One-Day Patent CLE Seminar
November 7, 2024

Election Outcomes and Discussion

- **Presidential Outcome (if known) & IP Implications**
- **Congressional Outcomes (if known) & IP Implications**

Judiciary Administration Updates

- JUDGES Act Update
- Federal Rules Process
  - Third Party Patent Litigation
    - Appropriations language pressure Administrative Office of the Courts to implement judicial guidance.
    - Rep Issa Bill - apply financial disclosure requirements to “a party or any counsel of record” “in any civil action”.
    - Corporate letter to Administrative Office of the Courts requesting *“uniform and efficient procedure for disclosure of TPLF agreements in civil cases.”*
  - Random Case Assignment
  - Evidentiary Authentication of AI Generated Evidence

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Legislative Topics

- Promoting and Respecting Economically Vital American Innovation Leadership Act (**PREVAIL Act**)
  - Establishes standing requirement at PTAB
  - Equivalent evidentiary standard of "clear and convincing evidence" at PTAB and District Court
  - Does not allow parallel challenges to the validity of the same patent in both the IPR process and district court litigation involving the same parties.
  - Requires PTAB to deny institution on petitions that rely on prior art PTO has previously considered, and on petitions where PTAB or district court has previously found validity.
- Patent Eligibility Restoration Act (**PERA**)
  - Eliminates all prior judicial exceptions to eligibility.
  - Replaces them with a limited set of statutory exclusions.
  - Under PERA, U.S. law would draw lines regarding what is <u>not</u> patent eligible, this includes: pure mathematical formulas and mental processes, unmodified genes in the human body and unmodified natural material existing in nature.
  - PERA also excludes substantially economic, financial, business, social, cultural, or artistic processes, even when followed by language like "do it on a computer,"

Legislative Topics

- Realizing Engineering, Science, and Technology Opportunities by Restoring Exclusive **(RESTORE)** Patent Rights Act of 2024
  - Establishes rebuttable presumption in statute in favor of granting permanent injunction when a court enters a judgement of infringement.

Administration, USPTO & Copyright Office Activity

- Bayh-Dole March In Proposed Guidelines
  - Proposed Guidelines introduced December 2023 by the National Institute of Standards and Technology providing federal agencies guidance relevant to potential march-in considerations based on reasonable price of products incorporating federally-licensed patents.
  - Thousands of comments, significant Congressional interest and comment from former USPTO Directors
  - Pending Biden Administration final approval

- USPTO Terminal Disclaimer NPRM
  - *"Require that any terminal disclaimer filed to overcome nonstatutory double patenting must include an agreement that the subject patent would be enforceable only if the reference patent is not tied – and has never been tied directly or indirectly – to a patent by one or more terminal disclaimers in which any claim has been finally held unpatentable or invalid over the prior art."*
  - USPTO comments closed, pending final rule.

Administration, USPTO & Copyright Office Activity

- Copyright Office AI & IP Report
  - Committed to Congress to complete remaining sections in 2024. Topics to be addressed include:
    - Copyrightability of GenAI output
    - Legal implications of training AI models on copyrighted works, including issues such as liability, licensing and fair use.

Administration & USPTO Activity

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Legislative Topics

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  - Equivalent evidentiary standard of “clear and convincing evidence” at PTAB and District Court
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Legislative Topics

- Realizing Engineering, Science, and Technology Opportunities by Restoring Exclusive **(RESTORE)** Patent Rights Act of 2024
  - Establishes rebuttable presumption in statute in favor of granting permanent injunction when a court enters a judgement of infringement.

- Third Party Litigation Finance
  - Appropriations language to pressure Administrative Office of the Courts to implement judicial guidance.
  - Legislation from House Judiciary IP Subcommittee Chairman Issa to apply disclosure requirements to “a party or any counsel of record” “in any civil action”.
  - Parties (unclear if this applies to only plaintiffs or if it’s applicable to defendants as well) would be required to disclose any party that might receive a “thing of value” (not defined) “that is contingent on the outcome.”

.....

(Original Signature of Member)

118TH CONGRESS
2D SESSION

H. R. | |

To amend title 28, United States Code, to provide for transparency and oversight of third-party beneficiaries in civil actions.

IN THE HOUSE OF REPRESENTATIVES

Mr. ISSA introduced the following bill; which was referred to the Committee on | | | | | | | | | | | | |

A BILL

To amend title 28, United States Code, to provide for transparency and oversight of third-party beneficiaries in civil actions.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Litigation Transparency Act of 2024''.

SEC. 2. TRANSPARENCY AND OVERSIGHT OF THIRD-PARTY BENEFICIARIES IN CIVIL CASES.

(a) IN GENERAL.—Chapter 111 of title 28, United States Code, is amended by adding at the end the following:

"§ 1660. Third-party beneficiary disclosure

"(a) IN GENERAL.—Except as provided in subsection (b), in any civil action, a party or any counsel of record for a party shall—

"(1) disclose in writing to the court and all other named parties to the civil action the identity of any person (other than counsel of record) that has a right to receive any payment or thing of value that is contingent on the outcome of the civil action or a group of actions of which the civil action is a part; and

"(2) produce to the court and to each other named party to the civil action, for inspection and copying, any agreement creating a contingent right referred to in paragraph (1), including any ancillary agreement or document, except as otherwise stipulated or ordered by the court.

"(b) EXCEPTION.—The requirements under subsection (a) shall not apply with respect to a person that has a right to receive payment described in subsection (a)(1) if the right to receive payment is solely—

"(1) the repayment of the principal of a loan;

"(2) the repayment of the principal of a loan plus interest that does not exceed the higher of 7 percent or a rate two times the annual average 30-year constant maturity Treasury yield, as published by the Board of Governors of the Federal Reserve System, for the year preceding the date on which the relevant agreement was executed; or

"(3) the reimbursement of attorney's fees.

"(c) TIMING.—The disclosures required by subsection (a) shall be made not later than the later of—

"(1) 10 days after the execution of any agreement described in subsection (a)(2); or

"(2) the time of the filing of the action before the court.

"(d) DUTY TO CORRECT.—A party or counsel of record that made a disclosure required by this section shall supplement or correct each such disclosure in a timely manner—

"(1) if such party or counsel of record learns that the disclosure is or has become incomplete or incorrect in some material respect, if the additional or corrective information has not otherwise been made known to the other parties during the discovery process or in writing; or

''(2) as ordered by the court.''.

(b) CLERICAL AMENDMENT.—The table of sections for chapter 111 of title 28, United States Code, is amended by adding at the end the following:

''1660. Third-party beneficiary disclosure.''.

SEC. 3. APPLICABILITY.

The amendments made by this Act shall apply to any civil action pending on or commenced after the date of enactment of this Act.

118TH CONGRESS
2D SESSION

S. 4199

AN ACT

To authorize additional district judges for the district courts and convert temporary judgeships.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Judicial Understaffing Delays Getting Emergencies Solved Act of 2024'' or the ''JUDGES Act of 2024''.

SEC. 2. FINDINGS.

Congress finds the following:

(1) Article III of the Constitution of the United States gives Congress the power to establish judgeships in the district courts of the United States.

(2) Congress has not created a new district court judgeship since 2003 and has not enacted comprehensive judgeship legislation since 1990.

(3) This represents the longest period of time since district courts of the United States were established in 1789 that Congress has not authorized any new permanent district court judgeships.

(4) By the end of fiscal year 2022, filings in the district courts of the United States had increased by 30 percent since the last comprehensive judgeship legislation.

(5) As of March 31, 2023, there were 686,797 pending cases in the district courts of the United States, with an average of 491 weighted case filings per judgeship over a 12-month period.

(6) To deal with increased filings in the district courts of the United States, the Judicial Conference

of the United States requested the creation of 66 new district court judgeships in its 2023 report.

SEC. 3. ADDITIONAL DISTRICT JUDGES FOR THE DISTRICT COURTS.

(a) ADDITIONAL JUDGESHIPS.—

(1) 2025.—

(A) IN GENERAL.—The President shall appoint, by and with the advice and consent of the Senate—

(i) 1 additional district judge for the central district of California;

(ii) 1 additional district judge for the eastern district of California;

(iii) 1 additional district judge for the northern district of California;

(iv) 1 additional district judge for the district of Delaware;

(v) 1 additional district judge for the middle district of Florida;

(vi) 1 additional district judge for the southern district of Indiana;

(vii) 1 additional district judge for the northern district of Iowa;

(viii) 1 additional district judge for the district of New Jersey;

(ix) 1 additional district judge for the southern district of New York;

(x) 1 additional district judge for the eastern district of Texas; and

(xi) 1 additional district judge for the southern district of Texas.

(B) TABLES.—The table contained in section 133(a) of title 28, United States Code, is amended—

(i) by striking the items relating to California and inserting the following:

"California:
Northern 15
Eastern 7
Central 28
Southern ..... 13";

(ii) by striking the item relating to Delaware and inserting the following:

"Delaware ..... 5";

(iii) by striking the items relating to Florida and inserting the following:

"Florida:
Northern 4
Middle 16
Southern ..... 17";

(iv) by striking the items relating to Indiana and inserting the following:

"Indiana:
Northern 5
Southern ..... 6";

(v) by striking the items relating to Iowa and inserting the following:

"Iowa:	
Northern	3
Southern	3";

(vi) by striking the item relating to New Jersey and inserting the following:

"New Jersey	18";

(vii) by striking the items relating to New York and inserting the following:

"New York:	
Northern	5
Southern	29
Eastern	15
Western	4"; and

(viii) by striking the items relating to Texas and inserting the following:

"Texas:	
Northern	12
Southern	20
Eastern	8
Western	13".

(C) EFFECTIVE DATE.—This paragraph shall take effect on January 21, 2025.

(2) 2027.—

(A) IN GENERAL.—The President shall appoint, by and with the advice and consent of the Senate—

(i) 1 additional district judge for the district of Arizona;

(ii) 2 additional district judges for the central district of California;

(iii) 1 additional district judge for the eastern district of California;

(iv) 1 additional district judge for the northern district of California;

(v) 1 additional district judge for the middle district of Florida;

(vi) 1 additional district judge for the southern district of Florida;

(vii) 1 additional district judge for the northern district of Georgia;

(viii) 1 additional district judge for the district of Idaho;

(ix) 1 additional district judge for the northern district of Texas; and

(x) 1 additional district judge for the southern district of Texas.

