U.S. Senate Committee on the Judiciary
"*From Genes to Machines: The Patent Eligibility Debate*"
Chairman Charles E. Grassley
Questions for the Record: Ms. Sue Peschin

QUESTION (1): The unanimous 2013 U.S. Supreme Court opinion *Association for Molecular Pathology v. Myriad Genetics* ruled that naturally occurring DNA segments could not be patented even though it took human effort to isolate the gene. This opinion radically changed public accessibility to genetic testing by lowering the cost from thousands of dollars to hundreds of dollars, particularly in breast cancer gene testing.

QUESTION (1a): Would PERA, S. 1546, change whether genes are patent eligible? Why or why not?

RESPONSE (1a): No. PERA would not make naturally occurring human genes patent eligible. Language in the 2025 legislation, S. 1546, expressly excludes an unmodified human gene as it exists in the human body, preserving the core holding of *Association for Molecular Pathology v. Myriad Genetics, Inc*. The bill therefore would not allow anyone to claim ownership of a naturally occurring human gene or the genetic information it contains.

PERA would preserve eligibility where there has been human modification, for gene modifications and practical applications. 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. Even then, eligibility is only the threshold question; an invention would still have to be useful, new, non-obvious, and adequately described to receive a patent.

QUESTION (1b): Would this bill change whether genes isolated using human effort are patent eligible? Why or why not?

RESPONSE (1b): No. Language in the PERA 2025 legislation, S. 1546, specifically provides that an unmodified human gene that has been isolated from the human body, but is otherwise the same as it exists in the body, is ineligible for patent protection.

PERA would codify *Myriad* by making clear that human genes, whether isolated or found in their natural state, are not patent-eligible. At the same time, the bill would preserve eligibility where there has been human modification, including for modifying genetic material and practical applications of genetic discoveries, the foundation of biotechnology. PERA would also leave the core safeguards of patent law intact: an invention must still be new, non-obvious, useful, and adequately described.

QUESTION (1c): Would enactment of this bill help or hurt the development of gene therapies and other medical treatments? Please explain.

RESPONSE (1c): PERA would help foster the development of gene therapies and other medical treatments. Bringing a promising therapy to patients requires years of research, clinical testing, regulatory review, manufacturing development, and substantial private investment.

When innovators cannot reliably predict whether a genuine, human-made invention will be eligible for patent protection, investors can rarely shoulder that risk. This is especially relevant to gene therapies, where the inventions may involve an engineered genetic sequence, a viral or nonviral delivery system, a manufacturing process, or a specific therapeutic use -- not the naturally occurring gene itself.

PERA would allow those inventions to be evaluated under the traditional patent requirements. The bill would not guarantee a patent or lower the standards for obtaining one. By providing greater certainty, PERA would improve the likelihood that researchers can attract the investment and commercial partners needed to bring new treatments to patients.

QUESTION (1d): How would enactment of this bill impact patient access to diagnostic tests? Please give examples of the cost of tests and Medicaid and Medicare coverage if you are able to do so.

RESPONSE (1d): PERA would improve patient access by increasing the likelihood that promising diagnostic discoveries are developed, clinically validated, and made available to the public. Patents do not determine prices or insurance coverage, but they determine whether an innovation can reach patients in the first place. Without predictable patent protection, companies are far less likely to invest the substantial resources required to turn a scientific insight into a reliable diagnostic test.

The bill would allow genuine human-made diagnostic inventions to be evaluated under the traditional patent requirements, supporting a broader pipeline of tests and, over time, greater choice and competition.

Medicare currently covers certain next-generation sequencing tests for beneficiaries with advanced cancer when the tests and patients meet Centers for Medicare & Medicaid Services (CMS) criteria, while other diagnostic tests may be covered through national or local coverage policies. Medicaid includes laboratory and X-ray services as a mandatory benefit, but coverage of a particular genetic or molecular test, utilization requirements, and beneficiary cost-sharing can vary by state and program. PERA would not alter those coverage rules.

QUESTION (2): Please share examples of processes similar in effort and knowledge to the process of isolating a gene that are used in scientific research and medical treatment. Do they also risk being patent eligible if PERA is enacted? If PERA is to be considered, we need to understand the full breadth of its impact on medicine and scientific research.

RESPONSE (2): Scientific research routinely involves isolating naturally occurring DNA, proteins, cells, and microorganisms, as well as identifying associations between biomarkers and disease. This work is fundamental to biomedical research and medical innovation.

