Statement of
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Before the
Subcommittee on Intellectual Property
of the
Committee on the Judiciary
United States Senate

Hearing on
The Patent Eligibility Restoration Act – Restoring Clarity, Certainty, and Predictability to the U.S. Patent System

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Dear Chair Tillis, Ranking Member Schiff, and other members of the Subcommittee:

Thank you for the opportunity to appear before the Subcommittee at the hearing on The Patent Eligibility Restoration Act – Restoring Clarity, Certainty, and Predictability to the U.S. Patent System. I greatly appreciate the opportunity to submit additional written testimony expressing the company's concern that the Patent Eligibility Restoration Act ("PERA"), as introduced, will unintentionally stifle innovation and harm patient care in the fields of diagnostic genetic testing and precision medicine.

I am a partner with the law firm Pillsbury Winthrop Shaw Pittman LLP and have been a practicing attorney since the mid-1990s. I am registered to practice before the U.S. Patent and Trademark Office and I routinely advise companies regarding the development and protection of new technologies related to therapeutics, genetic testing, molecular diagnostics, medical devices and digital health. My testimony is my own and does not necessarily represent the views of Pillsbury or any of its clients.

PERA as proposed would cause substantial harm to the research and clinical community as it relates to genetic testing

Some have suggested that the publication of the human genome has rendered moot the need for concern about patents related to human genes. The argument rests on the idea that the risk of patenting human genes has passed with the publication of the human genome because the sequences of human genes are no longer new. This represents a fundamental misunderstanding of the risks to science and patient care posed by permitting natural laws and natural materials to be patented.

Under current law, natural laws are not patent eligible subject matter. Nor are applications of conventional technology to natural laws. No person has the "standard" human genome. All of us have variants in our genetic sequences. Some of these variants are clinically significant. A well-known but small example is a collection of variants in the sequences of the *BRCA1* and *BRCA2* genes that, when present, indicate a substantially elevated lifetime risk of suffering from breast cancer as well as ovarian, pancreatic, prostate, and other types of cancer. Variants such as these are natural biomarkers and this information including its association with disease risk is an unpatentable natural law. Similarly, application of conventional technology (such as DNA sequencing) to detect the presence or absence of such biomarkers is an unpatentable conventional application of natural laws.

The purpose of clinical genetic testing is not the detection or sequencing of whole genes as such, but rather the detection of biomarkers that are specific variations in a patient's genes that are indicative of the patient's disease risk or status, as well as suitability for certain treatments. These biomarkers can be simple, involving the change of just one "letter" (otherwise known as single nucleotide polymorphisms or SNPs), or larger insertions, deletions, transpositions or copy number errors in the relevant genetic sequence. While some important biomarkers have been discovered the human genome is vast and many more biomarkers remain to be discerned. For

instance, researchers have newly discovered more than 275 million previously unreported genetic variants because of the National Institutes of Health's All of Us Research Program, and there is ongoing to work to understand the role of these variants in health and disease.[1] Our increasing sophistication in understanding these biomarkers and their clinical relevance is essential to the practice of precision or personalized medicine tailored to the unique needs of the individual patient.

The absence of patents on natural laws has not impaired innovation in the genetic diagnostics industry. Quite the opposite is true. In the last decade, the genetic testing industry has thrived. There is a large market with many actors all contributing to the advancement and development of high-quality clinical testing. The cost of genetic sequencing and therefore the barrier to innovation in detecting new clinically relevant biomarkers has fallen dramatically. With the vast increase in the volume of patient data new biomarkers are being recognized on a routine basis and readily being used to inform patient care.