(B) TABLES.—The table contained in section 133(a) of title 28, United States Code, as amended by paragraph (1) of this subsection, is amended—

(i) by striking the item relating to Arizona and inserting the following:

"Arizona ..... 13";

(ii) by striking the items relating to California and inserting the following:

"California:	
Northern	16
Eastern	8
Central	30
Southern	13";

(iii) by striking the items relating to Florida and inserting the following:

"Florida:	
Northern	4
Middle	17
Southern	18";

(iv) by striking the items relating to Georgia and inserting the following:

"Georgia:	
Northern	12
Middle	4
Southern	3";

(v) by striking the item relating to Idaho and inserting the following:

"Idaho	3"; and

(vi) by striking the items relating to Texas and inserting the following:

"Texas:	
Northern	13
Southern	21
Eastern	8
Western	13".

(C) EFFECTIVE DATE.—This paragraph shall take effect on January 21, 2027.

(3) 2029.—

(A) IN GENERAL.—The President shall appoint, by and with the advice and consent of the Senate—

(i) 1 additional district judge for the central district of California;

(ii) 1 additional district judge for the eastern district of California;

(iii) 1 additional district judge for the northern district of California;

(iv) 1 additional district judge for the district of Colorado;

(v) 1 additional district judge for the district of Delaware;

(vi) 1 additional district judge for the district of Nebraska;

(vii) 1 additional district judge for the eastern district of New York;

(viii) 1 additional district judge for the eastern district of Texas;

(ix) 1 additional district judge for the southern district of Texas; and

(x) 1 additional district judge for the western district of Texas.

(B) TABLES.—The table contained in section 133(a) of title 28, United States Code, as

amended by paragraph (2) of this subsection, is amended—

(i) by striking the items relating to California and inserting the following:

"California:
Northern 17
Eastern 9
Central 31
Southern ..... 13";

(ii) by striking the item relating to Colorado and inserting the following:

"Colorado ..... 8";

(iii) by striking the item relating to Delaware and inserting the following:

"Delaware ..... 6";

(iv) by striking the item relating to Nebraska and inserting the following:

"Nebraska ..... 4";

(v) by striking the items relating to New York and inserting the following:

"New York:
Northern 5
Southern 29
Eastern 16
Western ..... 4"; and

(vi) by striking the items relating to Texas and inserting the following:

"Texas:
Northern 13
Southern 22
Eastern 9

Western ..... 14".

(C) EFFECTIVE DATE.—This paragraph shall take effect on January 21, 2029.

(4) 2031.—

(A) IN GENERAL.—The President shall appoint, by and with the advice and consent of the Senate—

(i) 1 additional district judge for the district of Arizona;

(ii) 1 additional district judge for the central district of California;

(iii) 1 additional district judge for the eastern district of California;

(iv) 1 additional district judge for the northern district of California;

(v) 1 additional district judge for the southern district of California;

(vi) 1 additional district judge for the middle district of Florida;

(vii) 1 additional district judge for the southern district of Florida;

(viii) 1 additional district judge for the district of New Jersey;

(ix) 1 additional district judge for the western district of New York; and

(x) 2 additional district judges for the western district of Texas.

(B) TABLES.—The table contained in section 133(a) of title 28, United States Code, as amended by paragraph (3) of this subsection, is amended—

(i) by striking the item relating to Arizona and inserting the following:

"Arizona ..... 14";

(ii) by striking the items relating to California and inserting the following:

"California:
Northern 18
Eastern 10
Central 32
Southern ..... 14";

(iii) by striking the items relating to Florida and inserting the following:

"Florida:
Northern 4
Middle 18
Southern ..... 19";

(iv) by striking the item relating to New Jersey and inserting the following:

"New Jersey ..... 19";

(v) by striking the items relating to New York and inserting the following:

"New York:
Northern 5
Southern 29
Eastern 16

Western ..... 5''; and

(vi) by striking the items relating to Texas and inserting the following:

''Texas:
Northern 13
Southern 22
Eastern 9
Western ..... 16''.

(C) EFFECTIVE DATE.—This paragraph shall take effect on January 21, 2031.

(5) 2033.—

(A) IN GENERAL.—The President shall appoint, by and with the advice and consent of the Senate—

(i) 2 additional district judges for the central district of California;

(ii) 1 additional district judge for the northern district of California;

(iii) 1 additional district judge for the district of Colorado;

(iv) 1 additional district judge for the middle district of Florida;

(v) 1 additional district judge for the northern district of Florida;

(vi) 1 additional district judge for the northern district of Georgia;

(vii) 1 additional district judge for the southern district of New York;

(viii) 1 additional district judge for the southern district of Texas; and

(ix) 1 additional district judge for the western district of Texas.

(B) TABLES.—The table contained in section 133(a) of title 28, United States Code, as amended by paragraph (4) of this subsection, is amended—

(i) by striking the items relating to California and inserting the following:

"California:	
Northern	19
Eastern	10
Central	34
Southern	14";

(ii) by striking the item relating to Colorado and inserting the following:

"Colorado	9";

(iii) by striking the items relating to Florida and inserting the following:

"Florida:	
Northern	5
Middle	19
Southern	19";

(iv) by striking the items relating to Georgia and inserting the following:

"Georgia:	
Northern	13
Middle	4
Southern	3";

(v) by striking the items relating to New York and inserting the following:

"New York:	
Northern	5
Southern	30
Eastern	16
Western	5"; and

(vi) by striking the items relating to Texas and inserting the following:

"Texas:	
Northern	13
Southern	23
Eastern	9
Western	17".

(C) EFFECTIVE DATE.—This paragraph shall take effect on January 21, 2033.

(6) 2035.—

(A) IN GENERAL.—The President shall appoint, by and with the advice and consent of the Senate—

(i) 2 additional district judges for the central district of California;

(ii) 1 additional district judge for the northern district of California;

(iii) 1 additional district judge for the southern district of California;

(iv) 1 additional district judge for the middle district of Florida;

(v) 1 additional district judge for the southern district of Florida;

(vi) 1 additional district judge for the district of New Jersey;

(vii) 1 additional district judge for the eastern district of New York;

(viii) 2 additional district judges for the western district of Texas.

(B) TABLES.—The table contained in section 133(a) of title 28, United States Code, as amended by paragraph (5) of this subsection, is amended—

(i) by striking the items relating to California and inserting the following:

"California:
Northern 20
Eastern 10
Central 36
Southern ..... 15";

(ii) by striking the items relating to Florida and inserting the following:

"Florida:
Northern 5
Middle 20
Southern ..... 20";

(iii) by striking the item relating to New Jersey and inserting the following:

"New Jersey ..... 20";

(iv) by striking the items relating to New York and inserting the following:

"New York:
Northern 5

Southern	30
Eastern	17
Western	5''; and

(v) by striking the items relating to Texas and inserting the following:

''Texas:	
Northern	13
Southern	23
Eastern	9
Western	19''.

(C) EFFECTIVE DATE.—This paragraph shall take effect on January 21, 2035.

(b) TEMPORARY JUDGESHIPS.—

(1) IN GENERAL.—The President shall appoint, by and with the advice and consent of the Senate—

(A) 2 additional district judges for the eastern district of Oklahoma; and

(B) 1 additional district judge for the northern district of Oklahoma.

(2) VACANCIES NOT FILLED.—The first vacancy in the office of district judge in each of the offices of district judge authorized by this subsection, occurring 5 years or more after the confirmation date of the judge named to fill the temporary district judgeship created in the applicable district by this subsection, shall not be filled.

(3) EFFECTIVE DATE.—This subsection shall take effect on January 21, 2025.

(b) AUTHORIZATION OF APPROPRIATIONS.—

(1) IN GENERAL.—There is authorized to be appropriated to carry out this section and the amendments made by this section—

(A) for each of fiscal years 2025 and 2026, $12,965,330;

(B) for each of fiscal years 2027 and 2028, $23,152,375;

(C) for each of fiscal years 2029 and 2030, $32,413,325;

(D) for each of fiscal years 2031 and 2032, $42,600,370;

(E) for each of fiscal years 2033 and 2034, $51,861,320; and

(F) for fiscal year 2035 and each fiscal year thereafter, $61,122,270.

(1) INFLATION ADJUSTMENT.—For each fiscal year described in paragraph (1), the amount authorized to be appropriated for such fiscal year shall be increased by the percentage by which—

(A) the Consumer Price Index for the previous fiscal year, exceeds

(B) the Consumer Price Index for the fiscal year preceding the fiscal year described in subparagraph (A).

(3) DEFINITION.—In this subsection, the term ''Consumer Price Index'' means the Consumer Price Index for All Urban Consumers (all items, United States city average), published by the Bureau of Labor Statistics of the Department of Labor.

SEC. 4. ORGANIZATION OF UTAH DISTRICT COURTS.

Section 125(2) of title 28, United States Code, is amended by striking ''and St. George'' and inserting ''St. George, Moab, and Monticello''.

SEC. 5. ORGANIZATION OF TEXAS DISTRICT COURTS.

Section 124(b)(2) of title 28, United States Code, is amended, in the matter preceding paragraph (3), by inserting ''and College Station'' before the period at the end.

SEC. 6. ORGANIZATION OF CALIFORNIA DISTRICT COURTS.

Section 84(d) of title 28, United States Code, is amended by inserting ''and El Centro'' after ''at San Diego''.

SEC. 7. GAO REPORTS.

(a) JUDICIAL CASELOADS.—Not later than 2 years after the date of enactment of this Act, the Comptroller General of the United States shall submit to the Committee on the Judiciary of the Senate and the Committee on the Judiciary of the House of Representatives and make publicly available reports—

(1) evaluating—

(A) the accuracy and objectiveness of case-related workload measures and methodologies used by the Administrative Office of the United States Courts for district courts of the United States and courts of appeals of the United States;

(B) the impact of non-case-related activities of judges of the district courts of the United States and courts of appeals of the United States on judicial caseloads; and

(C) the effectiveness and efficiency of the policies of the Administrative Office of the United States Courts regarding senior judges; and

(2) providing any recommendations of the Comptroller General with respect to the matters described in paragraph (1).

(b) DETENTION SPACE.—The Comptroller General of the United States shall submit to the Committee on the Judiciary of the Senate and the Committee on the Judiciary of the House of Representatives a report on an assessment of—

(1) a determination of the needs of Federal agencies for detention space;

(2) efforts by Federal agencies to acquire detention space; and

(3) any challenges in determining and acquiring detention space.