Under PERA, the effort or technical skill involved would not, by itself, make the underlying material or scientific discovery patent eligible. An unmodified human gene would remain

ineligible, even if it had been isolated, and natural materials as they exist in nature would remain ineligible.

PERA would distinguish those natural discoveries from genuinely human-made inventions that build upon them. A new diagnostic method, therapeutic application, engineered composition, or research process developed through this work could be considered for patent protection. 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.

Eligibility would not guarantee a patent; the claimed invention would still have to be useful, new, non-obvious, and adequately described. A routine or previously known research technique would not receive a patent merely because it required significant expertise to perform.

QUESTION (3): On a more general note, where is the science around genetics headed? What are the next great, yet realistic discoveries and uses? Would enacting PERA affect this development and use? Would it impact financial investment in scientific research?

RESPONSE (3): Genetics is moving medicine toward earlier detection and more individualized care. Advances now in development include multi-cancer detection tests that look for DNA and protein signals in a simple blood draw; biomarker-based tests for diseases such as Parkinson's; and gene-editing, gene-replacement, and RNA-based therapies aimed at the underlying causes of disease.

These technologies could help patients receive a diagnosis sooner and obtain care tailored more closely to their biology. Whether those advances reach patients depends not only on scientific ingenuity, but also on sustained investment through clinical validation, regulatory review, manufacturing, and commercialization.

PERA would provide a clearer and more predictable framework for the human-made tests, therapies, and tools that put genetic knowledge to practical use. That certainty would make it more likely that private capital and commercial partners support promising work through the long development process.

QUESTION (4): Has there been a decrease in investment into medical research since *Myriad*?

RESPONSE (4): Yes, particularly in medical diagnostics. The Supreme Court's Section 101 decisions, including *Mayo Collaborative Services v. Prometheus Laboratories, Inc.* and *Association for Molecular Pathology v. Myriad Genetics, Inc.*, created substantial uncertainty over whether genuine diagnostic inventions could be eligible for patent protection. That uncertainty has discouraged the investment needed to turn promising scientific discoveries into clinically useful tests.

In a Winter 2022 *Washington and Lee Law Review* article, author A. Sasha Hoyt found that, in the four years after the *Mayo* decision, 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% 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% 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.

For patients, that lost investment can mean that a promising discovery never advances through clinical validation and commercialization. PERA would address this chilling effect by restoring a clear and predictable path to patent eligibility for genuine human-made diagnostic inventions, helping more potentially life-saving tests attract the investment needed to reach patients.

QUESTION (5): Would the development of the COVID-19 vaccine have been different if the Supreme Court had not previously ruled that genes, including the COVID-19 genome, are not patent eligible? If so, how would it have been different? Also, what would the impact have been on the cost of and access to the vaccine?

RESPONSE (5): The rapid development of COVID-19 vaccines depended not on ownership of the viral genome, but on decades of investment in human-made inventions -- including mRNA and viral-vector platforms, engineered genetic sequences, lipid-nanoparticle delivery systems, vaccine formulations, and manufacturing processes.

These were all supported by predictable patent rights, which supported the investment, licensing, knowledge-sharing, and manufacturing partnerships that allowed multiple vaccines and other COVID-19 products to be developed and produced at unprecedented speed. The key patent eligibility question was therefore not whether the virus itself could be owned, but whether the human-made technologies needed to create and produce vaccines could receive protection.

Patent eligibility, by itself, does not determine vaccine cost or access. Patents do not dictate prices; they help determine whether innovators can attract the investment required to develop a product in the first place. Vaccine affordability and availability during the COVID-19 pandemic were shaped by government procurement, manufacturing capacity, supply chains, distribution, and coverage policies -- not by the threshold question of patent eligibility.

PERA would preserve the distinction between naturally occurring genetic material and human-made inventions. The bill would not permit anyone to patent genes as they exist in nature. Instead, PERA would ensure that human-made vaccine platforms, engineered sequences, delivery technologies, formulations, and manufacturing processes developed using knowledge of

genetic material can be eligible for patent protection. That would strengthen the innovation ecosystem needed to confront future public-health threats.

QUESTION (6): Iowa, and similar states with long drives and rural areas, have challenges with patient access to medical care and treatment, particularly treatment by specialists and advanced treatments. Small, local and regional hospitals and clinics provide much of the services for my rural residents. How would PERA, if enacted, impact these people?

