PATENT ELIGIBILITY RESTORATION ACT (PERA) WOULD PROVIDE CLEAR, PREDICTABLE RULES FOR WHAT INVENTIONS ARE ELIGIBLE FOR PATENTS

Clear, consistent rules about what inventions are patent eligible allow inventors, venture capitalists, and other stakeholders to confidently invest in the research and development needed to invent new technologies and power the U.S. innovation economy. However, more than a decade of court decisions have muddled the waters and made it more difficult to obtain patents for inventions in critical technology areas, including artificial intelligence (AI), biotechnology, and personalized medicine.

The judicially created restrictions on patent eligibility puts the United States at a competitive disadvantage as foreign governments seize on opportunities to expand the scope of eligible subject matter in their countries. As a result, there are many inventions that are patentable in China and Europe but rejected as ineligible in the United States.

Congress should pass the Patent Eligibility Restoration Act (PERA) (S.2140)—a bipartisan bill introduced by Senate Judiciary IP Subcommittee Chair Chris Coons (D-DE) and Ranking Member Thom Tillis (R-NC)—to eliminate the confusion created by courts as to what inventions are patent eligible and to help regain the U.S. competitive edge in innovation.

Legislation Is Needed To Clarify Supreme Court Patent Eligibility Precedent

- Section 101 of the Patent Act (35 U.S.C. § 101) defines the categories of inventions that are eligible to receive patents.
- In a series of decisions beginning in 2010, the Supreme Court established a new test for patent eligibility and significantly expanded existing judicially created exceptions to patent eligibility for abstract ideas, mathematical formulas, and products of nature.¹
- Under the new test, a court must determine whether an invention is "directed to" one of the
 ineligible categories, and, if so, whether the claim contains an additional "inventive concept." Both
 of these determinations involve highly subjective decisions for which the Supreme Court has
 provided no further guidance. The "inventive concept" analysis also requires courts to consider
 novelty and non-obviousness, muddying the waters between Section 101 and distinct Section 102
 and 103 statutory requirements for patentability.
- Collectively, these decisions have all but eliminated inventors' ability to obtain patents for inventions in key sectors—including computer software, AI, and life sciences—and made patent rights less predictable across almost all technologies.
- Lower courts, the Solicitor General, USPTO directors, and other stakeholders have all acknowledged
 that the Supreme Court's test for patentability leads to inconsistent and unpredictable results. The
 Supreme Court has also declined to provide more guidance and certainty by rejecting review of more
 than 100 cases on these issues. This has led to calls for Congress to pass legislation to clarify patent
 subject-matter eligibility.

¹ Bilski v. Kappos, 561 U.S. 593 (2010) (under which most patents on business methods are now ineligible); Mayo Collaborative Services v. Prometheus Laboratories, 566 U.S. 66 (2012) (under which most diagnostic testing patents are now ineligible); Association for Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. 576 (2013) (under which gene-fragment patents are ineligible); Alice Corp. v. CLS Bank International, 573 U.S. 208 (2014) (under which most software patents are ineligible).

PERA Clarifies Patent Subject-Matter Eligibility

- PERA resolves confusion by retaining Section 101's existing statutory categories for patent-eligible subject matter (i.e., process, machine, manufacture, and composition of matter) and by replacing the ambiguous judicially created exceptions with more clearly defined exceptions.
- PERA lists specific exceptions to eligible subject matter and ensures that they will be the <u>only</u> exceptions. These exceptions include pure mathematical formulas, certain economic or social processes, processes that can be performed solely in the human mind, processes that can occur in nature independent of human activity, unmodified human genes, and unmodified natural material.
- PERA also clarifies the narrow conditions under which otherwise unpatentable processes, genes, and
 materials may be eligible for a patent, subject to other statutory requirements (e.g., novelty and nonobviousness). For example, under PERA, a process that cannot be practically performed without the
 use of a machine or computer may be eligible for a patent. The bill also clarifies that human genes
 and natural materials that are "isolated, purified, enriched, or otherwise altered by human activity"
 or "employed in a useful invention or discovery" may be eligible for a patent.

PERA Restores Clear Test for Patent Eligibility Determinations

- Under current law, patent examiners and courts determining whether a claimed invention is eligible
 for a patent under Section 101 must consider vague factors, including whether portions of a claim
 include elements that are "conventional" or "routine."
- These considerations blur the line between Section 101 and other statutory requirements for a patent, such as novelty and non-obviousness under Sections 102 and 103.
- PERA requires a patent claim to be read as a whole and prohibits the consideration of other patentability factors (e.g., novelty and non-obviousness), ensuring Section 101 focuses solely on subject-matter eligibility.