SEC. 8. PUBLIC ACCESSIBILITY OF THE ARTICLE III JUDGESHIP RECOMMENDATIONS OF THE JUDICIAL CONFERENCE OF THE UNITED STATES REPORT.

(a) IN GENERAL.—The Administrative Office of the United States Courts, in consultation with the Judicial Conference of the United States, shall make publicly available on their website, free of charge, the biennial report entitled ''Article III Judgeship Recommendations of the Judicial Conference of the United States''.

(b) CONTENTS.—The report described in subsection (a) should be released not less frequently than biennially and contain the summaries and all related appendixes supporting the judgeship recommendations of the Judicial Conference of the United States, including—

(1) the process used by the Judicial Conference in developing the recommendations;

(2) any caseload and methodology changes;

(3) judgeship surveys with recommendations; and

(4) specific information about each court for which the Judicial Conference recommends additional judgeships.

(c) SUBMISSION TO CONGRESS.—The Administrative Office of the United States Courts shall submit to the Committee on the Judiciary of the Senate and the Committee on the Judiciary of the House of Representatives copies of the report described in subsection (a).

Passed the Senate August 1, 2024.

Attest:

Secretary.

118TH CONGRESS
2D SESSION

S. 4199

AN ACT

To authorize additional district judges for the district courts and convert temporary judgeships.

118TH CONGRESS
1ST SESSION

S. 2140

To amend title 35, United States Code, to address matters relating to patent subject matter eligibility, and for other purposes.

IN THE SENATE OF THE UNITED STATES

JUNE 22, 2023

Mr. TILLIS (for himself and Mr. COONS) introduced the following bill; which was read twice and referred to the Committee on the Judiciary

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A BILL

To amend title 35, United States Code, to address matters relating to patent subject matter eligibility, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Patent Eligibility Restoration Act of 2023''.

SEC. 2. FINDINGS.

Congress finds the following:

(1) As of the day before the date of enactment of this Act, patent eligibility jurisprudence inter-

preting section 101 of title 35, United States Code, requires significant modification and clarification.

(2) For many years after the original enactment of section 101 of title 35, United States Code, the Supreme Court of the United States and other courts created judicial exceptions to the wording of that section, thereby rendering an increasing number of inventions ineligible for patent protection.

(3) Efforts by judges of district courts and courts of appeals of the United States to apply the exceptions described in paragraph (2) to specific circumstances have led to extensive confusion and a lack of consistency—

(A) throughout the judicial branch of the Federal Government and Federal agencies; and

(B) among patent practitioners.

(4) Many judges of the United States Court of Appeals for the Federal Circuit and of various district courts of the United States have explicitly expressed the need for more guidance with respect to the meaning of section 101 of title 35, United States Code, and many patent owners, and persons that engage with patent owners, complain that the interpretation of that section is extremely confusing and difficult to discern and apply with any confidence.

(5) Under this Act, and the amendments made by this Act, the state of the law shall be as follows:

(A) All judicial exceptions to patent eligibility are eliminated.

(B) Any invention or discovery that can be claimed as a useful process, machine, manufacture, or composition of matter, or any useful improvement thereof, is eligible for patent protection, except as explicitly provided in section 101 of title 35, United States Code, as amended by this Act, as described in subparagraphs (D) and (E) of this paragraph.

(C) Sections 102, 103, and 112 of title 35, United States Code, will continue to prescribe the requirements for obtaining a patent, but no such requirement will be used in determining patent eligibility.

(D) The following inventions shall not be eligible for patent protection:

(i) A mathematical formula that is not part of an invention that is in a category described in subparagraph (B).

(ii) A mental process performed solely in the mind of a human being.

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

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

(v) A process that is substantially economic, financial, business, social, cultural, or artistic.

(E) Under the exception described in subparagraph (D)(v)—

(i) process claims drawn solely to the steps undertaken by human beings in methods of doing business, performing dance moves, offering marriage proposals, and the like shall not be eligible for patent coverage, and adding a non-essential reference to a computer by merely stating, for example, ''do it on a computer'' shall not establish such eligibility; and

(ii) any process that cannot be practically performed without the use of a machine (including a computer) or manufacture shall be eligible for patent coverage.

SEC. 3. PATENT ELIGIBILITY.

(a) IN GENERAL.—Chapter 10 of title 35, United States Code, is amended—

(1) in section 100—

(A) in subsection (b), by striking ''includes a new use of a known process'' and inserting ''includes a use, application, or method of manufacture of a known or naturally-occurring process''; and

(B) by adding at the end the following:

''(k) The term 'useful' means, with respect to an invention or discovery, that the invention or discovery has a specific and practical utility from the perspective of a person of ordinary skill in the art to which the invention or discovery pertains.''; and

(2) by amending section 101 to read as follows:

''§ 101. Patent eligibility

''(a) IN GENERAL.—Whoever invents or discovers any useful process, machine, manufacture, or composition of matter, or any 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.".

(b) TECHNICAL AND CONFORMING AMENDMENT.—The table of sections for chapter 10 of title 35, United States Code, is amended by striking the item relating to section 101 and inserting the following:

"101. Patent eligibility.".

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118TH CONGRESS
1ST SESSION

S. 2220

To amend title 35, United States Code, to invest in inventors in the United States, maintain the United States as the leading innovation economy in the world, and protect the property rights of the inventors that grow the economy of the United States, and for other purposes.

IN THE SENATE OF THE UNITED STATES

JULY 10, 2023

Mr. COONS (for himself, Mr. TILLIS, Mr. DURBIN, and Ms. HIRONO) introduced the following bill; which was read twice and referred to the Committee on the Judiciary

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A BILL

To amend title 35, United States Code, to invest in inventors in the United States, maintain the United States as the leading innovation economy in the world, and protect the property rights of the inventors that grow the economy of the United States, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Promoting and Respecting Economically Vital American Innovation Leadership Act'' or the ''PREVAIL Act''.

SEC. 2. FINDINGS.

Congress finds the following:

(1) The patent property rights enshrined in the Constitution of the United States provide the foundation for the exceptional innovation environment in the United States.

(2) Reliable and effective patent protection encourages United States inventors to invest their resources in creating new inventions.

(3) United States inventors have made discoveries leading to patient cures, positive changes to the standard of living for all people in the United States, and improvements to the agricultural, telecommunications, and electronics industries, among others.

(4) The United States patent system is an essential part of the economic success of the United States.

(5) Reliable and effective patent protection improves the chances of success for individual inventors and small companies and increases the chances of securing investments for those inventors and companies.

(6) Intellectual property-intensive industries in the United States—

(A) generate tens of millions of jobs for individuals in the United States; and

(B) account for more than 1/3 of the gross domestic product of the United States.

(7) The National Security Commission on Artificial Intelligence has emphasized that—

(A) the People's Republic of China is leveraging and exploiting intellectual property as a critical tool within its national strategies for emerging technologies; and

(B) the United States has failed to similarly recognize the importance of intellectual property in securing its own national security, economic interests, and technological competitiveness.

(8) In the highly competitive global economy, the United States needs reliable and effective patent protections to safeguard national security interests and maintain its position as the most innovative country in the world.

(9) Congress last enacted comprehensive reforms of the patent system in 2011.

(10) Unintended consequences of the comprehensive 2011 reform of patent laws have become evident during the decade preceding the date of en-

actment of this Act, including the strategic filing of post-grant review proceedings to depress stock prices and extort settlements, the filing of repetitive petitions for inter partes and post-grant reviews that have the effect of harassing patent owners, and the unnecessary duplication of work by the district courts of the United States and the Patent Trial and Appeal Board, all of which drive down investment in innovation and frustrate the purpose of those patent reform laws.

(11) Efforts by Congress to reform the patent system without careful scrutiny create a serious risk of making it more costly and difficult for innovators to protect their patents from infringement, thereby—

(A) disincentivizing United States companies from innovating; and

(B) weakening the economy of the United States.

SEC. 3. PATENT TRIAL AND APPEAL BOARD.

Section 6 of title 35, United States Code, is amended—

(1) by redesignating subsections (b), (c), and (d) as subsections (c), (d), and (e), respectively;

(2) by inserting after subsection (a) the following:

''(b) CODE OF CONDUCT.—

''(1) IN GENERAL.—The Director shall prescribe regulations establishing a code of conduct for the members of the Patent Trial and Appeal Board.

''(2) CONSIDERATIONS.—In prescribing regulations under paragraph (1), the Director shall consider the Code of Conduct for United States Judges and how the provisions of that Code of Conduct may apply to the Patent Trial and Appeal Board.'';

(3) by striking subsection (d), as so redesignated, and inserting the following:

''(d) 3-MEMBER PANELS.—

''(1) IN GENERAL.—Each appeal, derivation proceeding, post-grant review, and inter partes review shall be heard by at least 3 members of the Patent Trial and Appeal Board, who shall be designated by the Director. The Patent Trial and Appeal Board may grant rehearings.

''(2) CHANGES TO CONSTITUTION OF PANEL.—After the constitution of a panel of the Patent Trial and Appeal Board under this subsection has been made public, any changes to the constitution of that panel, including changes that were made before the

constitution of the panel was made public, shall be noted in the record.

''(3) NO DIRECTION OR INFLUENCE.—An officer who has supervisory authority or disciplinary authority with respect to an administrative patent judge of the Patent Trial and Appeal Board (or a delegate of such an officer), and who is not a member of a panel described in this subsection, shall refrain from communications with the panel that direct or otherwise influence any merits decision of the panel.

''(4) INELIGIBILITY TO HEAR REVIEW.—A member of the Patent Trial and Appeal Board who participates in the decision to institute an inter partes review or a post-grant review of a patent shall be ineligible to hear the review.''; and

(4) in subsection (e), as so redesignated—

(A) in the first sentence—

(i) by striking ''this subsection'' and inserting ''the date of enactment of the Promoting and Respecting Economically Vital American Innovation Leadership Act'';

(ii) by striking ''by the Director'' and inserting ''by the Director or the Secretary''; and

(iii) by inserting ''or the Secretary, as applicable,'' after ''on which the Director''; and

(B) in the second sentence—

(i) by inserting after ''by the Director'' the following: '', or, before the date of enactment of the Promoting and Respecting Economically Vital American Innovation Leadership Act, having performed duties no longer performed by administrative patent judges,''; and

(ii) by striking ''that the administrative patent judge so appointed'' and inserting ''that the applicable administrative patent judge''.

SEC. 4. INTER PARTES REVIEW.