RESPONSE (6): PERA could help expand the pipeline of diagnostic tools and treatments, including technologies that allow more care to begin closer to home. Biomarker-based diagnostics for conditions such as Parkinson's, multi-cancer detection tests -- along with other tests that can be performed on a sample collected at a local clinic -- could allow patients to begin the diagnostic process without first traveling hours to an academic medical center or specialist.

That could prove especially valuable for older Iowans and patients served by small hospitals and regional clinics. Timely results could help local physicians determine whether specialty care is needed, facilitate remote consultations, identify appropriate treatments, and reduce unnecessary travel and delays in care.

By providing clearer, more predictable eligibility rules for genuine human-made inventions, PERA would increase the likelihood that these tools attract the investment needed for clinical validation and commercialization. The bill would complement broader efforts to address coverage, reimbursement, transportation, and rural workforce shortages so that new medical technologies are both affordable and accessible in rural communities.

Senate Committee on the Judiciary
Hearing: From Genes to Machines: The Patent Eligibility Debate
July 14, 2026
Questions for the Record for Sue Peschin from Senator Coons

QUESTION (1): You testified that judge-made exceptions to patent eligibility inhibit research and development in diagnostics, preventing life-saving inventions from ever reaching the market.

- **Would the Patent Eligibility Restoration Act (PERA) help foster innovation and lead to new scientific breakthroughs for patients, including diagnostic tools and therapies that could save lives? If so, why?**

RESPONSE (1): Yes. A new diagnostic or therapy reaches patients only after years of development, clinical validation, regulatory review, manufacturing, and commercialization -- all of which require substantial investment. Investors and commercial partners are far less likely to commit those resources when they cannot reliably predict whether a genuine, human-made invention will be eligible for patent protection.

Over the past decade, the judicial exceptions to Section 101 have created particular uncertainty for medical diagnostics. In a Winter 2022 *Washington and Lee Law Review* article, author A. Sasha Hoyt found that, in the four years after the *Mayo Collaborative Services v. Prometheus Laboratories, Inc.* decision, investment in diagnostics fell more than $9 billion short of what it otherwise would have been. That shortfall matters because private investment supports the critical work required to turn a promising laboratory finding into a clinically useful test.

PERA would replace the current unpredictable framework with clearer statutory rules while preserving the prohibition on patenting an unmodified human gene established by *Myriad*. The bill would neither guarantee patents nor relax the requirements that an invention be useful, new, non-obvious, and adequately described. It would allow genuine human-made inventions to be evaluated under those traditional standards rather than excluded at the threshold. 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. For patients, that could mean a better chance that emerging breakthroughs reach clinical care.

Questions from Senator Tillis
for Sue Peschin
Witness for the Senate Committee on the Judiciary Hearing
"From Genes to Machines: The Patent Eligibility Debate"

QUESTION (1): Do you agree that the courts, specifically the Supreme Court, have turned Section 101 from a historically coarse filter into a fine filter?

RESPONSE (1): Yes. The Supreme Court's judicial exceptions have transformed Section 101 from a coarse threshold screen into a fine-grained inquiry that can foreclose patent protection before the traditional patentability requirements are ever considered.

This has been particularly harmful to medical diagnostics. Under the current framework, a human-made method for detecting disease or translating a biomarker into an actionable clinical tool may be deemed ineligible because it involves a law or product of nature -- even when the invention applies that natural phenomenon in a new and useful way. As a result, the invention may never be evaluated for utility, novelty, non-obviousness, and adequate disclosure. That uncertainty discourages the investment needed to validate promising diagnostics and bring them to patients.

PERA would restore Section 101 to its intended role as a threshold filter. The bill would preserve clear exclusions, including for unmodified human genes, while allowing genuine human-made diagnostic inventions to be evaluated under the traditional requirements of patent law.

QUESTION (2): Do you agree that just because an invention is eligible under Section 101, it does not mean that the invention is automatically patentable?

RESPONSE (2): Yes. Eligibility under Section 101 is only a threshold inquiry. It determines whether the claimed invention is the type of subject matter that may be considered for patent protection -- not whether it satisfies the requirements for a patent to issue.

Under PERA, an eligible invention would still have to be useful, new, non-obvious, and adequately described. The U.S. Patent and Trademark Office could reject an application that fails any of those requirements. PERA would provide genuine human-made inventions a fair opportunity to be evaluated; it would neither make an invention automatically patentable nor guarantee that a patent will issue.

QUESTION (3): Do you agree that there is a need for patent eligibility reform?

