Questions from Senator Tillis
for Sue Peschin
Witness for the Senate Committee on the Judiciary
Subcommittee on Intellectual Property Hearing
"The Patent Eligibility Restoration Act –
Restoring Clarity, Certainty, and Predictability to the U.S. Patent System"

1. The first set of hearings on patent eligibility were held in 2019, with 45 witnesses over multiple days. In 2024, another hearing was held consisting of 8 witnesses. Since then, there has been guidance from the USPTO and additional court cases.

   Is there a continuing need for Congress to step in with patent eligibility legislation? Please explain.

RESPONSE TO QUESTION 1: The need for congressional action remains urgent. More than a decade after the Supreme Court's seminal decision in *Mayo v. Prometheus*, the uncertainty surrounding patent eligibility continues to hinder innovation that could save or improve lives. In some cases, courts and the U.S. Patent and Trademark Office have attempted to restore clarity around patent eligibility, but they do not have the authority to reverse the Supreme Court's misguided rulings. Only Congress can resolve the uncertainty those decisions created and restore the patent incentives necessary to maximize lifesaving innovation.

From a patient perspective, the need for legislative patent eligibility reform has arguably never been greater. Not only have patients lost out on years' worth of potentially life-changing innovations, but every year that passes without patent eligibility reform weakens the stature of America's biotech sector in comparison to our global rivals. In my testimony, I highlighted the fact that during the COVID-19 pandemic, the most effective COVID-19 testing kits were initially developed overseas. Even more extensive reliance on foreign innovation -- in biotech and beyond -- is in store for our future if Congress does not act to restore clarity to patent eligibility.

2. Despite how broken the current situation is regarding patent eligibility, is it in the interest of some parties to maintain the broken status quo? Why is this?

RESPONSE TO QUESTION 2: While members of the public, patients, and most innovators are harmed by the uncertainty that currently pervades high-tech patenting, large, entrenched players may benefit from the status quo. Patent rights are relatively more important for smaller companies than large ones in high-tech sectors, as patents ensure that innovators can gain a market foothold regardless of their existing stature or financial resources. When patent rights are weakened, large incumbents that already dominate their markets can take advantage by copying and adopting innovations pioneered by their smaller competitors. In the long run, such a dynamic means fewer competitors developing new diagnostics or treatments and less incentive for companies to take risks on unproven ideas. This dynamic is directly opposed to the innovation that patients and ordinary Americans rely on.

3. The technologies that the U.S. most needs to develop to compete with China's growth, including advanced computing, AI, and biotechnology, are often those that fall outside current patent eligibility standards.

   How will PERA help the U.S. maintain global leadership in these competitive sectors? What does a failure to enact such legislation mean to our global competitiveness in general?

RESPONSE TO QUESTION 3: America's leadership in life sciences, AI, and advanced computing depends on a patent system that provides confidence and predictability. The erosion of our patent system is causing private capital and scientific talent to migrate away from America and toward competitors like Europe and China, which routinely approve applications that the USPTO is forced to reject on patent eligibility grounds. Already, China is taking the lead in numerous biotech research areas.

PERA is vital to reversing the decline of U.S. innovation and ensuring our global leadership lasts long into the future. By restoring basic certainty to patent eligibility, the bill promises to return America to the strong system of intellectual property rights we had from the 1980s through the 2000s, the era during which we built our scientific lead. It is an indispensable reform not only for patients relying on new and cutting-edge technological developments, but for America's long-term success in the global marketplace.

4. PERA 2025 has several changes this year compared to PERA from the prior Congress.

   Do you believe that these were good changes to the bill? Why or why not?

RESPONSE TO QUESTION 4: The changes made to the most recent version of PERA reflect a thoughtful, balanced approach that strengthens clarity while addressing legitimate public concerns with prior versions. Importantly, the new language makes clear that human genes as they exist in the body, and those that are merely isolated, cannot be patented. This change effectively codifies the narrow holding of the *Myriad* case on human genes while otherwise ensuring that isolated natural products, whose properties are different than how they exist in nature, are patentable. This preserves patent eligibility for new chemical compounds isolated from plants, for example, which may be useful as new medicines. The bill also clarifies that simply using a computer is not enough to make an idea patent-eligible, addressing concerns expressed about companies attempting to patent non-technical areas such as finance by appending a financial process onto an existing computer platform.

These refinements are important because they show that Congress has listened to a range of stakeholders and thoughtfully considered the impact that PERA would have. That level of care is always commendable.

5. We are all concerned about the cost of prescription medication. Some have argued that the enactment of this bill would lead to higher drug prices for consumers.

   What do you say to that?

RESPONSE TO QUESTION 5: Affordability is a serious concern for patients and, as I mentioned in my testimony, it is one that the Alliance for Aging Research and our community take to heart. But the relationship between patent law and pricing is often misunderstood. Patents do not dictate prices; they determine whether an innovation can exist in the first place. Without patent protection, companies are unlikely to invest the millions -- and up to over a billion -- dollars necessary to validate and bring new medical diagnostics and drugs to market. With greater access to patent protections, companies will gain the ability to develop and commercialize a broader swathe of potentially lifesaving products.

PERA may not resolve existing issues with prescription drug affordability, but it is a necessary prerequisite for ensuring all patients have access to the medicines and diagnostics they need. PERA's purpose is to help keep valuable medical innovations from dying on the vine -- after which we can and should enact further reforms to promote greater affordability.

