Testimony of Sue Peschin, President and CEO, Alliance for Aging Research
Senate Judiciary Committee, Subcommittee on Intellectual Property
Hearing on the Patent Eligibility Restoration Act (PERA)
October 8, 2025

Chairman Tillis, Ranking Member Schiff, and members of the Subcommittee, thank you for the opportunity to testify today. My name is Sue Peschin. I serve as President and CEO of the Alliance for Aging Research. And, perhaps like some of you, I am also a family caregiver to my mom, who is 84 and lives with kidney disease, severe arthritis, and dementia.

The mission of the Alliance for Aging Research is simple: we are dedicated to changing the narrative to achieve healthy aging and fair access to care.

Today, that mission is jeopardized by unclear patent law that makes it harder for innovative individuals, research entities, and companies to develop and market medical discoveries.

I would like to begin by stating that I am not here as a patent lawyer, a company executive, or an investor. I am here as an advocate for older Americans. The Supreme Court has narrowed patent eligibility in many areas, but what most concerns me is how the Court has explicitly restricted protection for medical diagnostics. The Alliance for Aging Research cares about this issue because when incentives for developing diagnostics disappear, patients lose access to early detection, timely treatment, and ultimately better outcomes.

That is why we strongly support the bipartisan Patent Eligibility Restoration Act of 2025, or PERA. This legislation would restore clarity and predictability to our patent system and ensure that inventors and scientists can obtain the protection they need to bring new diagnostics, treatments, and cures to patients.

For older adults, who often live with multiple chronic or life-threatening conditions, PERA could give them access to a novel diagnostic or therapy that improves their health or extends their lives.

The need for PERA became clear in 2012 when the Supreme Court broke with long-standing precedent in a major intellectual property case, *Mayo v. Prometheus*, the second of its four cases of the last decade interpreting the limits of patent eligibility. The Court ruled that Prometheus had claimed "laws of nature" in its patent covering a method to determine optimal drug dosages and thus the innovation was not patent eligible, making the patent invalid.

I am not a lawyer, but I understand the practical effect this case had: diagnostic methods that apply human ingenuity to detect disease are now ineligible for patent protection. That has left many promising tests stranded in the lab because companies and researchers cannot justify the high costs of development without the ability to protect their discoveries.

In the years after *Mayo*, the Supreme Court issued its final two decisions that together made the situation even worse. One of these cases ostensibly went beyond medical diagnostics to address computer software and other technologies.

But its impact is felt in the medical space too -- since so much of today's diagnostic research relies on data analysis, artificial intelligence, and other computational tools, these entire categories of diagnostic methods are also vulnerable to being patent-ineligible, leaving researchers unable to protect their discoveries and investors unwilling to fund their development.

The combined effect of these cases has negatively impacted investment in diagnostics development.

In fact, in the four years after *Mayo*, investment in diagnostics fell more than $9 billion short of what it otherwise would have been. The startups and companies that rely on this sort of venture capital suffered, and the United States became more reliant on other countries for diagnostic technologies. It was no accident that, during the pandemic, the most effective COVID-19 testing kits were initially developed overseas where diagnostics remain eligible for patent protection.

Bound by these precedents, Federal Circuit judges have openly lamented that they must invalidate patents on inventions that undoubtedly would have been eligible for protection a decade ago. And the fallout for patients has been severe.

Take the case of *Ariosa v. Sequenom*. Sequenom developed a non-invasive prenatal test that could detect genetic abnormalities -- sparing pregnant women from riskier procedures like amniocentesis, which can cause miscarriages. The test was hailed as a medical breakthrough.

Yet the Federal Circuit invalidated the patents under *Mayo*, even while one judge acknowledged how counterproductive that outcome was. Judge Richard Linn wrote in his concurrence: "This case represents the consequence -- perhaps unintended -- of that broad language in excluding a meritorious invention from the patent protection it deserves and should have been entitled to retain."

He concluded that, "But for the sweeping language in the Supreme Court's *Mayo* opinion, I see no reason, in policy or statute, why this breakthrough invention should be deemed patent ineligible."

When judges themselves admit that the law is forcing them to strike down patents on life-saving diagnostics, something is deeply wrong. The victims are not the companies. It's the patients who are denied access to inventions that could improve or save their lives.

Sequenom is hardly an outlier.

