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Hearing on "From Genes to Machines: The Patent Eligibility Debate"
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Chairman Grassley, Ranking Member Durbin, and members of the Committee, thank you for the opportunity to testify today. My name is Sue Peschin, and I serve as President and CEO of the Alliance for Aging Research. Personally, I am also a family caregiver to my mom, who is 85 and lives with kidney disease, severe arthritis, and dementia.

The Alliance for Aging Research is the leading nonprofit organization dedicated to changing the narrative to achieve healthy aging and fair access to care. We advocate for policies that support medical innovation because older Americans—who frequently live with multiple chronic or life-threatening conditions—often have the most to gain from new diagnostics and treatments, and the least time to wait for them.

That is precisely why the Alliance for Aging Research strongly supports the bipartisan "Patent Eligibility Restoration Act," or PERA. The bill aims to restore clarity to Section 101 of the Patent Act, and by doing so, to restore predictability to the patent system—so that inventors of medical discoveries can reliably make their way from the lab to the clinic.

How the Supreme Court Created the Need for PERA

To understand why the Alliance supports urgent passage of the PERA bill, it is important to understand how we arrived at this moment.

The Patent Act was passed by the U.S. Congress in 1952. The basic purpose of the Patent Act is to encourage inventors to create and disclose new inventions by giving them a limited monopoly (usually 20 years from filing) in exchange for making the invention public.

Patents are valuable business assets. Anyone who has watched entrepreneurs pitch on *Shark Tank* knows that one of the first questions investors often ask is: **"Do you have a patent?"** The reason is simple: patents help protect innovative ideas from being immediately copied by competitors. Without that protection, inventors—and the investors who back them, including the Sharks—might be far less willing to devote the significant time, money, and effort required to develop, commercialize, and bring new inventions to market.

As stated in the intro, PERA would help clarify Section 101 of the Patent Act, which outlines which types of things are *eligible to be patented*. This section states that a patent may be obtained for "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof." It is important to note that *patent eligibility doesn't guarantee patent approval*; it just lets the Patent Office consider an invention. After an invention is deemed patent eligible, the Patent Office looks at other requirements in the Act, such as whether an invention is useful (also in Section 101); novel (Section 102); non-obvious (Section

103); and has been sufficiently described and properly claimed (Section 112). These are not easy legal hurdles, but they have generally provided clarity and predictability to inventors.

Starting in 2010, Supreme Court rulings in cases such as *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, *Association for Molecular Pathology v. Myriad Genetics, Inc.*, and *Alice Corp. v. CLS Bank International* significantly expanded longstanding judicial exceptions to Section 101 patent eligibility in three areas: 1) laws of nature (e.g., a naturally occurring biological relationship), 2) natural phenomena (something that exists in nature), and 3) abstract ideas (an undefined term that courts have found to include economic and other principles and concepts).

The result was a vague and unpredictable framework that lower courts have struggled to apply. The Court's rules became so broad that they have prevented patents not only on basic natural discoveries—which most people agree should remain unpatentable—but also on practical inventions and medical innovations that build on those discoveries. In addition, Federal Circuit judges have noted that they cannot reconcile the decisions and that they have been forced to invalidate patents for inventions that would have been eligible previously. With the Supreme Court declining to revisit the decisions, innovators, investors, and research institutions are left to operate in a system that no longer provides the stability Congress intended.

This is particularly acute in the field of medical diagnostics. Diagnostics sit at the intersection of biology, data analysis, and clinical practice. The Supreme Court's decisions have made it extraordinarily difficult to obtain patent protection for methods that detect disease, measure biomarkers, or translate biological insights into actionable clinical tools.

This instability concerns us because the road from scientific discovery to the clinic is long and expensive, with patients paying the ultimate price in missed diagnosis and care. A researcher may identify a biomarker or genomic pattern—but turning that insight into a viable and commercially available test requires years of research validation, clinical development, and regulatory review. Without reliable patent protection, investors and commercial partners can rarely shoulder that risk.

The Supreme Court's exceptions currently block many biotechnology and diagnostic patents before courts even examine whether they are genuine inventions—the Patent Office simply rejects them. PERA would largely eliminate those barriers for diagnostics and let those inventions be judged under the normal patentability rules.