6. Some argue that medical diagnostics will continue to be invented and developed notwithstanding the change in subject matter eligibility from the Supreme Court, because of other factors promoting or protecting innovation – such as the incentives to "publish or perish" in academia, or the ability to protect innovation through other means like trade secrets.

   Do you agree? Why or why not?

RESPONSE TO QUESTION 6: Past experience shows that this optimism is misplaced. Other forms of intellectual property protection and other policies promoting academic innovation are undoubtedly important, but they cannot replace the role of patents in promoting publicly disclosed innovation and attracting private-sector investment capital. As I highlighted in my testimony, we have already seen clearly what happens when patent protection is unavailable: Investment falls and innovation stalls. After the *Mayo* decision, investment in diagnostics fell more than $9 billion short of what it otherwise would have been. Policy changes that do not address harmful Supreme Court precedent -- the root cause of patent eligibility uncertainty -- are simply not sufficient to stave off investment declines like this one.

Senator Eric Schmitt
Senate Judiciary Subcommittee on Intellectual Property
Written Questions for Sue Peschin
Hearing on "The Patent Eligibility Restoration Act – Restoring Clarity, Certainty, and Predictability to the U.S. Patent System"
Wednesday, October 8th, 2025

1. On balance, would PERA make it easier or harder for patent trolls to extort U.S. businesses and companies?

RESPONSE TO QUESTION 1: PERA should have little to no effect on the behavior of so-called patent trolls, because it doesn't change the requirement that any invention be new, non-obvious, and useful in order to receive a patent. It merely expands the universe of inventions that are *eligible* to receive a patent so long as those other criteria are met.

Research has shown that the USPTO already does an excellent job of ensuring that only genuine inventions receive patents, and that the office grants patents to inventions with invalid claims at considerably lower rates than the patent offices in other developed nations.

Of course, no patent office is perfect. But the mere possibility that the USPTO makes a mistake, and grants a patent to an invention that isn't truly new, non-obvious, and useful isn't a good reason to preemptively deny whole categories of products, such as medical diagnostics, from patent *eligibility*. There is no alternative reform that would do as much as PERA to catalyze lifesaving diagnostic innovation.

2. How would expanding patent eligibility for AI processes under PERA impact the ability of businesses to implement those technologies?

RESPONSE TO QUESTION 2: AI-driven tools have extraordinary potential to transform medicine and public health, from drug discovery to predictive diagnostics. Yet under current law, innovations in AI technology are often legally considered to be "abstract ideas," rendering them ineligible for patent protection. By ensuring that more truly novel, useful, and non-obvious AI-based innovations are eligible for patenting, PERA would provide greater certainty to companies considering investing in AI technology. Ultimately, this would mean more innovation in the AI sector, translating into faster deployment of AI tools in business and clinical settings. In short, if PERA becomes law, companies will gain the ability to deploy new AI technologies that simply would not exist otherwise.

3. What are examples of the types of medical innovations that are ineligible under current law but would be eligible under PERA?

RESPONSE TO QUESTION 3: Under current law, some of the most impactful diagnostic methods are excluded from protection. I highlighted several of these in my testimony. Noninvasive prenatal testing for genetic abnormalities, for example, was invalidated in *Ariosa v. Sequenom* despite being recognized as a medical breakthrough. The Cleveland Clinic developed, patented, and began commercializing a revolutionary test for cardiovascular disease that it was

later forced to abandon when courts deemed that the test was ineligible for patent protection. Under PERA, tests such as these could obtain patent protection, allowing them to progress further in research and development, ultimately preserving the possibility that they could successfully be validated and then be widely marketed to patients.

Further, PERA would resolve the cloud of uncertainty that plagues diagnostic tests currently in development. As I stated in my testimony, researchers at top universities have stopped work to commercialize diagnostics for Alzheimer's, major depressive disorder, and various cancers because the mere possibility of those patents being invalidated makes successful commercialization prohibitively risky. Under PERA, researchers and entrepreneurs would have greater confidence to bring promising diagnostic candidates like these to market as well.

4. Why should Congress—or why should Congress not—expand eligibility to such medical innovations?

RESPONSE TO QUESTION 4: The reason to expand eligibility to these inventions is simple: They can save and improve lives. Yet under current law, the absence of reliable patent protection discourages both academic researchers and private investors from advancing promising discoveries. By ensuring that inventions like these are eligible to be patented, PERA would restore incentives for companies to develop diagnostic tests, shepherd them through further development, validation, and clinical trials, and, if successful, ultimately market them to patients. As a result, patients could receive earlier diagnoses and benefit from reduced costs, more targeted treatments, and better outcomes. This human benefit is the most important reason I urge Congress not to delay in passing PERA. The health and lives of Americans are at stake.

5. Critics of PERA have advocated a more narrowly tailored approach to expanding eligibility for specific innovation areas like medical diagnostics, arguing PERA is too broad. Are those concerns founded or unfounded? Please explain why.

RESPONSE TO QUESTION 5: Concerns that PERA is overly broad misunderstand the bill's purpose. PERA does not expand patent rights beyond their historical scope; it simply restores the clear and balanced patent eligibility framework that existed for decades before judicial decisions disrupted it in the early 2010s. During that earlier period, the United States rose to become the global leader in biotechnology, medical innovation, and other high-tech sectors -- without the problems critics now predict. There should be no cause for concern that restoring the historical system of patent eligibility will cause problems now.