient outcomes, advancing public health, and driving the biomedical economy. Our ability to develop novel laboratory tests—often based on groundbreaking scientific discoveries—relies on the availability of robust patent protection. PERA promises to restore eligibility for patents covering innovative diagnostic methods, thereby enabling companies to secure the investments needed to bring new tests to market.

Without clear and reliable patent eligibility, diagnostics companies face significant uncertainty. Investors are reluctant to support ventures when the prospects for protecting intellectual property are ambiguous or unattainable. This uncertainty stifles innovation delays the introduction of new tests, and ultimately harms patients who would benefit from early and accurate detection of disease.

Published studies have directly linked the Supreme Court's *Mayo v. Prometheus* (2012) and *Myriad Genetics v. AMP* (2013) decisions to a decline in equity investments in diagnostics companies.[1] Billions of dollars per year in venture capital is being diverted to sectors other than diagnostics according to these reports.[2] Survey evidence further confirms this—62% of investors agreed that their firms are less likely to invest in companies developing patent ineligible technologies.[3] Testimony presented to this Committee further affirms that investment in development of diagnostics cannot be justified without patent protection.[4]

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[1] *See* 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).
[2] Ibid.
[3] David O. Taylor, *Patent Eligibility and Investment*, Cardozo L. Rev. (2020), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3340937.
[4] Testimony of Peter O'Neill, Executive Director of Cleveland Clinic Innovations, before the Subcommittee on Intellectual Property, Senate Committee on the Judiciary (June 11, 2019) ("If an invention can't get intellectual property protection, usually that is a fatal flaw and the invention is

Many of the undersigned are prepared to offer real-world examples of how the current patent landscape has frustrated efforts to finance and scale innovative diagnostic tests.

Research has also shown that universities are especially sensitive to domestic patent policies, as they generally do not seek patents abroad if there is no domestic patent protection; as a consequence, the current patent eligibility jurisprudence is particularly harmful for our country's university-to-industry pipeline, which will have long-term national competitiveness consequences as our economic peer countries' universities do not have to contend with similar roadblocks.[5] In sum, the *Mayo* and *Myriad* rulings didn't just reshape patent law—they sent ripples through the diagnostics investment landscape, making it harder for all entrepreneurs to secure funding without strong IP protection.

These disparities show that the current patent landscape discourages investment in diagnostics, which often require substantial funds to run large clinical studies to prove correlations between biomarker levels and clinical outcome —precisely the types of innovations excluded under current eligibility rules. These expensive clinical trials are critical to gaining reimbursement and widespread adoption by the medical community of new tests. Furthermore, the ability to out-license patented tests leads to nationwide access, permits standardization, reduces variability between labs and lowers healthcare costs through economies of scale

Examples of promising diagnostics abandoned due to IP issues include tests to predict flare-ups for Systemic Lupus Erythematosus, detectrare genetic disorders in infants (Noonan Syndrome) causing developmental abnormalities and heart defects, and new methods for diagnosing schizophrenia, Alzheimer's and diabetes.[6]

As another example, the Cleveland Clinic developed a new diagnostic test for assessing risk for cardiovascular disease by analyzing a specific biomarker for inflammation of blood vessels. They obtained patents covering this diagnostic before these recent Supreme Court cases and asserted them against a competitor allegedly using their technology as

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abandoned at that point"), https://www.judiciary.senate.gov/imo/media/doc/O%27Neill%20Testimony.pdf.

[5] Liddicoat et al., *The Effects of Myriad and Mayo on Molecular-Test Development in the United States and Europe: Interviews from the Frontline*, 22 Vand. J. Ent. & Tech. L. 785 (2020) ("Notably, half of the US university technology-transfer offices interviewed decided not to develop [molecular] tests").

[6] Paul Michel et al., *Presenting the Evidence for Patent Eligibility Reform: Part III – Case Studies and Litigation Data Highlight Additional Evidence of Harm*, IPWatchdog (Oct. 18, 2022), https://ipwatchdog.com/2022/10/18/presenting-evidence-patent-eligibility-reform-part-iii-case-studies-litigation-data-highlight-additional-evidence-harm/id=152193/.

these cases were being decided. The patents were ultimately ruled to be patent ineligible based on these intervening new interpretations of patent eligibility by the Supreme Court. Understandably, as the Cleveland Clinic has explained, this experience has chilled their willingness to invest in the development of future diagnostic tests where patent protection is uncertain.[7] In similar cases, the very appellate judges affirming conclusions that diagnostic patents were ineligible decried the binding precedent tying their hands to make these decisions and calling for reconsideration by the Supreme Court or Congress.[8] This experience is all too familiar to the undersigned companies, leading to an untold number of diagnostics that are being quietly abandoned to the detriment of patient health. We recognize that some opposition to PERA has emerged from a few outspoken patient advocacy, medical, and civil rights organizations. These groups have voiced concerns regarding access, affordability, and competition. We respect their perspective and share a commitment to ensuring patients benefit from scientific progress.