(a) STANDING AND REAL PARTIES IN INTEREST.—Section 311 of title 35, United States Code, is amended by adding at the end the following:

''(d) PERSONS THAT MAY PETITION.—

''(1) DEFINITION.—In this subsection, the term 'charged with infringement' means a real and sub-

stantial controversy regarding infringement of a patent exists such that the person would have standing to bring a declaratory judgment action in Federal court.

"(2) NECESSARY CONDITIONS.—A person may not file with the Office a petition to institute an inter partes review of a patent unless the person, or a real party in interest or a privy of the person, has been—

"(A) sued for infringement of the patent;

or

"(B) charged with infringement of the patent.

"(e) REAL PARTY IN INTEREST.—For purposes of this chapter, a person that, directly or through an affiliate, subsidiary, or proxy, makes a financial contribution to the preparation for, or conduct during, an inter partes review on behalf of a petitioner shall be considered a real party in interest of that petitioner.".

(b) INSTITUTION DECISION REHEARING TIMING.—Section 314 of title 35, United States Code, is amended by adding at the end the following:

"(e) REHEARING.—Not later than 45 days after the date on which a request for rehearing from a determination by the Director under subsection (b) is filed, the Di-

rector shall finally decide any request for reconsideration, rehearing, or review with respect to the determination, except that the Director may, for good cause shown, extend that 45-day period by not more than 30 days.''.

(c) ELIMINATING REPETITIVE PROCEEDINGS.—

(1) IN GENERAL.—Section 315 of title 35, United States Code, is amended—

(A) in subsection (b), by amending the second sentence to read as follows: ''The time limitation set forth in the preceding sentence shall not bar a request for joinder under subsection (d), but shall establish a rebuttable presumption against joinder for the requesting person.'';

(B) by redesignating subsections (c), (d), and (e) as subsections (d), (e), and (f), respectively;

(C) by inserting after subsection (b) the following:

''(c) SINGLE FORUM.—

''(1) IN GENERAL.—If an inter partes review is instituted challenging the validity of a patent, the petitioner, a real party in interest, or a privy of the petitioner may not file or maintain, in a civil action arising in whole or in part under section 1338 of title 28, or in a proceeding before the International

Trade Commission under section 337 of the Tariff Act of 1930 (19 U.S.C. 1337), a claim, a counterclaim, or an affirmative defense challenging the validity of any claim of the patent on any ground described in section 311(b).

''(2) CONSIDERATIONS.—In determining whether to institute a proceeding under this chapter, subject to the provisions of subsections (a)(1) and (g), the Director may not reject a petition requesting an inter partes review on the basis of the petitioner, a real party in interest, or a privy of the petitioner filing or maintaining a claim, a counterclaim, or an affirmative defense challenging the validity of the applicable patent in any civil action arising in whole or in part under section 1338 of title 28, or in a proceeding before the International Trade Commission under section 337 of the Tariff Act of 1930 (19 U.S.C. 1337).'';

(D) by amending subsection (d), as so redesignated, to read as follows:

''(d) JOINDER.—

''(1) IN GENERAL.—If the Director institutes an inter partes review, the Director, in the discretion of the Director, may join as a party to that inter partes review any person that properly files a re-

quest to join the inter partes review and a petition under section 311 that the Director, after receiving a preliminary response under section 313 or the expiration of the time for filing such a response, determines warrants the institution of an inter partes review under section 314.

''(2) TIME-BARRED PERSON.—Pursuant to paragraph (1), the Director, in the discretion of the Director, may join as a party to an inter partes review a person that did not satisfy the time limitation under subsection (b) that rebuts the presumption against joinder, except that any such person shall not be permitted to serve as the lead petitioner and shall not be permitted to maintain the inter partes review unless a petitioner that satisfied the time limitation under subsection (b) remains in the inter partes review.'';

(E) by amending subsection (e), as so redesignated, to read as follows:

''(e) MULTIPLE PROCEEDINGS.—

''(1) IN GENERAL.—Notwithstanding sections 135(a), 251, and 252, and chapter 30, after a petition to institute an inter partes review is filed, if another proceeding or matter involving the patent is before the Office—

''(A) the parties shall notify the Director of that other proceeding or matter—

''(i) not later than 30 days after the date of entry of the notice of filing date accorded to the petition; or

''(ii) if the other proceeding or matter is filed after the date on which the petition to institute an inter partes review is filed, not later than 30 days after the date on which the other proceeding or matter is filed; and

''(B) the Director shall issue a decision determining the manner in which the inter partes review or other proceeding or matter may proceed, including providing for stay, transfer, consolidation, or termination of any such matter or proceeding.

''(2) CONSIDERATIONS.—In determining whether to institute a proceeding under this chapter, the Director shall, unless the Director determines that the petitioner has demonstrated exceptional circumstances, reject any petition that presents prior art or an argument that is the same or substantially the same as prior art or an argument that previously was presented to the Office.'';

(F) by amending subsection (f), as so redesignated, to read as follows:

"(f) ESTOPPEL.—

"(1) IN GENERAL.—A petitioner that has previously requested an inter partes review of a claim in a patent under this chapter, or a real party in interest or a privy of such a petitioner, may not request or maintain another proceeding before the Office with respect to that patent on any ground that the petitioner raised or reasonably could have raised in the petition requesting or during the prior inter partes review, unless—

"(A) after the filing of the initial petition, the petitioner, or a real party in interest or a privy of the petitioner, is charged with infringement of additional claims of the patent;

"(B) a subsequent petition requests an inter partes review of only the additional claims of the patent that the petitioner, or a real party in interest or a privy of the petitioner, is later charged with infringing; and

"(C) that subsequent petition is accompanied by a request for joinder to the prior inter partes review, which overcomes the rebuttable presumption against joinder set forth in

subsection (b), and which the Director shall grant if the Director authorizes an inter partes review to be instituted on the subsequent petition under section 314.

''(2) JOINED PARTY.—Any person joined as a party to an inter partes review, and any real party in interest or any privy of such person, shall be estopped under this subsection and subsections (c)(1) and (e)(2) to the same extent as if that person, real party in interest, or privy had been the first petitioner in that inter partes review.''; and

(G) by adding at the end the following:

''(g) FEDERAL COURT AND INTERNATIONAL TRADE COMMISSION VALIDITY DETERMINATIONS.—An inter partes review of a patent claim may not be instituted or maintained if, in a civil action arising in whole or in part under section 1338 of title 28, or in a proceeding before the International Trade Commission under section 337 of the Tariff Act of 1930 (19 U.S.C. 1337), in which the petitioner, a real party in interest, or a privy of the petitioner is a party, the court, or the International Trade Commission, as applicable, has entered a final judgment that decides a challenge to the validity of the patent claim with respect to any ground described in section 311(b).''.

(2) TECHNICAL AND CONFORMING AMENDMENTS.—Section 316(a) of title 35, United States Code, is amended—

(A) in paragraph (11), by striking ''section 315(c)'' and inserting ''section 315(d)''; and

(B) in paragraph (12), by striking ''section 315(c)'' and inserting ''section 315(d)''.

(d) CONDUCT OF INTER PARTES REVIEW.—Section 316 of title 35, United States Code, is amended—

(1) in subsection (a)—

(A) by amending paragraph (5) to read as follows:

''(5) setting forth standards and procedures for discovery of relevant evidence, including that such discovery shall be limited to—

''(A) the deposition of witnesses submitting affidavits or declarations;

''(B) evidence identifying the real parties in interest of the petitioner; and

''(C) what is otherwise necessary in the interest of justice;'';

(B) by amending paragraph (9) to read as follows:

''(9) setting forth standards and procedures for—

''(A) allowing the patent owner to move to amend the patent under subsection (d) to cancel a challenged claim or propose a reasonable number of substitute claims;

''(B) allowing the Patent Trial and Appeal Board to provide guidance on substitute claims proposed by the patent owner;

''(C) allowing the patent owner to further revise proposed substitute claims after the issuance of guidance described in subparagraph (B); and

''(D) ensuring that any information submitted by the patent owner in support of any amendment entered under subsection (d), and any guidance issued by the Patent Trial and Appeal Board, is made available to the public as part of the prosecution history of the patent;'';

(C) in paragraph (12), by striking ''and'' at the end;

(D) in paragraph (13), by striking the period at the end and inserting ''; and''; and

(E) by adding at the end the following:

"(14) setting forth the standards for demonstrating exceptional circumstances under sections 303(e)(1) and 315(e)(2).";

(2) by amending subsection (e) to read as follows:

"(e) EVIDENTIARY STANDARDS.—

"(1) PRESUMPTION OF VALIDITY.—The presumption of validity under section 282(a) shall apply to previously issued claims of a patent that is challenged in an inter partes review under this chapter.

"(2) BURDEN OF PROOF.—In an inter partes review under this chapter—

"(A) the petitioner shall have the burden of proving a proposition of unpatentability of a previously issued claim of a patent by clear and convincing evidence; and

"(B) the petitioner shall have the burden of persuasion, by a preponderance of the evidence, with respect to a proposition of unpatentability for any substitute claim proposed by the patent owner."; and

(3) by adding at the end the following:

"(f) CLAIM CONSTRUCTION.—For the purposes of this chapter—

''(1) each challenged claim of a patent, and each substitute claim proposed in a motion to amend, shall be construed as the claim would be construed under section 282(b) in an action to invalidate a patent, including by construing each such claim in accordance with—

''(A) the ordinary and customary meaning of the claim as understood by a person having ordinary skill in the art to which the claimed invention pertains; and

''(B) the prosecution history pertaining to the patent; and

''(2) if a court has previously construed a challenged claim of a patent or a challenged claim term in a civil action to which the patent owner was a party, the Office shall consider that claim construction.''.

(e) SETTLEMENT.—Section 317(a) of title 35, United States Code, is amended by striking the second sentence.

(f) TIMING TO ISSUE TRIAL CERTIFICATE AND DECISIONS ON REHEARING.—Section 318 of title 35, United States Code, is amended—

(1) in subsection (b), by inserting '', not later than 60 days after the date on which the parties to the inter partes review have informed the Director

that the time for appeal has expired or any appeal has terminated,'' after ''the Director shall''; and

(2) by adding at the end the following:

''(e) REHEARING.—Not later than 90 days after the date on which a request for rehearing of a final written decision issued by the Patent and Trial Appeal Board under subsection (a) is filed, the Board or the Director shall finally decide any request for reconsideration, rehearing, or review that is submitted with respect to the decision, except that the Director may, for good cause shown, extend that 90-day period by not more than 60 days.

