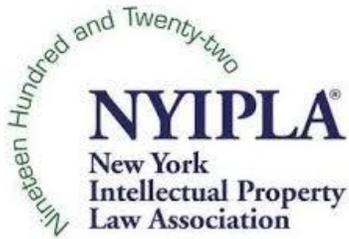


One-Day Patent CLE Seminar
November 7, 2024

Election Outcomes and Discussion

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

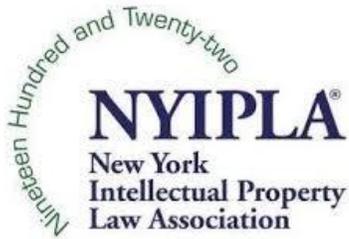




One-Day Patent CLE Seminar
November 7, 2024

Judiciary Administration Updates

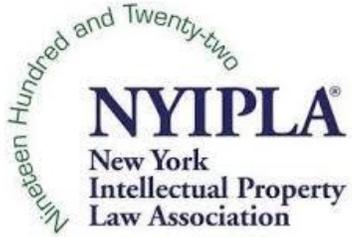
- JUDGES Act Update
- Federal Rules Process
 - Third Party Patent Litigation
 - Appropriations language pressure Administrative Office of the Courts to implement judicial guidance.
 - Rep Issa Bill - apply financial disclosure requirements to “a party or any counsel of record” “in any civil action”.
 - 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



One-Day Patent CLE Seminar
November 7, 2024

Legislative Topics

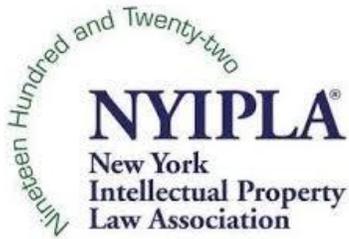
- Promoting and Respecting Economically Vital American Innovation Leadership Act (**PREVAIL Act**)
 - Establishes standing requirement at PTAB
 - Equivalent evidentiary standard of “clear and convincing evidence” at PTAB and District Court
 - Does not allow parallel challenges to the validity of the 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 not 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,”



One-Day Patent CLE Seminar
November 7, 2024

Legislative Topics

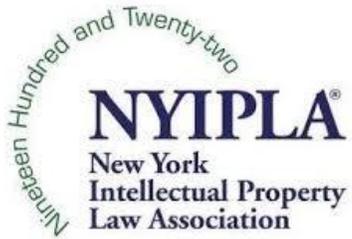
- Realizing Engineering, Science, and Technology Opportunities by Restoring Exclusive **(RESTORE)** Patent Rights Act of 2024
 - Establishes rebuttable presumption in statute in favor of granting permanent injunction when a court enters a judgement of infringement.



One-Day Patent CLE Seminar
November 7, 2024

Administration, USPTO & Copyright Office Activity

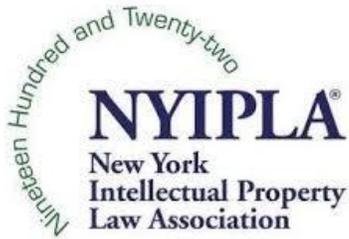
- Bayh-Dole March In Proposed Guidelines
 - Proposed Guidelines introduced December 2023 by the National Institute of Standards and Technology providing federal agencies guidance relevant to potential march-in considerations based on reasonable price of products incorporating federally-licensed patents.
 - 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.



One-Day Patent CLE Seminar
November 7, 2024

Administration, USPTO & Copyright Office Activity

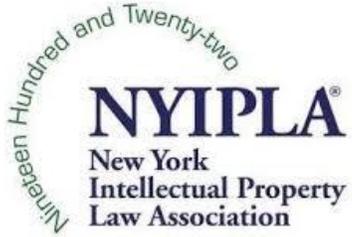
- Copyright Office AI & IP Report
 - Committed to Congress to complete remaining sections in 2024. Topics to be addressed include:
 - Copyrightability of GenAI output
 - Legal implications of training AI models on copyrighted works, including issues such as liability, licensing and fair use.



