

Summary of the Proposed U.S. Patent Eligibility Restoration Act of 2023

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Patent subject matter eligibility in the United States of America is governed by 35 U.S.C. § 101. The Patent Eligibility Restoration Act of 2023 (the “Act”) proposes revisions to clarify 35 U.S.C. § 101 by (i) eliminating judicial exceptions to patent eligibility, (ii) defining the subject matter excluded from patent eligibility, (iii) limiting what may be considered in determining whether a claimed invention is eligible for a patent, and (iv) defining when a court may determine whether an invention is eligible for a patent in an infringement action. U.S. Senators Thom Tillis (R-NC) and Chris Coons (D-DE) introduced the Act on June 22, 2023. The Senate Judiciary Committee’s Subcommittee on Intellectual Property held a hearing on the proposed Act on January 23, 2024.

The text of existing 35 U.S.C. § 101 broadly defines the subject matter eligible for patent protection, and its legislative history indicates that Congress intended eligible subject matter to broadly include anything under the sun that is made by man. However, in interpreting the statute, the courts created exceptions that limit the subject matter that is eligible for patent protection. These judicial exceptions include laws of nature, natural phenomena, and abstract ideas (e.g., mathematical concepts, certain methods of organizing human activity, and mental processes). The Act would eliminate these judicial exceptions, which “render[] an increasing number of inventions ineligible for patent protection”¹ and “have led to extensive confusion and a lack of consistency.”² The Act would replace the judicial exceptions with a list of exclusions to eligible subject matter.

The exclusions to eligibility listed in the Act include:

- (a) a mathematical formula that is not part of an invention that is in the category of a process, machine, manufacture, or composition of matter, or an improvement thereof,
- (b) a process that is substantially economic, financial, business, social, cultural, or artistic unless the process cannot practically be performed without the use of a machine or manufacture,
- (c1) a mental process performed solely in the human mind,
- (c2) a process that occurs in nature wholly independent of, and prior to, any human activity,
- (d) an unmodified human gene, as that gene exists in the human body, and
- (e) an unmodified natural material, as that material exists in nature.

Although the Act provides guidance on when a human gene or natural material is not “unmodified,” the Act would leave it to the courts to determine, for example, when a process is “substantially” economic, financial, business, social, cultural, or artistic and when a process cannot “practically” be performed without the use of a machine or manufacture.

According to the Act, patent eligibility would be determined by considering the claimed invention as a whole and without discounting or disregarding any claim element. The Act would explicitly exclude from

¹ Act at § 2(2).

² *Id.* at § 2(3).

the patent eligibility determination consideration of: (i) the manner in which the claimed invention was made, (ii) whether a claim element is known, conventional, routine, or naturally occurring, (iii) the state of the applicable art, as of the date on which the claimed invention is invented, and (iv) any other consideration in 35 U.S.C. §§ 102, 103, and 112, which define the conditions for patentability of novelty, non-obviousness, definiteness, written description, and enablement.

According to the Act, in an action for patent infringement, the court, at any time, may determine whether the invention is patent eligible, including on motion of a party when there are no genuine issues of material fact (e.g., a motion for summary judgment).

The revisions to 35 U.S.C. § 101 proposed by the Act are shown below with strikethrough indicating deletions and underlining indicating additions.

35 U.S.C. 101 ~~Inventions patentable.~~ Patent eligibility.

(a) In General.—Whoever invents or discovers any ~~new and~~ useful process, machine, manufacture, or composition of matter, or any ~~new and~~ 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.

(b) Eligibility Exclusions.—

(1) IN GENERAL.—Subject to paragraph (2), a person may not obtain a patent for any of the following, if claimed as such:

(A) A mathematical formula that is not part of a claimed invention in a category described in subsection (a).

(B) (i) Subject to clause (ii), a process that is substantially economic, financial, business, social, cultural, or artistic, even though not less than 1 step in the process refers to a machine or manufacture.

(ii) The process described in clause (i) shall not be excluded from eligibility for a patent if the process cannot practically be performed without the use of a machine or manufacture.

(C) A process that—

(i) is a mental process performed solely in the human mind; or

(ii) occurs in nature wholly independent of, and prior to, any human activity.

(D) An unmodified human gene, as that gene exists in the human body.

(E) An unmodified natural material, as that material exists in nature.

(2) CONDITIONS.—For the purposes of subparagraphs (D) and (E) of paragraph (1), a human gene or natural material shall not be considered to be unmodified if the gene or material, as applicable, is—

(A) isolated, purified, enriched, or otherwise altered by human activity; or

(B) otherwise employed in a useful invention or discovery.

(c) Eligibility.—

(1) IN GENERAL.—In determining whether, under this section, a claimed invention is eligible for a patent, eligibility shall be determined—

(A) by considering the claimed invention as a whole and without discounting or disregarding any claim element; and

(B) without regard to—

(i) the manner in which the claimed invention was made;

(ii) whether a claim element is known, conventional, routine, or naturally occurring;

(iii) the state of the applicable art, as of the date on which the claimed invention is invented; or

(iv) any other consideration in section 102, 103, or 112.

(2) INFRINGEMENT ACTION.—

(A) IN GENERAL.—In an action brought for infringement under this title, the court, at any time, may determine whether an invention or discovery that is a subject of the action is eligible for a patent under this section, including on motion of a party when there are no genuine issues of material fact.

(B) LIMITED DISCOVERY.—With respect to a determination described in subparagraph (A), the court may consider limited discovery relevant only to the eligibility described in that subparagraph before ruling on a motion described in that subparagraph.