PERA would slam the door shut on such innovation and also its clinical application in medicine. PERA would permit the privatization of natural laws in the form of knowledge of new biomarkers and their clinical relevance. Because the discernment of new (to us) biomarkers is highly distributed, patent filing on each new biomarker would proliferate with numerous and internationally dispersed patent applicants. The evolving standard of care for genetic testing relative to many medical purposes involves large panels of tests that are intended to detect the presence or absence of a very large number of possible variants. Any of scores of new patentees could stand in the way of a clinician's effort to conduct a comprehensive and complete analysis of a patient's genetic information because testing for a broad panel of possible variants would require permission from all of a large group of patentees, none of whom would be required to grant such permission. PERA would return the US to a time when patients had to fight for affordable access to the most scientifically up-to-date testing.

Contrary to the title of today's hearing, PERA will restore neither clarity, certainty nor predictability to the patent system.

Given PERA's purpose in reversing Supreme Court precedent with respect to the scope of subject matter deemed eligible for patent protection, it is instructive to review the motivating purposes behind the Court's recent decisions on patent subject matter eligibility.

It's now been 13 years since the Supreme Court's decision in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*[2] in which Justice Breyer, writing for a unanimous Court, articulated the core principle that natural laws should not be patented. Natural correlations between an observable state in the human body (such as the concentration of a material detectable in the blood) and a medical condition (such as the presence or absence of a disease or the need to adjust a medication). The *Mayo* Court recognized that permitting the patenting of discoveries of such natural correlations would pre-empt those correlations thereby depriving

[1] The All of Us Research Program Genomics Investigators. Genomic data in the All of Us Research Program. *Nature* **627**, 340–346 (2024). https://doi.org/10.1038/s41586-023-06957-x.
[2] 566 US 66 (2012).

patients and medical practitioners of the ability to access objective medical facts about a patient's medical status and medical needs.

Biomarkers are a prime example of the natural correlations that *Mayo* held to be patent ineligible. Modern genetic testing is performed to look for the presence or absence of multitudes of biomarkers in the form of mutations in a patient's germ-line genetic sequences. A variation in the typical sequence of a gene can correlate with a heightened lifetime risk of cancer or other disease or it may identify a patient that is a particularly good or poor candidate for a particular drug therapy. In some instances, the ability to use genetic screening to identify a sub-population of patients that benefit from a new drug are essential to the drug's approval and to limiting adverse effects in patients who benefit less from the drug. Other uses involve the detection of biomarkers that distinctively identify the presence of tumor cells in a patient allowing for more efficient and less invasive monitoring of the progress of cancer therapies. Access to this evolving basic biological knowledge is critical for patient care. Preempting such biomarkers through patenting effectively gives a single party a monopoly on a basic medical fact about a person and impedes access to medical self-knowledge and appropriate medical care.

It is important to recognize that biomarkers are discovered and not invented. The reason they are called natural laws is that the correlation exists naturally and is not the product of human ingenuity. By contrast, in the diagnostics industry there is tremendous innovative activity focused on inventing new tools with which biomarkers may be detected. For example, the U.S. has been a leader in developing and improving genetic sequencing instruments that have made genetic sequencing technology extraordinarily accessible. Other companies are developing robust point-of care technologies for detecting many biomarkers while the patient is in the clinic without needing to wait days for results. Unlike the discovery of biomarkers, these new platforms and their many incremental improvements are inventions and are unambiguously patent eligible under current law.

For the U.S. to be a leader in the development of precision medicine, it is necessary to be able to conduct genetic testing for patients where the presence or absence of thousands of biomarkers in a patient's genome can be detected. Given the size and complexity of the human genome, we are nowhere close to having identified all of the biomarkers important to the conduct of medicine. Nor will we be any time soon. For this reason, the patent eligibility of newly observed biomarkers remains an important consideration because a change in the law would suddenly create the opportunity for the ongoing privatization of knowledge about new medically relevant biomarkers. Moreover, in a post-PERA world, U.S. patents on new biomarkers would be obtained by a vast number of parties around the world (with many such patents being held by companies or institutions outside the U.S.) As a consequence, medical practitioners and their patients would face a daunting and ever-growing patent thicket barring their conduct and interpretation of the kinds of patient genetic tests that will be standard of care for the practice of precision medicine. Whereas in the past, patents on biomarkers had the effect of severely limiting access to important individual genetic tests (*e.g.*, the $4k cost for a BRCA1/BRCA2 test), PERA would create a situation where the "owners" of important biomarkers would be too numerous and mutually competitive to enable comprehensive testing of large panels of important biomarkers at all. In fact, patents were actively used prior to 2013 to halt scientific advancements and limit access to care.