One-Day Patent CLE Seminar
November 7, 2024

Administration & USPTO Activity

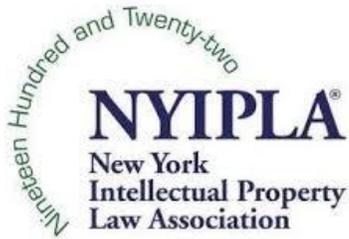
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One-Day Patent CLE Seminar November 7, 2024

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 not 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,”



One-Day Patent CLE Seminar
November 7, 2024

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.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Litigation Trans-
5 parency Act of 2024”.

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

3 (a) IN GENERAL.—Chapter 111 of title 28, United
4 States Code, is amended by adding at the end the fol-
5 lowing:

6 **“§ 1660. Third-party beneficiary disclosure**

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

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

17 “(2) produce to the court and to each other
18 named party to the civil action, for inspection and
19 copying, any agreement creating a contingent right
20 referred to in paragraph (1), including any ancillary
21 agreement or document, except as otherwise stipu-
22 lated or ordered by the court.

23 “(b) EXCEPTION.—The requirements under sub-
24 section (a) shall not apply with respect to a person that
25 has a right to receive payment described in subsection
26 (a)(1) if the right to receive payment is solely—

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

2 “(2) the repayment of the principal of a loan

3 plus interest that does not exceed the higher of 7

4 percent or a rate two times the annual average 30-

5 year constant maturity Treasury yield, as published

6 by the Board of Governors of the Federal Reserve

7 System, for the year preceding the date on which the

8 relevant agreement was executed; or

9 “(3) the reimbursement of attorney’s fees.

10 “(c) TIMING.—The disclosures required by subsection

11 (a) shall be made not later than the later of—

12 “(1) 10 days after the execution of any
agree-

13 ment described in subsection (a)(2); or

14 “(2) the time of the filing of the action before

15 the court.

16 “(d) DUTY TO CORRECT.—A party or counsel of

17 record that made a disclosure required by this section shall

18 supplement or correct each such disclosure in a timely

19 manner—

20 “(1) if such party or counsel of record learns

21 that the disclosure is or has become incomplete or

22 incorrect in some material respect, if the additional

23 or corrective information has not otherwise been

24 made known to the other parties during the dis-

25 covery process or in writing; or

1 “(2) as ordered by the court.”.

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

“1660. Third-party beneficiary disclosure.”.

5 SEC. 3. APPLICABILITY.

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

118TH CONGRESS
2^D SESSION

S. 4199

AN ACT

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

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “Judicial Understaffing
3 Delays Getting Emergencies Solved Act of 2024” or the
4 “JUDGES Act of 2024”.

5 **SEC. 2. FINDINGS.**

6 Congress finds the following:

7 (1) Article III of the Constitution of the United
8 States gives Congress the power to establish judge-
9 ships in the district courts of the United States.

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

13 (3) This represents the longest period of time
14 since district courts of the United States were estab-
15 lished in 1789 that Congress has not authorized any
16 new permanent district court judgeships.

17 (4) By the end of fiscal year 2022, filings in the
18 district courts of the United States had increased by
19 30 percent since the last comprehensive judgeship
20 legislation.

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

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

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

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

5 (a) **ADDITIONAL JUDGESHIPS.—**

6 (1) **2025.—**

7 (A) **IN GENERAL.—**The President shall ap-
8 point, by and with the advice and consent of the
9 Senate—

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

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

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

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

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

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

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

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

- 1 (ix) 1 additional district judge for the
 2 southern district of New York;
 3 (x) 1 additional district judge for the
 4 eastern district of Texas; and
 5 (xi) 1 additional district judge for the
 6 southern district of Texas.

7 (B) TABLES.—The table contained in sec-
 8 tion 133(a) of title 28, United States Code, is
 9 amended—

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

“California:	
Northern	15
Eastern	7
Central	28
Southern	13”;

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

“Delaware	5”;
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- 14 (iii) by striking the items relating to
 15 Florida and inserting the following:

“Florida:	
Northern	4
Middle	16
Southern	17”;

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

“Indiana:	
Northern	5
Southern	6”;

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

“Iowa:
Northern 3
Southern 3”;

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

“New Jersey 18”;

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

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

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

“Texas:
Northern 12
Southern 20
Eastern 8
Western 13”.

