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EXPERT OPINION

The Patent Eligibility Restoration Act (PERA) could provide a much-needed boost to key technology sectors of the U.S. economy

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OVERVIEW

The Patent Eligibility Restoration Act (PERA), introduced as bill S1546 in the U.S. Sente, represents a major legislative effort to rectify the harm caused by a series of Supreme Court decisions which dramatically narrowed the scope of what inventions were patentable in the United States. (see *Bill S1546*, May 1, 2025, https://www.congress.gov/bill/119th-congress/senate-bill/1546). The unintended result of these cases was that important innovations in many critical fields, such as medical diagnostics and artificial intelligence (AI), were deemed unpatentable in the U.S., but were patentable in competitive countries, such as Europe and China. If PERA is enacted, it would go a long way in helping to restore America's competitive edge in key technologies over its economic adversaries, which has been in decline for over a decade.

BACKGROUND AND NEED TO REFORM

Starting with the landmark decisions of *Mayo Collaborative Services v. Prometheus Labs, Inc.*, 566 U.S. 66 (2012) ("Mayo") and *Alice Corp. v. CLS Bank International*, 573 U.S. 208 (2014) ("Alice"), the Supreme Court greatly expanded the boundaries of three previously limited judicial exceptions, i.e., "abstract ideas", "natural phenomenon" and "laws of nature", as non-patentable subject matter. In the Alice decision, the Court warned against too great an expansion of these judicial exceptions when it stated that:

"we tread carefully in construing this exclusionary principle lest it swallow all of patent law. At some level, all inventions...embody, use reflect rest upon or apply laws of nature, natural phenomena or abstract ideas."

Unfortunately, the Court did not tread carefully enough. The application of what became known as the Mayo/Alice test proved to be subjective and hard to apply consistently. The uncertainty that resulted caused almost immediate financial harm to important fields of technology. For example, by some estimates, in just the first four years following the Alice/Mayo decisions, medical diagnostic investments fell by about $9 billion dollars. (*Patent Eligibility Restoration Act Would Fuel US Competitiveness*, P. Michel et al., July 9, 2025, https://news.bloomberglaw.com/us-law-week/patent-eligibility-restoration-act-would-fuel-us-competitiveness).

Moreover, since the Alice/Mayo decisions, many AI inventions were rejected by the courts and the United States Patent and Trademark Office (USPTO) as being directed toward an unpatentable abstract idea. This is in large part because the Supreme Court left

the concept of an abstract idea up to lower courts to define on a case-by-case basis. Moreover, an abstract idea may be loosely defined as any concept that can be theoretically performed in the human mind, which closely parallels the definition of AI as:

"The capability of a machine to imitate intelligent human behavior (such as reasoning, learning, or the understanding of speech)." (*Merriam Webster-Unabridged*, https://unabridged.merriam-webster.com)

Judges, industry leaders, investors, USPTO personnel and many others have all cited a growing need to reform the U.S. patent eligibility standards. Standards that have invalidated numerous advances in the fields of medical diagnostics, AI and other cutting-edge technologies, which almost certainly would have been deemed patentable prior to the Alice/Mayo decisions. (*Why C4IP Supports the Patent Eligibility Restoration Act*, April 2, 2024, https://c4ip.org/why-c4ip-supports-the-patent-eligibility-restoration-act-pera).

WHAT PERA WOULD DO IF ENACTED

If enacted, PERA would eliminate the judicially created exceptions to patent eligibility of abstract ideas, natural phenomenon and laws of nature, effectively overruling the Alice/Mayo decisions. PERA would accomplish this by amending 35 United States Code section 101, titled: "Inventions Patentable" (herein "USC 101"). More specifically, PERA would explicitly amend USC 101 to state that anyone who invents or discovers:

"any useful process, machine, manufacture or composition of matter, or any useful improvement thereof, may obtain a patent therefor, subject **only** to the exclusions in subsection (b) and to the further conditions and requirements of this title."