''(f) REVIEW BY DIRECTOR.—

''(1) IN GENERAL.—The Director may grant rehearing, reconsideration, or review of a decision by the Patent Trial and Appeal Board issued under this chapter.

''(2) REQUIREMENTS.—Any reconsideration, rehearing, or review by the Director, as described in paragraph (1), shall be issued in a separate written opinion that—

''(A) is made part of the public record; and

''(B) sets forth the reasons for the reconsideration, rehearing, or review of the applicable decision by the Patent Trial and Appeal Board.

''(g) RULE OF CONSTRUCTION.—For the purposes of an appeal permitted under section 141, any decision on rehearing, reconsideration, or review of a final written decision of the Patent Trial and Appeal Board under subsection (a) of this section that is issued by the Director shall be deemed to be a final written decision of the Patent Trial and Appeal Board.''.

(g) TIMING TO ISSUE DECISIONS ON REMAND.—Section 319 of title 35, United States Code, is amended—

(1) by striking ''A party'' and inserting the following:

''(a) IN GENERAL.—A party''; and

(2) by adding at the end the following:

''(b) TIMING ON REMAND AFTER APPEAL.—Not later than 120 days after the date on which a mandate issues from the court remanding to the Patent Trial and Appeal Board after an appeal under subsection (a), the Board or the Director shall finally decide any issue on remand, except that the Director may, for good cause shown, extend that 120-day period by not more than 60 days.''.

SEC. 5. POST-GRANT REVIEW.

(a) REAL PARTIES IN INTEREST.—Section 321 of title 35, United States Code, is amended by adding at the end the following:

''(d) REAL PARTY IN INTEREST.—For purposes of this chapter, a person that, directly or through an affiliate, subsidiary, or proxy, makes a financial contribution to the preparation for, or conduct during, a post-grant review on behalf of a petitioner shall be considered a real party in interest of that petitioner.''.

(b) TIMING TO ISSUE DECISIONS ON REHEARING.—Section 324 of title 35, United States Code, is amended by adding at the end the following:

''(f) REHEARING.—Not later than 45 days after the date on which a request for rehearing from a determination by the Director under subsection (c) is filed, the Director shall finally decide any request for reconsideration, rehearing, or review with respect to the determination, except that the Director may, for good cause shown, extend that 45-day period by not more than 30 days.''.

(c) ELIMINATING REPETITIVE PROCEEDINGS.—Section 325 of title 35, United States Code, is amended—

(1) by redesignating subsections (c) through (f) as subsections (d) through (g), respectively;

(2) by inserting after subsection (b) the following:

''(c) SINGLE FORUM.—

''(1) IN GENERAL.—If a post-grant review is instituted challenging the validity of a patent, the peti-

tioner, a real party in interest, or a privy of the petitioner may not file or maintain, in a civil action arising in whole or in part under section 1338 of title 28, or in a proceeding before the International Trade Commission under section 337 of the Tariff Act of 1930 (19 U.S.C. 1337), a claim, a counterclaim, or an affirmative defense challenging the validity of any claim of the patent.

''(2) CONSIDERATIONS.—In determining whether to institute a proceeding under this chapter, subject to the provisions of subsections (a)(1) and (h), the Director may not reject a petition requesting a post-grant review on the basis of the petitioner, a real party in interest, or a privy of the petitioner filing or maintaining a claim, a counterclaim, or an affirmative defense challenging the validity of the patent in any civil action arising in whole or in part under section 1338 of title 28, or in a proceeding before the International Trade Commission under section 337 of the Tariff Act of 1930 (19 U.S.C. 1337).'';

(3) by amending subsection (e), as so redesignated, to read as follows:

''(e) MULTIPLE PROCEEDINGS.—

"(1) IN GENERAL.—Notwithstanding sections 135(a), 251, and 252, and chapter 30, after a petition to institute a post-grant review is filed, if another proceeding or matter involving the patent is before the Office—

"(A) the parties shall notify the Director of that other proceeding or matter—

"(i) not later than 30 days after the date of entry of the notice of filing date accorded to the petition; or

"(ii) if the other proceeding or matter is filed after the date on which the petition to institute an inter partes review is filed, not later than 30 days after the date on which the other proceeding or matter is filed; and

"(B) the Director shall issue a decision determining the manner in which the post-grant review or other proceeding or matter may proceed, including providing for stay, transfer, consolidation, or termination of any such matter or proceeding.

"(2) CONSIDERATIONS.—In determining whether to institute a proceeding under this chapter, the Director shall, unless the Director determines that

the petitioner has demonstrated exceptional circumstances, reject any petition that presents prior art or an argument that is the same or substantially the same as prior art or an argument that previously was presented to the Office.'';

(4) by amending subsection (f), as so redesignated, to read as follows:

''(f) ESTOPPEL.—

''(1) IN GENERAL.—A petitioner that has previously requested a post-grant review of a claim in a patent under this chapter, or a real party in interest or a privy of a petitioner, may not request or maintain another proceeding before the Office with respect to that patent on any ground that the petitioner raised or reasonably could have raised in the petition requesting or during the prior post-grant review, unless—

''(A) after the filing of the initial petition, the petitioner, or a real party in interest or a privy of the petitioner, is charged with infringement of additional claims of the patent;

''(B) a subsequent petition requests an inter partes review of only the additional claims of the patent that the petitioner, or a real party

in interest or a privy of the petitioner, is later charged with infringing; and

"(C) that subsequent petition is accompanied by a request for joinder to the prior post-grant review, which the Director shall grant if the Director authorizes a post-grant review to be instituted on the subsequent petition under section 324.

"(2) JOINED PARTY.—Any person joined as a party to a post-grant review, and any real party in interest or any privy of such person, shall be estopped under this subsection and subsections (c)(1) and (e)(2) to the same extent as if that person, real party in interest, or privy had been the first petitioner in that post-grant review."; and

(5) by adding at the end the following:

"(h) FEDERAL COURT AND INTERNATIONAL TRADE COMMISSION VALIDITY DETERMINATIONS.—A post-grant review of a patent claim may not be instituted or maintained if, in a civil action arising in whole or in part under section 1338 of title 28, or in a proceeding before the International Trade Commission under section 337 of the Tariff Act of 1930 (19 U.S.C. 1337), in which the petitioner, a real party in interest, or a privy of the petitioner is a party, the court, or the International Trade Commis-

sion, as applicable, has entered a final judgment that decides a challenge to the validity of the patent claim.''.

(d) CONDUCT OF POST-GRANT REVIEW.—Section 326 of title 35, United States Code, is amended—

(1) in subsection (a)—

(A) by amending paragraph (5) to read as follows:

''(5) setting forth standards and procedures for discovery of relevant evidence, including that such discovery shall be limited to—

''(A) the deposition of witnesses submitting affidavits or declarations;

''(B) evidence identifying the real parties in interest of the petitioner; and

''(C) what is otherwise necessary in the interest of justice;'';

(B) by amending paragraph (9) to read as follows:

''(9) setting forth standards and procedures for—

''(A) allowing the patent owner to move to amend the patent under subsection (d) to cancel a challenged claim or propose a reasonable number of substitute claims;

"(B) allowing the Patent Trial and Appeal Board to provide guidance on substitute claims proposed by the patent owner;

"(C) allowing the patent owner to further revise proposed substitute claims after the issuance of guidance described in subparagraph (B); and

"(D) ensuring that any information submitted by the patent owner in support of any amendment entered under subsection (d), and any guidance issued by the Patent Trial and Appeal Board, is made available to the public as part of the prosecution history of the patent;";

(C) in paragraph (11), by striking "section 325(c)" and inserting "section 325(d)";

(D) in paragraph (12), by striking the period at the end and inserting "; and"; and

(E) by adding at the end the following:

"(13) setting forth the standards for demonstrating exceptional circumstances under section 325(e)(2).";

(2) by amending subsection (e) to read as follows:

"(e) EVIDENTIARY STANDARDS.—

"(1) PRESUMPTION OF VALIDITY.—The presumption of validity under section 282(a) shall apply to previously issued claims of a patent that is challenged in a post-grant review under this chapter.

"(2) BURDEN OF PROOF.—In a post-grant review under this chapter—

"(A) the petitioner shall have the burden of proving a proposition of unpatentability of a previously issued claim of a patent by clear and convincing evidence; and

"(B) the petitioner shall have the burden of persuasion, by a preponderance of the evidence, with respect to a proposition of unpatentability for any substitute claim proposed by the patent owner."; and

(3) by adding at the end the following:

"(f) CLAIM CONSTRUCTION.—For the purposes of this chapter—

"(1) each challenged claim of a patent, and each substitute claim proposed in a motion to amend, shall be construed as the claim would be construed under section 282(b) in an action to invalidate a patent, including by construing each such claim in accordance with—

''(A) the ordinary and customary meaning of the claim as understood by a person having ordinary skill in the art to which the claimed invention pertains; and

''(B) the prosecution history pertaining to the patent; and

''(2) if a court has previously construed a challenged claim of a patent or a challenged claim term in a civil action to which the patent owner was a party, the Office shall consider that claim construction.''.

(e) SETTLEMENT.—Section 327(a) of title 35, United States Code, is amended by striking the second sentence.

(f) TIMING TO ISSUE TRIAL CERTIFICATES AND DECISIONS ON REHEARING.—Section 328 of title 35, United States Code, is amended—

(1) in subsection (b), by inserting '', not later than 60 days after the date on which the parties to the post-grant review have informed the Director that the time for appeal has expired or any appeal has terminated,'' after ''the Director shall''; and

(2) by adding at the end the following:

''(e) REHEARING.—Not later than 90 days after the date on which a request for rehearing of a final written decision issued by the Patent and Trial Appeal Board

under subsection (a) is filed, the Board or the Director shall finally decide any request for reconsideration, rehearing, or review that is submitted with respect to the decision, except that the Director may, for good cause shown, extend that 90-day period by not more than 60 days.

''(f) REVIEW BY DIRECTOR.—

''(1) IN GENERAL.—The Director may grant rehearing, reconsideration, or review of a decision by the Patent Trial and Appeal Board issued under this chapter.

''(2) REQUIREMENTS.—Any reconsideration, rehearing, or review by the Director, as described in paragraph (1), shall be issued in a separate written opinion that—

''(A) is made part of the public record; and

''(B) sets forth the reasons for the reconsideration, rehearing, or review of the decision by the Patent Trial and Appeal Board.

