



Congress Should Pass PERA to Fix What the Supreme Court Unintentionally Broke

Patent eligibility under 35 U.S.C. § 101 is not a constitutional command. It is a policy judgment about which inventions should qualify for patent protection — a judgment that belongs to Congress, which can weigh the effects of patent policy on innovation, investment, economic growth, national competitiveness, and national security. Courts, by contrast, resolve individual disputes based on the cases before them.

Over the past fifteen years, however, the Supreme Court fundamentally reshaped patent eligibility through a series of decisions that expanded judicially created exceptions to the statutory text. The result has been widespread uncertainty over what inventions remain eligible for patent protection. After repeatedly declining opportunities to revisit these decisions, the Court has effectively signaled that it does not intend to resolve the confusion it created. That leaves Congress as the appropriate — and only — institution able to restore a clear, predictable patent eligibility standard.

Today's innovation economy depends on a patent system that protects the full range of technologies critical to American leadership. Instead, current eligibility doctrine has produced uncertainty for courts and patent examiners, increased risk for innovators and investors, and weakened incentives to develop breakthrough technologies. Restoring clarity to Section 101 is essential to maintaining U.S. technological leadership.

The Supreme Court's Decisions Created Uncertainty

In *Bilski v. Kappos* (2010), *Mayo Collaborative Services v. Prometheus Laboratories* (2012), *Association for Molecular Pathology v. Myriad Genetics* (2013), and *Alice Corp. v. CLS Bank* (2014), the Supreme Court expanded vague judicial exceptions not found in the Section 101 text, and the resulting framework drastically narrowed eligibility and proved challenging to administer. Uncertainty now defines patent eligibility law.

- Inventors, investors, patent examiners, and courts often cannot predict outcomes under the test.
- Similar technologies can receive different treatment depending on the court reviewing the case.
- Lower courts' inconsistent application of these decisions has further complicated eligibility determinations, leading to the invalidation of patents in fields such as diagnostics, artificial intelligence, software, and personalized medicine and deepening uncertainty over what is — and is not — patent eligible.

The Experts Responsible for Applying Patent Law Have Raised Concerns

Congress created the U.S. Court of Appeals for the Federal Circuit in 1982 to bring expertise and uniformity to patent law. The Federal Circuit regularly hears patent cases and has spent over a decade trying to apply an eligibility framework that its judges have described as leaving them "at a loss."

- Federal Circuit judges have described the framework as producing inconsistent, hard-to-reconcile outcomes — and have warned of its consequences for medical innovation, particularly diagnostics.
 - When the court denied en banc review in *Athena Diagnostics v. Mayo Collaborative Services* (2019), the judges called for Congress to intervene. Judges noted they were "bound" by the Supreme Court's *Mayo Collaborative Services v. Prometheus Laboratories* decision, which they found unworkable.

- One judge observed “[the bottom line for diagnostics patents is problematic.](#)” [but that the court lacked the power to reach that result.](#) [Another](#) stated: “New methods for diagnosing medical conditions... intuitively seem to be the kind of subject matter the patent system is designed for: to encourage the risky, expensive, unpredictable technical research and development that people would not otherwise pursue in the hope that if they discover something of great medical value, then they will be protected and rewarded...with a patent.” Yet he was bound by the “recent direction of the Supreme Court.”
- The court’s divided opinions in cases [such as American Axle](#) revealed similar concerns over how to [apply](#) the eligibility doctrine. When the court charged with administering patent law repeatedly signals that the current framework is broken but beyond its power to fix, Congress ought to listen.

Patent Eligibility Is a Policy Question for Congress

Section 101 is a statutory framework established by Congress and interpreted by the courts, including the Supreme Court. Because it is a matter of statute — not a constitutional mandate — Congress can clarify the law when judicial interpretations produce unintended consequences, as Federal Circuit judges have noted.

- Congress routinely updates laws when courts interpret statutes in ways that create practical issues.
- The Supreme Court’s role is to resolve individual disputes based on the facts, arguments, and amicus briefs before it. Congress’s role is broader: to assess how patent eligibility rules affect innovation, investment, economic growth, U.S. competitiveness, and technological leadership.
- Decisions about which technologies are patent-eligible require broad economic and policy judgments best made by lawmakers.
- When courts struggle to apply an unworkable standard, Congress can and should provide clarity.

The Cost of Inaction

Uncertainty surrounding Section 101 patent eligibility carries real-world consequences that the Supreme Court is not institutionally positioned to anticipate or correct, but Congress can address:

- Reduced [investment](#) in diagnostics, AI, software, biotechnology, and [key emerging technologies](#).
- Inventors and research entities [abandoning development](#) of promising innovations where applicable patents either will not be granted or will not be upheld by courts under the current Section 101.
- Greater risk for startups, universities, and smaller inventors seeking to commercialize discoveries.
- A competitive disadvantage [relative to](#) countries with more predictable patent systems — threatening American technological leadership.

Patent Eligibility Restoration Act (PERA) Provides the Solution

[PERA](#) would reverse the uncertainty surrounding Section 101 by:

- Establishing patent eligibility standards with new, updated statutory text adapted from the judicial exceptions but with clearer language concerning their scope.
- Replacing today’s unpredictable framework with clearer rules and providing innovators, investors, examiners, and courts with greater certainty.
- Bolstering investment in new technologies and boosting U.S. competitiveness in key industries.