Myths vs. Facts: The Patent Eligibility Restoration Act (PERA)

Diagnostics & Life Sciences

The Patent Eligibility Restoration Act (PERA), sponsored by Sens. Thom Tillis (R-NC) and Chris Coons (D-DE), is bipartisan legislation that would make critical reforms to the U.S. patent system.

In recent years, a series of Supreme Court decisions have created major uncertainty around U.S. patent eligibility for cutting-edge inventions in a number of crucial fields, including diagnostic testing, personalized medicine, software, and artificial intelligence. Meanwhile, other countries — like China, Japan, and many European nations — have maintained patent eligibility for innovations in these highly competitive sectors, putting U.S. industries at a severe disadvantage.

The "exceptions" to patent eligibility created by the Supreme Court were not drafted or endorsed by Congress. They also represent a misapplication of the statutes that govern the U.S. patent system. In particular, 35 U.S.C. § 101 — the section governing eligibility — is meant to delineate broad categories of inventions that may be considered for patent protection, while Sections 102, 103, and 112 set forth specific requirements that an eligible invention must meet in order to receive a patent, such as being new and non-obvious. The Court has conflated the distinct functions of the different sections of the Patent Act.

By amending Section 101 and related sections, PERA would restore patent eligibility to categories of inventions that the Supreme Court's decisions have rendered ineligible while clarifying which kinds of inventions are ineligible for patents.

Below are some misconceptions about PERA related to the diagnostics and life sciences industries that have circulated in recent months:

Myth: The role of Section 101 is to ensure "bad" patents aren't granted.

Fact: This is wrong. Section 101 is not a "quality control" statute: it simply states the categories of inventions eligible for patents. Any issue with the quality of a particular patent application should be addressed by Sections 102, 103, and 112.

Myth: PERA would dramatically expand patent eligibility to include ideas and even natural phenomena.

Fact: PERA would not "expand" patent eligibility beyond what patent statutes permitted prior to the Supreme Court's rulings. Rather, PERA would restore patent eligibility to categories of economically important innovations that the Supreme Court has arbitrarily determined to be ineligible for patents, such as medical diagnostics. Further, contrary to the "myth," the text of PERA does not allow patents on mere ideas or natural phenomena — the text clearly states that mental processes, unmodified human genes, and unmodified natural materials *"shall not be eligible for patent protection."*

Myth: PERA would hinder competition and impede innovation.

Fact: A quick look at thriving industries in other countries dispels this claim. Nations that allow patents for innovations that the Supreme Court has ruled off-limits, such as patents on diagnostics, are out-competing the United States. For example, Asia hosts 40% of molecular diagnostic kit manufacturers, while the United States and Canada combined are home to just 29%. Europe's contributions to diagnostic kit manufacturing are on par with those of the United States, despite the United States owning a significant lead in other innovation metrics. Court-imposed limits on patent eligibility are the real threat to competition and innovation.

Myth: Diagnostic tests that measure the body's response to a drug rely on unpatentable laws of nature and therefore should not receive patents.

Fact: It is incorrect to call the body's response to a drug that does not occur naturally a law of nature. Observations of how natural systems respond to external stimuli applied intentionally form the basis of countless important inventions.

Myth: Diagnostic innovation is flourishing in the United States.

Fact: The U.S. diagnostic industry is far from thriving. Americans currently rely heavily on Europe and Asia for innovative at-home tests, for example. In the four years following *Mayo*, research shows that investment in diagnostics dropped $9.3 billion below what it would have been.

Myth: Court-imposed limits on patent eligibility have not harmed U.S. global competitiveness in high-tech sectors.

Fact: The explosion of Europe's in vitro diagnostics (IVD) industry coincided almost perfectly with the Court's decisions in *Mayo* and *Myriad*. A report on the European medical technology industry found that the European IVD market declined until 2013. Since then, the trend has reversed markedly, with the industry growing at an average annual rate of 2.7%, and 25% in 2020 alone.

Myth: The American public had access to tests during the Covid-19 pandemic thanks to robust diagnostics innovation in the United States. Therefore, patent eligibility isn't an issue.

Fact: Americans' access to Covid-19 tests was substantially supported by innovation being done in other countries. Europe and Asia — which allow patents on diagnostics — dominated at-home Covid-19 test kit development, accounting for 74% of all manufacturers by April 2020. The United States and Canada, meanwhile, were home to only 24% of test kit makers.

Myth: Patent eligibility limits on diagnostic tests never slowed the U.S. response to the Covid-19 pandemic.

Fact: In the early days of the pandemic, the CDC promoted the use of RNA extraction kits from a company based in Germany, which led to unnecessary delays in testing. Had the U.S. patent system been more welcoming to diagnostics innovation, American companies may have been in position to meet domestic demand.