After *Mayo* and related rulings, other important diagnostics were deemed ineligible for patent protection, leaving promising discoveries stranded in the lab. As a result, researchers in the United States have abandoned or never developed tests that otherwise could have reached patients.

For example, researchers at numerous top American universities have left behind novel diagnostics for lupus, Alzheimer's, major depressive disorder, cancer, including metastatic

cancers, schizophrenia, and rare pediatric disorders, after the USPTO rejected or weakened their patents because of the eligibility rules in *Mayo*.

Consider what this means for cancer patients. Researchers at an East Coast medical school developed biopsy tests that could predict brain metastases in melanoma patients. These tests held the promise of catching cancers -- including aggressive, metastatic forms -- at their earliest stages. Once brain metastasis is detected, patients have a median survival of just four months. A reliable diagnostic could have spared patients from invasive procedures, enabled earlier interventions, and given families more precious time together.

Yet because patents on these methods were denied under the *Mayo* standard, researchers abandoned efforts to bring the diagnostic to patients. The result is that many melanoma patients still learn of their brain cancer only after it has spread, when treatment is more difficult and when they may only have weeks left to live.

This is not a failure of science. It is a failure of our patent system. And for patients and their families, the price of that failure is measured in lost time, diminished health, and lives cut short.

Consider three of the most devastating and unpredictable diseases facing seniors: Cancer, Parkinson's, and Alzheimer's.

By the time Alzheimer's is formally diagnosed, the disease may have advanced beyond the point where interventions can make a meaningful difference. New blood-based diagnostic tests could detect the disease earlier, giving families time to plan and patients a better chance at meaningful treatment. Yet future research into many of these tests are at risk of being stalled because companies cannot secure reliable patent protection.

Seniors facing Parkinson's often endure years of uncertainty, visiting multiple doctors before receiving a diagnosis. Even today, there is no single definitive test. Promising biomarker-based diagnostics are in development, but without strong intellectual property protections, companies will likely be reluctant to take the financial risk of bringing them to market.

Early detection is one of the most powerful tools for improving cancer survival rates, yet many cancers are not discovered until they have spread and are difficult to treat. Cutting-edge diagnostics -- such as liquid biopsies that detect cancer through a simple blood test -- offer the potential to catch the disease at its earliest, most treatable stages. But without reliable patent protection, companies may walk away from the costly, risky research into these diagnostics.

In fact, the Cleveland Clinic told this very Subcommittee that uncertainty over patent eligibility forces them to abandon promising inventions, citing *Mayo*. If one of the world's leading medical centers cannot bring a test to market under the current rules, you can imagine how many smaller labs never even try.

The pattern is the same across conditions. Without reliable patent protection, discoveries that can change patients' lives remain stuck in the lab.

PERA would restore much-needed clarity so scientists can move medical inventions forward and patients can benefit from these inventions. What the bill does is simple. It eliminates confusing, judicially created exclusions and replaces them with clear statutory rules.

Lastly, I want to address directly the matter of cost. Patents are not about setting prices. They are about whether a product exists at all. They are the tool that enables the upfront investment needed to turn a discovery into a clinically validated, widely available test.

Affordability is a separate issue, and it matters deeply to our community. But for many of our members, the more immediate problem is that they cannot get the right diagnostic *at any price*, because the incentives to develop and scale those tests have withered.

Without reliable patent eligibility, the most impactful diagnostics will never reach patients. That is exactly what PERA restores: the basic certainty inventors need to develop and market tests to patients. Only once those tests are developed can we work together on reimbursement and fair pricing.

Members of the Subcommittee, we stand at a crossroads. We can continue down the current path, where innovation leaves our shores and seniors wait for answers, or we can restore clarity, predictability, and fairness to our patent system. If we do not pass PERA, we risk losing medical innovation, jobs, and our competitive edge. Most importantly, we risk losing lives.

That is why it is so encouraging to see bipartisan leadership on this issue. At a time when Washington is divided on many issues, it is refreshing to see members of both parties working together on legislation that will mean so much to so many patients. Passing PERA would not only strengthen medical innovation and save lives, it also shows the country that Congress can still come together to solve real problems.

PERA is bipartisan, balanced, and urgently necessary to advance the health and well-being of older Americans. On behalf of the Alliance for Aging Research, and on behalf of caregivers across our country, I urge you to advance this legislation.

###