Patent '101 Eligibility Reform Returns to the Hill: PERA 2025 Explained



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Earlier today, the <u>Patent Eligibility Restoration Act of 2025</u> was introduced in both the Senate and House of Representatives, with Senator Thom Tillis (R-NC), Senator Chris Coons (D-DE), Representative Kevin Kiley (R-CA) and Representative Scott Peters (D-CA) sponsoring largely the same bill as the version presented during the 118th Congress, but with several differences.

Why is Patent Eligibility Reform Necessary

Due to a series of judicial decisions beginning in 2012—both from the U.S. Supreme Court and the Court of Appeals for the Federal Circuit—patent eligibility law in the United States has become confused, inconsistent, and unclear. The lack of a clear, consistent, repeatable test for what inventions possess the basic threshold characteristics necessary to obtain a patent there has been well-documented and wide-ranging negative impacts within the innovation and investment communities, which has led to unpredictable business outcomes and a stagnation of innovation in certain high-tech industries.

Virtually all the judges of the United States Court of Appeals for the Federal Circuit have lamented the sad state of the patent eligibility law, and so too have well regarded and highly respected retired judges of the Federal Circuit. Witnesses and stakeholders from a wide array of industries, fields, interest groups, and academia have testified and submitted comments confirming the uncertainty and detailing the detrimental effects of patent eligibility confusion in the United States. And virtually everyone in the industry recognizes that Supreme Court and Federal Circuit precedent has gone too far, resulting in a patent eligibility test that is subjective at best. Indeed, much like criticized tests that existed relating to software eligibility from the 1970s and 1980s, the current test provides no guardrails or safe harbor. Everyone agrees on the words of the test that apply, but diametrically opposite views of what those words mean and allow can and are held by even the most experienced patent practitioners, innovators and judges too.

There is growing bipartisan agreement that reforms are necessary to restore the United States to a position of global strength and leadership in key areas of technology and innovation, such as medical diagnostics, biotechnology, personalized medicine, artificial intelligence (AI), 5G, and blockchain, all of which have fallen as the result of innovations being denied patent protection based on lack of eligibility, and without ever considering whether the underlying innovation is new, unique, and adequately described.

What Would PERA 2025 Do?

PERA 2025 would restore patent eligibility to important inventions critical to the growth of the U.S. economy, and critical to delivering on the Trump Administration's stated goal for the United States to become the dominate AI superpower. If passed, the bill would accomplish this while also prevent the patenting of mere ideas, what

already exists in nature, and social and cultural content that virtually everyone agrees is beyond the scope of the patent system.

Specifically, PERA 2025 would reset the law of patent eligibility in the United States to where it was before the United States Supreme Court substantially and significantly changed the law with landmark decisions in Mayo Collaborative Services v. Prometheus Labs., Inc., 566 U.S. 66 (2012) and *Alice Corp. v. CLS Bank Int'l*, 573 U.S. 208 (2014). Earlier versions of PERA would have also directly overruled the Supreme Court decision in Assoc. for Molecular Pathology v. Myriad *Genetics*, 569 U.S. 576 (2013), which held that isolated DNA is not patent eligible. However, PERA 2025 is slightly different than the bill introduced in 2023, at least relating to human genes. PERA 2025 still says that unmodified human genes as they exist in the human body are not patent eligible, but prior versions of the bill said that isolation of genes was considered a modification. PERA 2025, however, leaves out the world "isolated" and says that "a human gene shall not be considered to be unmodified if that human gene is purified, enriched, or otherwise altered by human activity; or otherwise employed in a useful invention or discovery."

Notwithstanding subtle changes that will likely be interpreted as not directly overruling the core holding in *Myriad*, PERA 2025 does continue to explicitly eliminate the so-called judicial exceptions to patent eligibility created by the Supreme Court, which find no support in either the Patent Act or the Constitution. By eliminating and replacing the current judicial exceptions to patent eligibility Congress would reassert its proper Constitutional role to define the law, and in this case what qualifies for patent protection, and put the courts back into their proper lane, which is to interpret the laws passed by Congress; not to make the law up by layering on judicially created requirements not found in the statute.

PERA 2025 accomplishes the dismantling of current judicial exceptions by explicitly stating that eligibility for any useful process, machine, manufacture or composition of matter is "subject only to the exclusions in sub-section (b) and to the further conditions and requirements of this title." The four exclusions contained in sub-section (b) are limited to:

- 1. A mathematical formula that is not part of a claimed invention.
- 2. A process that is substantially economic, financial, business, social, cultural or artistic, even though at least 1 step in the process refers to a machine or manufacture.
- 3. A mental process performed solely in the human mind, or which occurs in nature wholly independent of any human activity.
- 4. An unmodified human gene, as the gene exists in the human body.
- 5. An unmodified natural material, as the material exists in nature.

While isolation of human genes does not appear to be enough to qualify as modification for purposes of conferring patent eligibility, PERA 2025 would specifically consider isolation of a "natural material" to be sufficient. Specifically, the bill says that a natural material would be considered modified and patent eligible if it is "isolated, purified, enriched, or otherwise altered by human activity; or otherwise employed in a useful invention or discovery."

PERA 2025 also continues to explicitly recite the caveat that notwithstanding anything else, "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 goal is obviously to allow for the patentability of

inventions that necessarily require a computer, for example. This understanding is bolstered by new Section 4(b), which states that "pre- or post-solution activity by a computer (or other machine or manufacture) in claim language shall not be sufficient to confer patent eligibility on the claim if that computer (or other machine or manufacture) is not necessary to practically perform the invention."

Thus, claims that merely add a computer as window dressing to the invention will be insufficient to confer patent eligibility, which is consistent with the law—and common sense really. It has never made sense to pretend that a purely mental process can be converted to something eligible by merely displaying results or transmitting results, which could be accomplished by having results pop up on a monitor or sent via email, respectively. But for those inventions that can only be performed in a computerized environment, such as artificial intelligence (AI) related innovations, a computer is necessary to accomplish the invention and should easily—and obviously—be considered far more than insignificant pre- or post-solution activity by even the most patent skeptical judges.

Despite the introduction of this latest version of PERA, the future of patent eligibility reform in the 119th Congress remains uncertain. Many believe there is at best a 50-50 chance that eligibility reform will pass this term, with some believing even that is a particularly optimistic view. However, if President Donald Trump were to see patent eligibility reform as an important step toward empowering U.S. innovators and the U.S. high-tech economy, all bets are off and the odds of patent eligibility reform becoming a reality would rise dramatically.

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