''(g) RULE OF CONSTRUCTION.—For the purposes of an appeal permitted under section 141, any decision on rehearing, reconsideration, or review of a final written decision of the Patent Trial and Appeal Board under subsection (a) of this section that is issued by the Director shall be deemed to be a final written decision of the Patent Trial and Appeal Board.''.

(g) TIMING TO ISSUE DECISIONS ON REMAND.—Section 329 of title 35, United States Code, is amended—

(1) by striking ''A party'' and inserting the following:

''(a) IN GENERAL.—A party''; and

(2) by adding at the end the following:

''(b) TIMING ON REMAND AFTER APPEAL.—Not later than 120 days after the date on which a mandate issues from the court remanding to the Patent Trial and Appeal Board after an appeal under subsection (a), the Board or the Director shall finally decide any issue on remand, except that the Director may, for good cause shown, extend that 120-day period by not more than 60 days.''.

SEC. 6. REEXAMINATION OF PATENTS.

(a) REQUEST FOR REEXAMINATION.—Section 302 of title 35, United States Code, is amended by inserting after the second sentence the following: ''The request must identify all real parties in interest and certify that reexamination is not barred under section 303(d).''.

(b) REEXAMINATION BARRED.—Section 303 of title 35, United States Code, is amended—

(1) in subsection (a), by striking the third sentence; and

(2) by adding at the end the following:

''(d) An ex parte reexamination may not be ordered if the request for reexamination is filed more than 1 year after the date on which the requester or a real party in interest or a privy of the requester is served with a complaint alleging infringement of the patent. For purposes of this chapter, a person that directly or through an affiliate, subsidiary, or proxy makes a financial contribution to the preparation for, or conduct during, an ex parte reexamination on behalf of a requester shall be considered a real party in interest of the requester.

''(e) In determining whether to order an ex parte reexamination, the Director—

''(1) shall, unless the Director determines that the requestor has demonstrated exceptional circumstances, reject any request that presents prior art or an argument that is the same or substantially the same as prior art or an argument that previously was presented to the Office; and

''(2) may reject any request that the Director determines has used a prior Office decision as a guide to correct or bolster a previous deficient request filed under this chapter or a previous deficient petition filed under chapter 31 or 32.''.

(c) REEXAMINATION ORDER BY DIRECTOR.—Section 304 of title 35, United States Code, is amended, in the

first sentence, by inserting after ''resolution of the question'' the following: '', unless the Director determines that the request for reexamination should be rejected under subsection (d) or (e) of section 303, in which case the Director shall issue an order denying reexamination''.

SEC. 7. ELIMINATION OF USPTO FEE DIVERSION.

(a) FUNDING.—Section 42 of title 35, United States Code, is amended—

(1) in subsection (a), by striking ''All fees'' and inserting the following:

''(a) FEES FOR SERVICE BY PTO.—All fees'';

(2) in subsection (b)—

(A) by striking ''All fees paid to the Director and all appropriations'' and inserting the following:

''(b) INNOVATION PROMOTION FUND.—All fees paid to the Director''; and

(B) by striking ''Patent and Trademark Office Appropriation Account'' and inserting ''United States Patent and Trademark Office Innovation Promotion Fund'';

(3) by striking subsection (c) and inserting the following:

''(c) COLLECTION OF FUNDS FOR PTO ACTIVITIES.—

''(1) IN GENERAL.—Fees authorized in this title or any other Act to be charged or established by the Director shall be collected by the Director and shall be available to the Director until expended to carry out the activities of the Patent and Trademark Office.

''(2) USE OF FEES.—

''(A) PATENT FEES.—Any fees that are collected under this title, and any surcharges on such fees, may only be used for expenses of the Office relating to the processing of patent applications and for other activities, services, and materials relating to patents and to cover a proportionate share of the administrative costs of the Office.

''(B) TRADEMARK FEES.—Any fees that are collected under section 31 of the Trademark Act of 1946 (as defined in subsection (d)(1)) (15 U.S.C. 1113), and any surcharges on such fees, may only be used for expenses of the Office relating to the processing of trademark registrations and for other activities, services, and materials relating to trademarks and to cover a proportionate share of the administrative costs of the Office.'';

(4) by redesignating subsections (d) and (e) as subsections (e) and (f), respectively;

(5) by inserting after subsection (c) the following:

''(d) REVOLVING FUND.—

''(1) DEFINITIONS.—In this subsection—

''(A) the term 'Fund' means the United States Patent and Trademark Office Innovation Promotion Fund established under paragraph (2); and

''(B) the term 'Trademark Act of 1946' means the Act entitled 'An Act to provide for the registration and protection of trademarks used in commerce, to carry out the provisions of certain international conventions, and for other purposes', approved July 5, 1946 (15 U.S.C. 1051 et seq.) (commonly referred to as the 'Trademark Act of 1946' or the 'Lanham Act').

''(2) ESTABLISHMENT.—There is established in the Treasury a revolving fund to be known as the 'United States Patent and Trademark Office Innovation Promotion Fund'.

''(3) DERIVATION OF RESOURCES.—There shall be deposited into the Fund any fees collected under—

''(A) this title; or

''(B) the Trademark Act of 1946.

''(4) EXPENSES.—Amounts deposited into the Fund under paragraph (3) shall be available, without fiscal year limitation, to cover—

''(A) to the extent consistent with the limitation on the use of fees under subsection (c), all expenses, including all administrative and operating expenses, determined by the Director to be ordinary and reasonable, incurred by the Director for the continued operation of all services, programs, activities, and duties of the Office relating to patents and trademarks, as such services, programs, activities, and duties are described under—

''(i) this title; and

''(ii) the Trademark Act of 1946; and

''(B) all expenses incurred pursuant to any obligation, representation, or other commitment of the Office.'';

(6) in subsection (e), as so redesignated, by striking ''The Director'' and inserting the following:

''(e) REFUNDS.—The Director''; and

(7) in subsection (f), as so redesignated, by striking ''The Secretary'' and inserting the following:

''(f) REPORT.—The Secretary''.

(b) EFFECTIVE DATE; TRANSFER FROM AND TERMINATION OF OBSOLETE FUNDS.—

(1) EFFECTIVE DATE.—The amendments made by subsection (a) shall take effect on the first day of the first fiscal year that begins on or after the date of enactment of this Act.

(2) REMAINING BALANCES.—On the effective date described in paragraph (1), there shall be deposited in the United States Patent and Trademark Office Innovation Promotion Fund established under section 42(d)(2) of title 35, United States Code (as added by subsection (a)), any available unobligated balances remaining in the Patent and Trademark Office Appropriation Account, and in the Patent and Trademark Fee Reserve Fund established under section 42(c)(2) of title 35, United States Code, as in effect on the day before that effective date.

(3) TERMINATION OF RESERVE FUND.—Upon the payment of all obligated amounts in the Patent and Trademark Fee Reserve Fund under paragraph

(2), the Patent and Trademark Fee Reserve Fund shall be terminated.

SEC. 8. INSTITUTIONS OF HIGHER EDUCATION.

Section 123(d) of title 35, United States Code, is amended to read as follows:

"(d) INSTITUTIONS OF HIGHER EDUCATION.—

"(1) DEFINITION.—In this subsection, the term 'institution of higher education' has the meaning given the term in section 101(a) of the Higher Education Act of 1965 (20 U.S.C. 1001(a)).

"(2) INCLUSIONS.—For purposes of this section, a micro entity shall include an applicant who certifies that—

"(A) the applicant's employer, from which the applicant obtains the majority of the applicant's income, is an institution of higher education;

"(B) the applicant has assigned, granted, conveyed, or is under an obligation by contract or law to assign, grant, or convey, a license or other ownership interest in the particular applications to an institution of higher education;

"(C) the applicant is an institution of higher education; or

"(D) the applicant is an organization described in section 501(c)(3) of the Internal Revenue Code of 1986 and exempt from taxation under section 501(a) of such Code that holds title to patents and patent applications on behalf of an institution of higher education for the purpose of facilitating commercialization of the technologies of the patents and patent applications.".

SEC. 9. ASSISTING SMALL BUSINESSES IN THE UNITED STATES PATENT SYSTEM.

(a) DEFINITION.—In this section, the term "small business concern" has the meaning given the term in section 3 of the Small Business Act (15 U.S.C. 632).

(b) SMALL BUSINESS ADMINISTRATION REPORT.—Not later than 1 year after the date of the enactment of this Act, the Administrator of the Small Business Administration, using existing resources, shall submit to the Committee on Small Business and Entrepreneurship of the Senate and the Committee on Small Business of the House of Representatives a report analyzing the impact of—

(1) patent ownership by small business concerns; and

(2) civil actions against small business concerns arising under title 35, United States Code, relating to patent infringement.

(c) FREE ONLINE AVAILABILITY OF PUBLIC SEARCH FACILITY MATERIALS.—Section 41(i) of title 35, United States Code, is amended by adding at the end the following:

"(5) FREE ONLINE AVAILABILITY OF PUBLIC SEARCH FACILITY MATERIALS.—The Director shall make available online and at no charge all patent and trademark information that is available at the Public Search Facility of the Office located in Alexandria, Virginia, including, except to the extent that licenses with third-party contractors would make such provision financially unviable—

"(A) search tools and databases;

"(B) informational materials; and

"(C) training classes and materials.".

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118TH CONGRESS
2D SESSION

S. l l

To amend title 35, United States Code, to establish a rebuttable presumption that a permanent injunction should be granted in certain circumstances, and for other purposes.

IN THE SENATE OF THE UNITED STATES

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Mr. COONS (for himself and Mr. COTTON) introduced the following bill; which was read twice and referred to the Committee on l l l l l l l l l l

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A BILL

To amend title 35, United States Code, to establish a rebuttable presumption that a permanent injunction should be granted in certain circumstances, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Realizing Engineering, Science, and Technology Opportunities by Restoring Exclusive Patent Rights Act of 2024'' or the ''RESTORE Patent Rights Act of 2024''.

SEC. 2. FINDINGS.

Congress finds the following:

(1) Securing effective and reliable patent protection for new technologies is critical to maintaining the competitive advantage of the United States in the global innovation economy.

(2) The Constitution of the United States empowers Congress to grant inventors the ''exclusive Right'' to their inventions in order to ''promote the Progress of Science and the useful Arts''.

(3) The right to prevent others from making, using, offering to sell, selling, or importing a patented invention without authority from the inventor is the core of the patent right, ensuring that an inventor enjoys, for a limited time, the sole benefit of the inventor's invention or discovery.