RESPONSE (3): Yes. Patent eligibility reform is urgently needed. The current framework is unpredictable, inconsistently applied, and particularly harmful to medical diagnostics. Innovators and investors cannot reliably determine whether a genuine human-made invention will be eligible for protection, even before the U.S. Patent and Trademark Office considers whether it is new, non-obvious, useful, and adequately described.

That uncertainty has real consequences. In a Winter 2022 *Washington and Lee Law Review* article, author A. Sasha Hoyt found that, in the four years after the *Mayo Collaborative Services v. Prometheus Laboratories, Inc*. decision, 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% 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% 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."

PERA would replace the current judge-made framework with clear statutory rules. The bill would preserve the prohibition on patenting an unmodified human gene while restoring a predictable path to protection for genuine human-made inventions. That clarity would encourage investment, public disclosure, and the development of diagnostics and treatments that patients are waiting for.

QUESTION (4): What's really at stake for patients -- especially older Americans -- when a promising diagnostic never makes it out of the lab?

RESPONSE (4): When a promising diagnostic never makes it out of the laboratory, patients lose the opportunity for an earlier, more accurate, or less invasive diagnosis. For older Americans -- who frequently live with multiple chronic or life-threatening conditions -- that can mean missed opportunities to participate in clinical trials and fewer treatment options.

A scientific discovery alone cannot help a patient. Researchers must validate a test, demonstrate that it works in clinical settings, navigate regulatory and reimbursement pathways, establish manufacturing capacity, and make the test available to physicians. Those steps require substantial investment and commercial partners. Without predictable patent protection, promising diagnostics can lose that support before they ever reach clinical care.

PERA would give genuine human-made diagnostic inventions a fair opportunity to be evaluated for patent protection. For older Americans, who often face multiple serious conditions and have the least time to wait, that could mean a better chance that the next life-saving diagnostic reaches the patients who need it.

QUESTION (5): The Federal Circuit judges themselves say they can't apply this law consistently, and the Supreme Court won't revisit the law. Why is Congress the right body to fix this and what would it mean, for patients and for the country, if this Committee passed PERA?

RESPONSE (5): Congress is the right body to act because Section 101 is a federal statute, and Congress has the authority and responsibility to define the scope of patent eligibility. The current confusion stems from judicially created exceptions that lower courts have been unable to apply consistently. Federal Circuit judges have repeatedly explained that they are bound by Supreme Court precedent and cannot resolve the current uncertainty on their own. Meanwhile, the Supreme Court has repeatedly declined to revisit its patent eligibility decisions.

The onus is on Congress to establish clear, durable, and nationally consistent standards. PERA would fulfill that responsibility by replacing the current, unworkable judge-made framework with clear statutory language. The bill would preserve existing specific exclusions, such as the prohibition on patenting an unmodified human gene, while ensuring that genuine human-made inventions are evaluated under the traditional patent requirements.

For patients, particularly older Americans, passage would increase the likelihood that promising diagnostics and therapies attract the investment needed to advance from scientific discovery to clinical care. For the country, it would strengthen confidence in the U.S. patent system, encourage investment in U.S. startups and research institutions, promote public disclosure, and reinforce American leadership in biotechnology and precision medicine.

QUESTION (6): Some argue the current law is working -- that the diagnostics industry has grown and patients are getting more tests than ever. As someone focused on patients rather than markets, how do you respond?

RESPONSE (6): The available evidence demonstrates substantial losses in both investment and the development of promising diagnostics. As noted above, a Winter 2022 *Washington and Lee Law Review* article found that, in the four years following the *Mayo Collaborative Services v. Prometheus Laboratories, Inc.* decision, investment in diagnostics fell over $9 billion short of what it otherwise would have been.

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. After the *Mayo* decision, later-filed patent applications on this technology were rejected, already-issued patents appeared increasingly vulnerable, and the commercial partner withdrew; the test never reached patients.

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, potentially allowing patients to receive more effective treatment. When patents on these methods were denied under the *Mayo* and *Myriad* standards, efforts to bring those tests to patients were abandoned.

Similar challenges have repeated across disorders and diseases that frequently and disproportionately impact older adults.

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.

From a patient's perspective, the relevant measure of success is whether all promising human-made breakthroughs have a fair chance of being validated, commercialized, and made available to the people who need them. PERA would remove an arbitrary threshold barrier and help more potentially life-saving diagnostics secure the support required to reach patients.

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