The above "further conditions and requirements" refer to the well-established and long-standing considerations of whether an invention is new, non-obvious and properly described. However, the exclusions referred to in subsection (b) are exclusively limited to the following five:

- A mathematical formula that is not part of a claimed invention.
- A process that is substantially economic, financial, business, social, cultural, or artistic, even though at least one step in the process refers to a machine or manufacture.
- A process that:
  (i) is a mental process performed solely in the human mind, or
  (ii) a process that occurs in nature wholly independent of, and prior to, any human activity.
- An unmodified human gene, as that gene exists in the human body.
- An unmodified natural material, as that material exists in nature.

PERA would also add a "CONDITIONS" paragraph to subsection (b) of USC 101, which establishes rules of construction on how the exclusions are to be interpreted. For example, with regard to exclusion A. (i.e., mathematical formula) and exclusion B. (i.e., a process that is substantially economic, financial, business, social, cultural or artistic), PERA would amend USC 101 to explicitly apply the rule of construction that:

"the claimed invention shall not be excluded from eligibility for a patent if the invention cannot practically be performed without the use of a machine or manufacture."

The purpose of this rule of construction is to emphasize the allowance of inventions that could only be practically performed with the use of a machine, while excluding certain areas that common sense dictates were never intended to be patentable subject matter. Such as, for example, a method of performing dance moves.

PERA emphasizes this rule in its "Finding" section, wherein it states:

"**any process** that cannot be practically performed without the use of a machine **(including a**

computer) or manufacture shall be eligible for patent coverage."

The above caveat, of any process being patent eligible if it cannot be practically performed without the use of a computer, should clearly apply to exclusion C (i.e., **a process** that: (i) is solely a mental process performed in the human mind, or (ii) occurs wholly in nature). This clarifying condition is critical for the patent eligibility of many AI innovations, which, as mentioned earlier, can be defined as the capability of a machine to imitate intelligent human behavior. However, this author notes, with a bit of concern, that the present draft of PERA does not amend USC 101 to explicitly state as a "rule of construction" that the above condition applies to exclusion C, as it does to exclusions A and B.

Exclusion D (i.e., an unmodified human gene, as that gene exists in the human body) applies to medical diagnostic innovations, which have been almost categorically excluded from patent eligibility by the Supreme Court's expansion of the judicial exceptions of "laws of nature" and "natural phenomenon." PERA, in its Findings section, makes it clear that exclusion D applies to:

"an unmodified human gene that is **isolated** from the human body, but otherwise the same as that gene exists in the human body."

The above caveat, that simply isolating an unmodified human gene is not enough to obtain patent eligibility, is in recognition that the technology to sequence a human genome already exists and is no longer considered novel.

However, PERA would include in the amended USC 101 a rule of construction specific to Exclusion D which states:

- "a human gene **shall not be considered to be unmodified** if that human gene is—
- "(i) purified, enriched, or otherwise altered by human activity; or
- "(ii) otherwise employed in a useful invention or discovery."

So, for example, an innovation that utilizes an unmodified human gene for the earlier detection of different types of cancer, would be patent eligible under amended USC 101.

The rules of construction established by PERA for exclusion E (i.e., an unmodified natural material, as that material exists in nature) are very similar to the rules of construction for exclusion D. However, unlike the rules of construction for human genes, innovations which *isolate* a natural material would be considered patent eligible and may be patented, if the innovations meet the other statutory requirements of novelty, non-obviousness and adequate description.

CONCLUSION

PERA represents a substantial legislative effort to correct what many perceive as detrimental shifts in U.S. patent eligibility law caused by Supreme Court rulings, which started with the Alice/Mayo decisions more than a decade ago. (*Patent Eligibility Reform Returns to the Hill: PERA 2025 Explained*, G. Quinn, May 1, 2025, https://ipwatchdog.com/2025/05/01/patent-eligibility-reform-returns-hill-pera-2025-explained/id=188610/). PERA would replace judicially created exceptions, which have no support in the Constitution or federal statutes, with a clearer and more balanced standard for patent eligibility. PERA aims to provide a more certain legal framework that protects inventions essential to economic growth, technological leadership, and innovation. If enacted, PERA would fundamentally reshape how courts and the USPTO evaluate patent eligibility, potentially leading to a more innovation-friendly environment in the United States.

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