(4) Congress and the courts of the United States have long secured the constitutionally protected patent right through the traditional equitable remedy of an injunction.

(5) Given the irreparable harm that is caused by multiple acts of infringement or willful infringement of a patent, courts historically presumed that an injunction should be granted to prevent such acts, with a burden on defendants to rebut such a presumption with standard equitable defenses.

(6) Recently, courts have ended the approach described in paragraph (5), which contradicts the traditional, historical practice governing the equitable remedy described in that paragraph.

(7) Eliminating the traditional, historical equitable practice of applying a rebuttable presumption of injunctive relief in the case of continuing acts of infringement or willful infringement of a patent has—

(A) substantially reduced the ability of patent owners to obtain injunctions to stop continuing or willful infringement of patents; and

(B) created incentives for large, multinational companies to commit predatory acts of infringement, especially with respect to patents owned by undercapitalized entities, such as individual inventors, institutions of higher education, startups, and small or medium-sized enterprises.

SEC. 3. REBUTTABLE PRESUMPTION THAT INJUNCTIVE RELIEF IS WARRANTED.

Section 283 of title 35, United States Code, is amended—

(1) by striking ‘‘The several’’ and inserting the following:

''(a) IN GENERAL.—The several''; and

(2) by adding at the end the following:

''(b) REBUTTABLE PRESUMPTION.—If, in a case under this title, the court enters a final judgment finding infringement of a right secured by patent, the patent owner shall be entitled to a rebuttable presumption that the court should grant a permanent injunction with respect to that infringing conduct.''.

118TH CONGRESS
1ST SESSION

S. 2780

To require sponsors of drug applications and holders of approved applications to provide certain submissions and communications to the Food and Drug Administration and the United States Patent and Trademark Office.

IN THE SENATE OF THE UNITED STATES

SEPTEMBER 13, 2023

Ms. HASSAN (for herself and Mr. BRAUN) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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A BILL

To require sponsors of drug applications and holders of approved applications to provide certain submissions and communications to the Food and Drug Administration and the United States Patent and Trademark Office.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Medication Affordability and Patent Integrity Act''.

SEC. 2. DISCLOSURE OF INFORMATION.

(a) IN GENERAL.—

(1) IN GENERAL.—Section 505(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)) is amended by adding at the end the following:

''(7)(A) With respect to any application submitted under this subsection or approved under subsection (c), the sponsor of the application or holder of the approved application shall, for any applicable patent—

''(i) certify to the Food and Drug Administration that the information described in subparagraph (B) that is submitted to the Secretary is complete and consistent with the information such sponsor or holder provided to the United States Patent and Trademark Office and any communications such sponsor or holder had with the United States Patent and Trademark Office; and

''(ii)(I) submit to the United States Patent and Trademark Office any information material to patentability with respect to such applicable patent that the sponsor or holder submits to the Food and Drug Administration, and any communications with the Food and Drug Administration that are related to such submissions; and

''(II) certify to the United States Patent and Trademark Office that the information provided

under subclause (I) is complete and consistent with the information such sponsor or holder provided to the Food and Drug Administration and any communications such sponsor or holder had with the Food and Drug Administration.

''(B) The information described in this subparagraph is—

''(i) any statement or characterization of analytical or clinical data disclosed by the sponsor of the application or holder of the approved application under this section to the United States Patent and Trademark Office that has been, or will be, submitted to the Food and Drug Administration to support the approval of an application under this section;

''(ii) any statement or characterization with respect to an applicable patent, including any statement or characterization of prior art, submitted by the sponsor of the application or holder of the approved application to the United States Patent and Trademark Office in support of patentability; and

''(iii) other information, as the Secretary or the Secretary of Commerce may require.

''(C) In this paragraph, the term 'applicable patent' means—

''(i) a patent that—

''(I) claims a drug that is the subject of an application described in subparagraph (A), including any patent that claims, with respect to such a drug, a formulation or composition, method of use, or method of manufacturing; and

''(II) is issued, assigned, or licensed to the sponsor of the application or holder of the approved application described in subparagraph (A);

''(ii) an application for a patent described in clause (i)(I) that is sought by the sponsor of the application or holder of the approved application described in subparagraph (A); or

''(iii) such other patent or application for a patent as the Secretary determines appropriate.

''(D)(i) Except as provided in clause (ii), subparagraph (A) shall apply with respect to any original application submitted under this subsection on or after the date of enactment of the Medication Affordability and Patent Integrity Act and to any amendments or supplements to such original application.

''(ii) In the case of an application submitted before the date of enactment of the Medication Affordability and

Patent Integrity Act, the requirements of subparagraph (A) apply with respect to—

''(I) any applicable patent issued on or after such date of enactment; and

''(II) in the case of an applicable patent issued before such date of enactment, only to submissions and communications described in clauses (i) and (ii) of subparagraph (A) made on or after such date of enactment.''.

(2) CONDITION FOR APPROVAL.—Section 505(d)(6) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 505(d)(6)) is amended by inserting

'', or the sponsor failed to comply with a requirement of subsection (b)(7)(A)(i)'' after ''subsection (b)''.

(b) BIOLOGICAL PRODUCT APPLICATIONS.—Section 351(a)(2) of the Public Health Service Act (42 U.S.C. 262(a)(2)) is amended by adding at the end the following:

''(F)(i) With respect to any application submitted under this subsection or biological product licensed under this subsection, the sponsor of the application or holder of the licensure shall, for any applicable patent—

''(I) certify to the Food and Drug Administration that the information described in clause (ii) that is submitted to the Secretary is complete and con-

sistent with the information such sponsor or holder provided to the United States Patent and Trademark Office and any communications such sponsor or holder had with the United States Patent and Trademark Office; and

''(II)(aa) submit to the United States Patent and Trademark Office any information material to patentability with respect to such applicable patent that the sponsor or holder submits to the Food and Drug Administration, and any communications with the Food and Drug Administration that are related to such submissions; and

''(bb) certify to the United States Patent and Trademark Office that the information provided under item (aa) is complete and consistent with the information such sponsor or holder provided to the Food and Drug Administration and any communications such sponsor or holder had with the Food and Drug Administration.

''(ii) The information described in this clause is—

''(I) any statement or characterization of analytical or clinical data disclosed by the sponsor of the application or holder of the approved application under this section to the United States Patent and Trademark Office that has been, or will be, sub-

mitted to the Food and Drug Administration to support the approval of an application under this section;

''(II) any statement or characterization with respect to an applicable patent, including any statement or characterization of prior art, submitted by the sponsor of the application or holder of the approved application to the United States Patent and Trademark Office in support of patentability; and

''(III) other information, as the Secretary or the Secretary of Commerce may require.

''(iii) In this subparagraph, the term 'applicable patent' means—

''(I) a patent—

''(aa) with respect to which a reference product sponsor could reasonably assert a claim of patent infringement, if a person not licensed by the reference product sponsor engaged in the making, using, offering to sell, selling, or importing into the United States of a biological product that relies on such patent; and

''(bb) that is issued, assigned, or exclusively licensed to the sponsor of the application or holder of the licensure described in clause (i);

''(II) an application for a patent described in subclause (I)(aa) that is sought by the sponsor of the application or holder of the licensure described in clause (i); or

''(III) such other patent or application for a patent as the Secretary determines appropriate.

''(iv)(I) Except as provided in subclause (II), clause (i) shall apply with respect to any original application submitted under this subsection on or after the date of enactment of the Medication Affordability and Patent Integrity Act and to any amendments or supplements to such original application.

''(II) In the case of an application submitted under this subsection before the date of enactment of the Medication Affordability and Patent Integrity Act, the requirements of clause (i) apply with respect to—

''(aa) any applicable patent issued on or after such date of enactment; and

''(bb) in the case of an applicable patent issued before such date of enactment, only to submissions and communications described in subclauses (I) and (II) of clause (i) made on or after such date of enactment.

''(v) Notwithstanding subparagraph (C), the Secretary may not approve an application for a biological

product if the sponsor of such application is out of compliance with the requirements of clause (i)(I) with respect to such application.''.

(c) ENFORCEMENT.—

(1) FDA ENFORCEMENT.—Section 301 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331) is amended by adding at the end the following:

''(jjj) A failure to comply with a requirement of section 505(b)(7) of this Act or section 351(a)(2)(F) of the Public Health Service Act.''.

(2) DEFENSE AGAINST PATENT INFRINGEMENT ACTIONS.—

(A) IN GENERAL.—Chapter 28 of title 35, United States Code, is amended by adding at the end the following:

''§ 274. Non-disclosure defense to infringement of drug patent

''A person shall be entitled to a defense under section 282(b) in an action asserting infringement of an applicable patent (as defined in paragraph (7)(B) of section 505(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)) or subparagraph (F)(ii) of section 351(a)(2) of the Public Health Service Act (42 U.S.C. 262(a)(2))) if the owner or predecessor owner of the applicable patent violated paragraph (7)(A) of such section

505(b) or subparagraph (F)(i) of such section 351(a)(2) with respect to the applicable patent by negligently or intentionally failing to disclose any information required to be disclosed pursuant to such paragraph (7)(A) or such subparagraph (F)(i).''.

(B) TECHNICAL AND CONFORMING AMENDMENT.—The table of sections for chapter 28 of title 35, United States Code, is amended by adding at the end the following:

''274. Non-disclosure defense to infringement of drug patent.''.

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~~S 2780 IS~~

~~II~~
~~118th CONGRESS~~
~~1st Session~~ **Purpose: In the nature of a substitute.**

S. 2780

To require sponsors of drug applications and holders of approved applications to provide certain submissions and communications to the Food and Drug Administration and the United States Patent and Trademark Office.

~~IN THE SENATE OF THE UNITED STATES~~

~~September 13, 2023~~

~~Ms. Hassan (for herself and Mr. Braun) introduced the following bill; which was read twice and referred~~ **Referred** to the Committee on ~~Health, Education, Labor, and Pensions~~ **_____ and ordered to be printed**

~~A BILL~~ **Ordered to lie on the table and to be printed**

~~TO REQUIRE SPONSORS OF DRUG APPLICATIONS AND HOLDERS OF APPROVED APPLICATIONS TO PROVIDE CERTAIN SUBMISSIONS AND COMMUNICATIONS TO THE FOOD AND DRUG ADMINISTRATION AND THE UNITED STATES PATENT AND TRADEMARK OFFICE.~~ **AMENDMENT IN THE NATURE OF A SUBSTITUTE INTENDED TO BE PROPOSED BY _____**

~~Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,~~ **Viz:**

Strike all after the enacting clause and insert the following:

SECTION 1. SHORT TITLE.