The *Mayo* Court recognized that creative patent drafting should not be allowed to overcome the patent ineligibility of natural laws by simply combining a natural law with conventional process techniques such as using routine laboratory tests to detect a biomarker. The effect of *Mayo* for these past 13 years has been to maintain as pre-competitive knowledge all biomarkers and similar natural correlations so that no one party can preempt all others from accessing or exploiting such knowledge. Nonetheless, the diagnostic industry remains vibrant as better and more efficient tools for detecting various biomarkers continue to be developed and brought to market. U.S. dominance in the field of wearable continuous glucose monitors illustrates just how vibrant innovation can be in the diagnostic industry in circumstances where the ability to patent the biomarker of interest is unavailable but the availability of patents on the technology remains. Industry leaders Abbott and Dexcom have competed through the introduction of multiple generations of wearable monitors and obtained hundreds of patents each without the ability to patent the biomarker that is blood glucose concentration. Others are actively developing newer and even more advanced approaches for continuous glucose monitoring.

If PERA were adopted in its current form, newly discovered biomarkers and their clinical relevance would suddenly become patentable eligible and allow their discoverers to preempt all others from detecting such biomarkers in the practice of medicine.

The current law has not prevented the rapid accumulation of knowledge of new genetic biomarkers or their implementation in precision medicine, because the rapidly falling cost of genetic sequencing has resulted in a torrent of new data from which new biomarkers can be discerned. There has been no need to award twenty year monopolies on each such observation to encourage their discovery, development, or commercialization.

The Court's 2013 unanimous decision in *Association for Molecular Pathology v. Myriad Genetics*, Inc. held that naturally occurring genetic sequences, even when isolated from the body, are patent ineligible. While the patent in issue in *Alice v. CLS Bank International* was unrelated to the life sciences, the Court in its *Alice* decision confirmed the framework for assessing patent subject matter eligibility in all patents. The unanimous decision held that patent claims that are directed to patent ineligible subject matter such as natural laws (*e.g.*, biomarkers) or naturally occurring phenomena (*e.g.*, genetic sequences), or algorithms and mental processes cannot be rendered patent eligible by dressing up patent claims with conventional implementation.

Where a patent application incorporates a newly discovered natural law or natural material in an inventive, new process, its subject matter is patent eligible. Preemption concerns arise in the genetic testing context only when a newly discovered genetic mutation is claimed with reference to using known methods of genetic sequencing or detection to determine whether the mutation is present.

The Supreme Court in *Mayo*, *Myriad*, and *Alice* seriously grappled with the effort to balance concerns about preempting natural laws and natural phenomena. Notably, PERA in its preamble and in the advocacy for it, there is no effort to acknowledge the serious policy concerns raised by those cases. Congress is, of course, the right venue for evaluating how to balance the desire of a discoverer of new biomarkers to benefit from a patent monopoly and the public's interest in not

seeing basic knowledge in the form of natural correlations between biomarkers and personal health status preempted by such patents. I encourage the Subcommittee to give serious consideration to these concerns and how to manage them rather than simply sweeping away the accumulated jurisprudence on patent subject matter eligibility.