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

11 (2) 2027.—

12 (A) IN GENERAL.—The President shall ap-
13 point, by and with the advice and consent of the
14 Senate—

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

- 1 (ii) 2 additional district judges for the
 2 central district of California;
- 3 (iii) 1 additional district judge for the
 4 eastern district of California;
- 5 (iv) 1 additional district judge for the
 6 northern district of California;
- 7 (v) 1 additional district judge for the
 8 middle district of Florida;
- 9 (vi) 1 additional district judge for the
 10 southern district of Florida;
- 11 (vii) 1 additional district judge for the
 12 northern district of Georgia;
- 13 (viii) 1 additional district judge for
 14 the district of Idaho;
- 15 (ix) 1 additional district judge for the
 16 northern district of Texas; and
- 17 (x) 1 additional district judge for the
 18 southern district of Texas.

19 (B) TABLES.—The table contained in sec-
 20 tion 133(a) of title 28, United States Code, as
 21 amended by paragraph (1) of this subsection, is
 22 amended—

- 23 (i) by striking the item relating to Ar-
 24 izona and inserting the following:

“Arizona 13”;

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

“California:
Northern 16
Eastern 8
Central 30
Southern 13”;

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

“Florida:
Northern 4
Middle 17
Southern 18”;

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

“Georgia:
Northern 12
Middle 4
Southern 3”;

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

“Idaho 3”; and

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

“Texas:
Northern 13
Southern 21
Eastern 8
Western 13”.

11 (C) EFFECTIVE DATE.—This paragraph
12 shall take effect on January 21, 2027.
13 (3) 2029.—

- 1 (A) IN GENERAL.—The President shall ap-
2 point, by and with the advice and consent of the
3 Senate—
- 4 (i) 1 additional district judge for the
5 central district of California;
 - 6 (ii) 1 additional district judge for the
7 eastern district of California;
 - 8 (iii) 1 additional district judge for the
9 northern district of California;
 - 10 (iv) 1 additional district judge for the
11 district of Colorado;
 - 12 (v) 1 additional district judge for the
13 district of Delaware;
 - 14 (vi) 1 additional district judge for the
15 district of Nebraska;
 - 16 (vii) 1 additional district judge for the
17 eastern district of New York;
 - 18 (viii) 1 additional district judge for
19 the eastern district of Texas;
 - 20 (ix) 1 additional district judge for the
21 southern district of Texas; and
 - 22 (x) 1 additional district judge for the
23 western district of Texas.
- 24 (B) TABLES.—The table contained in sec-
25 tion 133(a) of title 28, United States Code, as

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

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

“California:
 Northern 17
 Eastern 9
 Central 31
 Southern 13”;

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

“Colorado 8”;

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

“Delaware 6”;

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

“Nebraska 4”;

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

“New York:
 Northern 5
 Southern 29
 Eastern 16
 Western 4”; and

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

“Texas:
 Northern 13
 Southern 22
 Eastern 9

Western 14”.

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

3 (4) 2031.—

4 (A) IN GENERAL.—The President shall ap-
5 point, by and with the advice and consent of the
6 Senate—

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

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

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

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

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

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

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

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

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

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

3 (B) TABLES.—The table contained in sec-
4 tion 133(a) of title 28, United States Code, as
5 amended by paragraph (3) of this subsection, is
6 amended—

7 (i) by striking the item relating to Ar-
8 izona and inserting the following:

“Arizona 14”;

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

“California:
Northern 18
Eastern 10
Central 32
Southern 14”;

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

“Florida:
Northern 4
Middle 18
Southern 19”;

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

“New Jersey 19”;

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

“New York:
Northern 5
Southern 29
Eastern 16

Western 5"; and

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(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;

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

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

5 (B) TABLES.—The table contained in sec-
 6 tion 133(a) of title 28, United States Code, as
 7 amended by paragraph (4) of this subsection, is
 8 amended—

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

“California:	
Northern	19
Eastern	10
Central	34
Southern	14”;

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

“Colorado	9”;
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13 (iii) by striking the items relating to
 14 Florida and inserting the following:

“Florida:	
Northern	5
Middle	19
Southern	19”;

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

“Georgia:	
Northern	13
Middle	4
Southern	3”;

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

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

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

“Texas:	
Northern	13
Southern	23
Eastern	9
Western	17”.