This Act may be cited as the "Medication Affordability and Patent Integrity Act".

SEC. 2. DISCLOSURE OF INFORMATION.

(a) In General.—

(1) IN GENERAL.—Section 505(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)) is amended by adding at the end the following:

"(7)(A) With respect to any application submitted under this subsection or approved under subsection (c), the sponsor of the application or holder of the approved application shall, for any applicable patent—

"(i) certify to the Food and Drug Administration that the information described in subparagraph (B) that is submitted to the Secretary is ~~complete and~~**, to the best knowledge of the sponsor or holder,** consistent with the information such sponsor or holder provided to the United States Patent and Trademark Office and any communications such sponsor or holder had with the United States Patent and Trademark Office; and

"(ii)(I) submit to the United States Patent and Trademark Office any information material to patentability with respect to such applicable patent that the sponsor or holder submits to the Food and Drug Administration, and any ~~communications with~~ **information** the Food and Drug Administration ~~that are related to such submissions~~ **provided in response**; and

"(II) certify to the United States Patent and Trademark Office that the ~~information provided under subclause (I) is complete and~~ **submission under subclause (I), to the best knowledge of the sponsor or holder, includes all information material to patentability, and is** consistent with the information such sponsor or holder provided to the Food and Drug Administration and any communications such sponsor or holder had with the Food and Drug Administration.

"(B) The information described in this subparagraph **is limited to information that is material to patentability, as defined in regulations promulgated by the United States Patent and Trademark Office, and that** is—

"(i) any statement or characterization of analytical ~~or clinical data~~ **data set forth in the chemistry, manufacturing, and controls section of a new drug application** disclosed by the sponsor of the application or holder of the approved application under this section to the United States Patent and Trademark Office that has been, or will be, submitted to the Food and Drug Administration to support the approval of an application under this section;

"(ii) any statement or characterization with respect to an applicable patent, including any statement or characterization of prior art, submitted by the sponsor of the application or holder of the approved application to the United States Patent and Trademark Office in support of patentability; ~~and~~ **or**

"(iii) other information, as the Secretary or the Secretary of Commerce may **by regulation** require.

"(C) In this paragraph, the term 'applicable patent' means—

"(i) a patent that—

"(I) claims a drug that is the subject of an application described in subparagraph (A),

including any patent that claims, with respect to such a drug, a formulation or composition, method of use, or method of manufacturing; and

"(II) is issued, assigned, or licensed to the sponsor of the application or holder of the approved application described in subparagraph (A);

"(ii) an application for a patent described in clause (i)(I) that is sought by the sponsor of the application or holder of the approved application described in subparagraph (A); or

"(iii) such other patent or application for a patent as the Secretary ~~determines appropriate.~~ **or the Secretary of Commerce may by regulation require.**

"(D)(i) Except as provided in clause (ii), subparagraph (A) shall apply with respect to any original application submitted under this subsection on or after the date of enactment of the Medication Affordability and Patent Integrity Act and to any amendments or supplements to such original application.

"(ii) In the case of an application submitted before the date of enactment of the Medication Affordability and Patent Integrity Act, the requirements of subparagraph (A) apply **only** with respect to—

"(I) any applicable patent issued on or after such date of enactment; and

"(II) in the case of an applicable patent issued before such date of enactment, only to submissions and communications described in clauses (i) and (ii) of subparagraph (A) made on or after such date of ~~enactment.".~~ **enactment.**

~~(2) Condition for approval.—Section 505(d)(6)~~**"(E)(i) Any information that the sponsor or holder of the application has submitted to or received from the Food and Drug Administration that is submitted to the United States Patent and Trademark office to fulfill the requirements of subparagraph (A) shall remain subject to application protections for trade secret or confidential information or financial information as if the information were held by the Food and Drug Administration.**

"(ii) The United States Patent and Trademark Office shall, as necessary, update its applicable regulations or establish new procedures to ensure compliance with clause (i) for information submitted under this paragraph.".

(2) INCLUSION OF CERTIFICATIONS IN APPLICATION.—Section 505(b)(1)(A) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. ~~505(d)(6)) is amended by inserting ", or the sponsor failed to comply with a requirement of subsection (b)(7)(A)(i)" after "subsection (b)".~~ **355(b)(1)(A)) is amended—**

(A) in clause (vii), by striking "and" at the end;

(B) in clause (viii)(II), by striking the period and inserting "; and"; and

(C) by adding at the end the following:

"(ix) with respect to each patent listed in the application pursuant to clause (viii) that is an applicable patent (as defined in paragraph (7)(C)), the certifications required under clauses (i) and (ii)(II) of paragraph (7)(A).".

(b) Biological Product Applications.—Section 351(a)(2) of the Public Health Service Act (42 U.S.C. 262(a)(2)) is amended by adding at the end the following:

"(F)(i) With respect to any application submitted under this subsection or biological product licensed under this subsection, the sponsor of the application or holder of the licensure shall, for any applicable patent—

"(I) certify to the Food and Drug Administration that the information described in clause (ii) that is submitted to the Secretary is ~~complete and~~**, to the best knowledge of the sponsor or holder,** consistent with the information such sponsor or holder provided to the United States Patent and Trademark Office and any communications such sponsor or holder had with the United States Patent and Trademark Office; and

"(II)(aa) submit to the United States Patent and Trademark Office any information material to patentability with respect to such applicable patent that the sponsor or holder submits to the Food and Drug Administration ~~, and any communications with the Food and Drug Administration that are related to such submissions~~ **provided in response**; and

"(bb) certify to the United States Patent and Trademark Office that the ~~information provided under item (aa) is complete and~~ **submission under item (aa), to the best knowledge of the sponsor or holder, includes all information material to patentability and is** consistent with the information such sponsor or holder provided to the Food and Drug Administration and any communications such sponsor or holder had with the Food and Drug Administration.

"(ii) The information described in this clause ~~is—~~ **is limited to information that is material to patentability, as defined in regulations promulgated by the United States Patent and Trademark Office, and that is——**

"(I) any statement or characterization of analytical ~~or clinical data~~ **data set forth in the chemistry, manufacturing, and controls section in a biological product license application** disclosed by the sponsor of the application or holder of the approved application under this section to the United States Patent and Trademark Office that has been, or will be, submitted to the Food and Drug Administration to support the approval of an application under this section;

"(II) any statement or characterization with respect to an applicable patent, including any statement or characterization of prior art, submitted by the sponsor of the application or holder of the approved application to the United States Patent and Trademark Office in support of patentability; ~~and~~ **or**

"(III) other information, as the Secretary or the Secretary of Commerce may **by regulation** require.

"(iii) In this subparagraph, the term 'applicable patent' means—

"(I) a patent—

"(aa) ~~with respect to which a reference product sponsor could reasonably assert a claim of patent infringement, if a person not licensed by the reference product sponsor engaged in the making, using, offering to sell, selling, or importing into the United States of a biological product that relies on such patent~~ **claims a biological product that is the subject of an application described in clause (i), including any patent that claims, with respect to such biological product, a formulation or composition, method of use, or method of manufacturing**; and

"(bb) that is issued, assigned, or exclusively licensed to the sponsor of the application or holder of the licensure described in clause (i);

"(II) an application for a patent described in subclause (I)(aa) that is sought by the sponsor of the application or holder of the licensure described in clause (i); or

"(III) such other patent or application for a patent as the Secretary ~~determines appropriate~~ **or Secretary of Commerce may by regulation require**.

"(iv)(I) Except as provided in subclause (II), clause (i) shall apply with respect to any original application submitted under this subsection on or after the date of enactment of the Medication Affordability and Patent Integrity Act and to any amendments or supplements to such original application.

"(II) In the case of an application submitted under this subsection before the date of enactment of the Medication Affordability and Patent Integrity Act, the requirements of clause (i) apply **only** with respect to—

"(aa) any applicable patent issued on or after such date of enactment; and

"(bb) in the case of an applicable patent issued before such date of enactment, only to submissions and communications described in subclauses (I) and (II) of clause (i) made on or after such date of enactment.

"(v) ~~Notwithstanding subparagraph (C), the Secretary may not approve an application for a biological product if the sponsor of such application is out of compliance with~~**(I) Any information that the sponsor of the application or holder of the licensure has submitted to or received from the Food and Drug Administration that is submitted to the United States Patent and Trademark office to fulfill** the requirements of clause (i) ~~(I) with respect to such application.".~~ **shall remain subject to application protections for trade secret or confidential information or financial information as if the information were held by the Food and Drug Administration.**

"(II) The United States Patent and Trademark Office shall, as necessary, update its applicable regulations or create new procedures to ensure compliance with subclause (I) for information submitted under this subparagraph.".

(c) Enforcement.—

(1) FDA ENFORCEMENT.—Section 301 **(q)(1)** of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331~~) is amended~~**(q)(1)) is amended—**

(A) in clause (B), by striking "; or" and inserting a semicolon;

(B) in clause (C), by striking the period and inserting "; or"; and

(C) by adding at the end the following:

~~"(jjj) A failure to comply with a requirement of~~**"(D) to submit the certification required under** section 505(b)(7) of this Act or section 351(a)(2)(F) of the Public Health Service Act.".

(2) DEFENSE AGAINST PATENT INFRINGEMENT ACTIONS.—

(A) IN GENERAL.—Chapter 28 of title 35, United States Code, is amended by adding at the end the following:

"274. Non-disclosure defense to infringement of drug patent

"A person shall be entitled to a defense under section 282(b) in an action asserting infringement of an applicable patent (as defined in paragraph (7)(B) of section 505(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)) or subparagraph (F)(ii) of section 351(a)(2) of the Public Health Service Act (42 U.S.C. 262(a)(2))~~,~~ if the owner or predecessor owner of the applicable patent violated paragraph (7)(A) of such section 505(b) or subparagraph (F)(i) of such section 351(a)(2) with respect to the applicable patent by negligently or intentionally failing to disclose any information required to be disclosed pursuant to such paragraph (7)(A) or such subparagraph (F)(i).".

(B) TECHNICAL AND CONFORMING AMENDMENT.—The table of sections for chapter 28 of title 35, United States Code, is amended by adding at the end the following:

"274. Non-disclosure defense to infringement of drug patent.".