It is disappointing to see the justification for PERA rest on procedural complaints that it is not always facile to assess whether or not the subject matter for a patent application is eligible for patenting. Many aspects of a proper functioning patent system rest on careful consideration of questions that are deeply dependent upon the specific facts and circumstances. Standard inquiries into questions of novelty, nonobviousness, enablement, adequacy of the written description, claim construction, and infringement by equivalent are often difficult to resolve and may not lend themselves to confident prediction of the ultimate decision rendered by an agency or court. In this context, it makes no sense to argue that difficulty in predicting the outcome of a small minority of cases that pose close questions of subject matter eligibility merits disregarding the serious policy considerations and principles that have informed over a century of Supreme Court patent jurisprudence on the scope of subject matter eligibility. Given these difficult questions that underlie the routine evaluation of a patent, neither certainty nor ready predictability are reasonable expectations for many aspects of our patent system. In any event, the desire for certainty or predictability should not be allowed to override the proper balancing of the interests of the public and inventors.

Flaws in the structure of PERA

PERA, as currently drafted, suffers from significant defects that undermine the goal of clarity, certainty, and predictability. These defects can reasonably be expected to lead to litigation and quite likely greater uncertainty than that which is decried by public supporters regarding the current state of the law of patent subject matter eligibility.

PERA would define the scope of patent subject matter eligibility quite expansively to cover any "useful process, machine, manufacture, or composition of matter, or any useful improvement thereof," subject to just five listed exceptions, two of which are particularly relevant to the life sciences. Specifically, PERA, as currently drafted would appear to exclude from eligible subject matter patents claiming either

> (D) An unmodified human gene, as that gene exists in the human body. [or]
> (E) An unmodified natural material, as that material exists in nature.

As limited as these exclusions are, they are misleading because they are subject to "conditions" which render these exclusions nullities. The condition in Subsection 101(b)(2)(C) states that

> [for the purposes of] paragraph (1)(E), a natural material shall not be considered to be unmodified if that natural material is—
>
> (i) Isolated, purified, enriched, or otherwise altered by human activity; or
> (ii) Otherwise employed in a useful invention or discovery.

Thus, under PERA, any natural material, even if it is unmodified and in the form that it exists in nature would still be patent eligible subject matter if it were simply isolated from its natural source, purified from its natural state, enriched in concentration compared to its natural state, or just altered in some way by human activity. Even if none of those conditions were satisfied, an unmodified natural material, exactly as it exists in nature, that is neither isolated, purified nor enriched would still be eligible subject matter so long as it is employed in a useful invention or discovery. Since "useful" is defined in PERA to mean anything that has a specific and practical utility, this alone is a very broad exception to the point that there is no plausible category of patent claims a patent applicant would reasonably seek that is directed to an unmodified natural material that would not be eligible for patenting. Condition (2)(C) essentially inverts the objectives of the current patent subject matter eligibility jurisprudence. Under PERA, even subject matter that is manifestly not eligible under its listed exceptions can be made patent eligible merely be combining it with any non-inventive conventional technology to which some specific and practical utility can be ascribed. In short, given Condition (2)(C), the Exclusion (1)(E) serves no purpose other than to mislead one to believe that at least unmodified natural materials are outside the scope of patentable subject matter when that would not be the case if PERA were law.

Exclusion (1)(D) referring to unmodified human genes seems to serve no purpose and this undermines the clarity of PERA. First, unmodified human genes are examples of unmodified natural materials and therefore this specific exclusion would appear to be unnecessary. Moreover, the term "gene" is not defined in the statute and it is unclear how or whether the exclusion would apply to fragments of a gene, variants or mutations in a gene, or genetic sequences in the human genome that are drawn from the vast regions of DNA that are not currently recognized as genes. As with natural materials, even human genes as they exist in the human body would be patent eligible subject matter so long as they are purified, enriched, or used in any invention or discovery that has a specific and practical utility. Importantly, this exclusion also does not apply to pathogenic organisms and the role of viral, bacterial, and fungal nucleic acid sequences in human disease.