However, it is important to distinguish between the role of patents and the issue of access to medicines and medical diagnostics. Patents are a vehicle of investment; their function is to provide a legal mechanism that can justify significant investment in research and development—investment that is critical in the diagnostic space, where estimates range from $40 to $75 million for the cost of validating and bringing a newly discovered diagnostic test to market. Questions of access arise only after the diagnostic test in question exists,

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[7] Testimony of Peter O'Neill, Executive Director of Cleveland Clinic Innovations, before the Subcommittee on Intellectual Property, Senate Committee on the Judiciary (June 11, 2019), https://www.judiciary.senate.gov/imo/media/doc/O%27Neill%20Testimony.pdf.

[8] *Athena Diagnostics, Inc. v. Mayo Collaborative Servs.*, 927 F.3d 1333 (Fed. Cir. 2019) (denying rehearing en banc) (denying patent eligibility for a method of diagnosing a rare cause of certain neurological diseases due to a particular type of autoimmune response); *id.* at 1363 (Judges Moore, O'Malley, Wallach, Stoll) (dissenting from denial of rehearing en banc) ("Since *Mayo*, every diagnostic claim to come before this court has been held ineligible. While we believe that such claims should be eligible for patent protection, the majority of this court has definitively concluded that the Supreme Court prevents us from so holding. No need to waste resources with additional en banc requests. *Your only hope lies with the Supreme Court or Congress*. I hope that they recognize the importance of these technologies, the benefits to society, and the market incentives for American business. And, oh yes, that the statute clearly permits the eligibility of such inventions and that no judicially created exception should have such a vast embrace. It is neither a good idea, nor warranted by the statute.") (emphasis added); Ariosa Diagnostics, Inc. v. Sequenom, Inc., 809 F.3d 1282, 1284 (Fed. Cir. 2015) (en banc) (denying eligibility for a patent on a method for detecting paternally inherited fetal DNA in maternal blood samples, obviating the need for more invasive tests); id. at 2187 (Judges Lourie and Moore) (concurring in denial of en banc rehearing) ("[I]t is unsound to have a rule that takes inventions of this nature out of the realm of patent-eligibility . . . .").

and our concern is that fewer diagnostics are going to reach the market at all. Accordingly, it is not surprising that the views of these academic and advocacy groups differ from those of the undersigned biomedical entrepreneurs. Unlike start-ups and emerging growth companies, these organizations do not need to obtain, enforce, or license patents for novel diagnostic tests or technologies. Their role, while important, does not require substantial investments, risks, and regulatory hurdles faced by diagnostics companies seeking to commercialize laboratory innovations.

The Patent Eligibility Restoration Act seeks to restore balance by allowing innovators in the field of medical diagnostics to protect their inventions—just as companies ranging from aerospace engineering to consumer electronics to pharmaceutical drug products do. The current regime favors certain sectors while leaving others behind. Potential breakthroughs are shelved, collaborations stall, and promising startups struggle to survive. Restoring patent eligibility is vital to ensuring that the United States remains a global leader in medical innovation and that patients continue to benefit from state-of-the-art diagnostic technologies.

For these reasons, we urge the Senate and House Judiciary Committees to advance the Patent Eligibility Restoration Act of 2025 without delay. Passage of this legislation will remove barriers to innovation, stimulate investment in new diagnostic methods, and strengthen the nation's capacity to respond to emerging health challenges.

We appreciate your attention to this urgent matter and stand ready to support efforts that advance the interests of patients, entrepreneurs, and the broader biomedical community. Thank you for your leadership and commitment to restoring America's leadership in medical innovation.

Respectfully,

[Signatures & Affiliations of Diagnostics Companies, their Investors, Patent Attorneys and Medical Practitioners that Use These Innovative Tests]