Patients Pay the Price of Congressional Inaction

Under the current eligibility framework, post-*Mayo* and related rulings, many potentially life-changing discoveries—particularly in diagnostics—have failed to reach patients. One of the clearest examples is in *Ariosa Diagnostics, Inc. v. Sequenom, Inc.* Sequenom developed a non-invasive prenatal test that could detect fetal abnormalities from a simple maternal blood sample, sparing mothers and babies the risks of invasive procedures like amniocentesis. It was a genuine scientific breakthrough.

Yet the Federal Circuit invalidated the patents. Judge Richard Linn acknowledged in his concurrence that the invention was exactly the kind of advance the patent system is meant to encourage and protect. However, he was compelled to strike it down because of the Supreme Court's broad language in the *Mayo* decision. In his decision, Judge Linn called on Congress to resolve the confusion resulting from the Supreme Court's decisions, stating:

> "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… In my view, the breadth of the second step of the *Mayo* test is such that it is difficult to imagine any diagnostic claim that could survive. [...] ***If the law is to be changed, and I believe it should be, that change must come from Congress*** [emphasis added]."

PERA would restore the basic principle that a new method for putting a natural discovery to practical use—like detecting fetal DNA in maternal blood in a way no one had done before—should be judged on its merits under the traditional patent requirements, rather than being disqualified at the outset.

Similar challenges have repeated across a number of diseases and conditions that disproportionately impact older adults.

Consider Alzheimer's disease, which over seven million Americans age 65 and older live with. University researchers developed a novel imaging diagnostic for assessing the progression of the disease. The test could have made Alzheimer's monitoring faster, more practical, and significantly less expensive. The doctor received the AAIC Lifetime Achievement Award from the Alzheimer's Association for his work specializing in diagnostics for Alzheimer's disease.

Before the Supreme Court's recent eligibility rulings, the university secured patents and licensed them to a company for development and commercialization. After *Mayo*, however, the legal landscape changed. Follow-on applications covering new aspects of the invention were rejected, and considering *Mayo* and *Myriad*, even the original patents appeared increasingly vulnerable. The commercial partner ultimately walked away, and the diagnostic never reached patients.

PERA would help protect breakthroughs like this by confirming that inventions that apply human insight to nature—in this case, human-created methods for measuring and monitoring disease progression—can be eligible for patent protection. A genuinely cutting-edge Alzheimer's diagnostic deserves that chance.

A similar situation arose in university-led melanoma research, a disease that disproportionately affects older adults. Researchers 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 spare patients from invasive procedures, enable earlier interventions, and give families more time.

Yet patents on these methods were denied under the *Mayo* and *Myriad* standards, forcing researchers to abandon efforts to bring the diagnostic to patients. As a result, 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.

PERA would address that failure of the system. The bill would recognize that diagnostic tools that translate biological markers into actionable clinical predictions are eligible for patent protection—providing universities and their partners with a stronger basis to develop tests that help physicians intervene earlier.

Major depressive disorder, which affects millions of older adults, offers yet another example. A university researcher found evidence that late-life depression is associated with changes in the metabolism of amyloid-beta, a peptide long linked to Alzheimer's disease.

Based on that insight, the researcher developed a diagnostic test, and the university secured one patent before the Supreme Court's recent eligibility decisions. When the university later sought patent protection for additional aspects of the diagnostic method, each application was denied based on *Mayo*. The one patent issued before *Mayo* and *Myriad* ultimately failed to attract investment in this legal environment, and the promising diagnostic never made it to market.

PERA would address this problem by making clear that a diagnostic built on human-identified biomarkers and human-created testing methods can be patent-eligible, allowing the university to secure the protection needed to sustain development and commercialization.

Importantly, PERA Intends to Codify the *Myriad* Decision, *Not* Overturn It

As this Committee examines the merits of PERA, I would like to clarify an important point.

Some critics have suggested that PERA would overturn part of the Supreme Court's decision in *Myriad* and open the door to patents on human genes. In fact, language in the PERA 2025 legislation, S. 1546, before you today—introduced by Senators Tillis and Coons on May 1, 2025—**is intended to codify the core holding of *Myriad*** by explicitly excluding from patent eligibility "[a]n unmodified human gene, as that gene exists in the human body," even if that human gene is "isolated."[1] This is a significant change from the version introduced in the last Congress, which excluded human genes only "as [they] exist in the human body" and did not expressly reach human genes that have been *isolated*—the very issue at the heart of *Myriad*.