Exclusion (1)(B) purports to exclude processes that are substantially "economic, financial, business, social, cultural, or artistic, even though at least 1 step in the process refers to a machine or manufacture. This exclusion, if enacted, could be counted on to spawn a substantial amount of litigation as it is rife with undefined and unclear terms. For example, there are many enterprises whose business is manufacturing or the conduct of services (such as the conduct of clinical laboratory tests) that may involve the use of machines. By canons of statutory instruction, "business" could be expected to be interpreted as something other than economic or financial and therefore may embrace in this exclusion many processes that the sponsors of PERA do not intend to exclude from patentability. Additionally, the Condition (2)(A) which provides as an exception to Exclusion (1)(B) any process that "cannot practically be performed without the use of a machine or manufacture," will engender litigation over how to determine what "practically" means.

Subsection (c) concerning general guidance for eligibility determinations does not cohere with the balance of PERA. For example, subsection (c)(1)(B)(ii) instructs that eligibility

determinations shall be made without regard to "whether a claim element is … naturally occurring," yet Exclusion (1)(E) turns, in part, on whether a natural material is as it exists in nature (*i.e.*, naturally occurring). Thus the instruction is to disregard the criteria upon which two of the five exclusions rely.

As an additional example, the combined effect of Exclusion (1)(B) and Condition (2)(A) is that PERA would render economic, financial, business, social cultural and artistic processes patent eligible so long as they cannot be practically performed without the use of a machine or manufacture. However, subsection (c)(1)(B)(iii) instructs that no consideration should be given to the state of the applicable art even though it is hard to understand how a determination that a process cannot be performed practically without a machine or manufacture without taking into account information about the state of the applicable art.

PERA is unnecessary as the law on patent subject matter eligibility does not require the wholesale changes it proposes.

As discussed above, recent Supreme Court decisions concerning patent subject matter eligibility, including the *Association for Molecular Pathology v. Myriad Genetics, Inc.*, *Alice v. CLS Bank International*, and *Mayo Collaborative Services v. Prometheus Laboratories, Inc.* have sought to protect the public's interest in stopping the preemption of basic medical knowledge in the form of natural laws. I believe that any efforts to reform or revise Section 101 of the U.S. Patent Act should maintain these protections and continue to prohibit patents on biomarkers, even in their isolated form, and their association with a disease or health condition.

The Patent Act of 1952 largely codified and clarified longstanding caselaw related to the U.S. patent system. Congress would do well to follow the example of the Patent Act of 1952 and seek to codify and clarify existing caselaw on patent subject matter eligibility rather than the approach embodied in PERA which is the wholesale abandonment of decades of Supreme Court jurisprudence coupled with ambiguous standards that will destabilize the field of patent subject matter eligibility for many years while the courts work out new tools applying the new standards.

In the years since the Supreme Court decisions giving rise to the current patent eligibility jurisprudence, investment and innovation in diagnostics and precision medicine has increased dramatically. The benefit of these advancements lies not just in maintaining American leadership in the field, but also in the improved standard of care allowing many more patients to obtain an earlier diagnosis, prevent disease altogether, or receive a tailored more effective treatment. The current patent eligibility jurisprudence has greatly benefited and accelerated both clinical availability and continuing innovation in precision medicine which is rooted in an evolving understanding of the human genome and other biomarkers. I urge the Subcommittee to proceed cautiously with any legislative efforts to modify patent eligibility that would allow patents on laws and products of nature.

For all of the reasons discussed above, I believe that PERA is both unnecessary and harmful to the genetic testing industry, patient access to self-knowledge regarding the significance of their genetic characteristics, and the evolution and delivery of precision medicine. I urge the Subcommittee to consider instead the codification of existing Supreme Court jurisprudence on

patent subject matter eligibility. I offer any assistance the Subcommittee may request in order to approach patent law reform while preserving the vitality of the genetic testing industry and the promise of precision medicine and 21st century healthcare.

Conclusion

Thank you again for the opportunity to serve as a witness in the Subcommittee's hearing and to provide this additional written testimony for your consideration. I oppose PERA as proposed because it will harm patients and the healthcare industry while delivering neither clarity, certainty, nor predictability to the patent system.