In the case, Myriad obtained patents after discovering the precise location and sequence of the BRCA1 and BRCA2 genes, mutations of which can dramatically increase the risk of breast and ovarian cancer. The discovery enabled Myriad to exclusively develop genetic blood tests for detecting mutations for assessing cancer risk. I have personally taken Myriad's panel tests due to a family history of ovarian cancer, and I am grateful for the information I received about my increased lifetime risk.

[1] S. 1546, proposed 35 U.S.C. § 101(b)(1)(D).

In the *Myriad* case, the Supreme Court held that a naturally occurring human gene is not patentable simply because someone isolated it from the body. In other words: finding a gene and extracting it from a chromosome does not make it an invention. The Supreme Court specifically rejected the argument that "isolation" alone was enough to transform a human gene into patent-eligible subject matter.

PERA aims to codify *Myriad* by making clear that human genes, whether isolated or found in their natural state, are not patent-eligible. At the same time, like the Supreme Court itself did in *Myriad*, it would preserve eligibility where there has been human modification, for gene modifications and practical applications, the foundation of biotechnology. This includes cDNA, modified genes, genes applied and used in gene therapy or an engineered vector used to deliver a gene into cells, as well as other useful applications of genes. PERA would also leave the core safeguards of patent law intact: an invention must still be new, non-obvious, useful, and adequately described.

To be clear: The goal of PERA is to restore patent protection for diagnostics, therapeutics, or research inventions involving genes, *not* for the genes themselves. I would welcome further discussion of any wording Members or other stakeholders think could make that even clearer within the legislation.

Here's What We Stand to Lose Without PERA

What we stand to lose if Congress does not pass PERA is as concerning as what patients have already lost.

Researchers are currently developing multi-cancer detection tests that have the potential to identify several cancers at once through a simple blood draw. These tests look for patterns in DNA and protein markers that can indicate the presence of early-stage cancer cells. Catching these cancers before they advance is essential for improving survival rates and reducing the burden of treatment for older adults.

Promising biomarker-based diagnostics for Parkinson's are also in development. That work is critical, as seniors facing Parkinson's often endure years of uncertainty, visiting multiple doctors before receiving a diagnosis. Today, there is no single definitive test.

This is exactly the kind of innovation America should be leading. But researchers and innovators can advance their science only as far as investors are willing to fund it—and investors will commit only when the patent system provides reliable protection. If diagnostic patents remain unpredictable, capital will move elsewhere, and breakthroughs like these may never reach patients.

Startups and researchers must make decisions years before a product exists. At the beginning of that process, the company needs to know: "Will we be able to get a patent that protects this investment?" In a Winter 2022 *Washington and Lee Law Review* article, author A. Sasha Hoyt found that, 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.

In a 2020 *SMU Scholar* article, Southern Methodist University Professor David O. Taylor interviewed 475 venture capital and other private equity investors to study the impact of the Supreme Court's Section 101 cases on investment behaviors. He found that 74 percent of investors considered patent eligibility to be an important factor when their firms decide to invest in companies developing new technology. He further found that 62 percent of investors "agreed that their firms are less likely to invest [in companies developing patent-ineligible technologies] given the unavailability of patents, while only 20% disagreed." Additionally, Professor Taylor found that investors overwhelmingly would decrease investment in industries lacking patent protection, and that the effect predominated in the pharmaceutical, biotechnology, and medical devices industries.

Aside from the impacts of decreased investment—when innovators cannot obtain patents, they often withhold discoveries as trade secrets, especially in diagnostics. That hurts scientific transparency and slows progress. During the patent application process, companies publicly disclose their invention, which allows for future innovation. Trade secrets stay secret.

PERA is Your Opportunity to Do Good Together

Members of the Committee, you have an opportunity to fix a real and well-documented problem. The current eligibility framework is one that Federal Circuit judges themselves have struggled to apply consistently. As the Supreme Court has repeatedly declined to revisit this doctrine, the very judges charged with administering patent law have made clear that Congress is the best institution positioned to restore clarity.

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

When patent law works, patients benefit. We get earlier diagnoses, more effective treatments, and more personalized care. When it doesn't, we lose time. We lose tools. We lose lives.

On behalf of the Alliance for Aging Research, older patients, and caregivers across the country, I respectfully urge this Committee and Congress to pass PERA before the end of this year.

Thank you so much for the opportunity to testify, and I look forward to your questions.

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