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

7 (6) 2035.—

8 (A) IN GENERAL.—The President shall ap-
 9 point, by and with the advice and consent of the
 10 Senate—

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

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

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

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

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

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

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

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

7 (B) TABLES.—The table contained in sec-
 8 tion 133(a) of title 28, United States Code, as
 9 amended by paragraph (5) of this subsection, is
 10 amended—

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

“California:	
Northern	20
Eastern	10
Central	36
Southern	15”;

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

“Florida:	
Northern	5
Middle	20
Southern	20”;

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

“New Jersey	20”;
-------------------	------

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

“New York:	
Northern	5

Southern	30
Eastern	17
Western	5"; and

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

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

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

5 (b) TEMPORARY JUDGESHIPS.—

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

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

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

12 (2) VACANCIES NOT FILLED.—The first va-
 13 cancy in the office of district judge in each of the
 14 offices of district judge authorized by this sub-
 15 section, occurring 5 years or more after the con-
 16 firmation date of the judge named to fill the tem-
 17 porary district judgeship created in the applicable
 18 district by this subsection, shall not be filled.

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

21 (b) AUTHORIZATION OF APPROPRIATIONS.—

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

4 (A) for each of fiscal years 2025 and 2026,
5 \$12,965,330;

6 (B) for each of fiscal years 2027 and
7 2028, \$23,152,375;

8 (C) for each of fiscal years 2029 and 2030,
9 \$32,413,325;

10 (D) for each of fiscal years 2031 and
11 2032, \$42,600,370;

12 (E) for each of fiscal years 2033 and
13 2034, \$51,861,320; and

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

16 (1) INFLATION ADJUSTMENT.—For each fiscal
17 year described in paragraph (1), the amount author-
18 ized to be appropriated for such fiscal year shall be
19 increased by the percentage by which—

20 (A) the Consumer Price Index for the pre-
21 vious fiscal year, exceeds

22 (B) the Consumer Price Index for the fis-
23 cal year preceding the fiscal year described in
24 subparagraph (A).

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

6 SEC. 4. ORGANIZATION OF UTAH DISTRICT COURTS.

7 Section 125(2) of title 28, United States Code, is
8 amended by striking “and St. George” and inserting “St.
9 George, Moab, and Monticello”.

10 SEC. 5. ORGANIZATION OF TEXAS DISTRICT COURTS.

11 Section 124(b)(2) of title 28, United States Code, is
12 amended, in the matter preceding paragraph (3), by in-
13 serting “and College Station” before the period at the end.

14 SEC. 6. ORGANIZATION OF CALIFORNIA DISTRICT COURTS.

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

18 SEC. 7. GAO REPORTS.

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

25 (1) evaluating—

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

7 (B) the impact of non-case-related activi-
8 ties of judges of the district courts of the
9 United States and courts of appeals of the
10 United States on judicial caseloads; and

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

15 (2) providing any recommendations of the
16 Comptroller General with respect to the matters de-
17 scribed in paragraph (1).

18 (b) DETENTION SPACE.—The Comptroller General of
19 the United States shall submit to the Committee on the
20 Judiciary of the Senate and the Committee on the Judici-
21 ary of the House of Representatives a report on an assess-
22 ment of—

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

1 (2) efforts by Federal agencies to acquire de-
2 tention space; and

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

5 **SEC. 8. PUBLIC ACCESSIBILITY OF THE ARTICLE III JUDGE-**
6 **SHIP RECOMMENDATIONS OF THE JUDICIAL**
7 **CONFERENCE OF THE UNITED STATES RE-**
8 **PORT.**

9 (a) **IN GENERAL.**—The Administrative Office of the
10 United States Courts, in consultation with the Judicial
11 Conference of the United States, shall make publicly avail-
12 able on their website, free of charge, the biennial report
13 entitled “Article III Judgeship Recommendations of the
14 Judicial Conference of the United States”.

15 (b) **CONTENTS.**—The report described in subsection
16 (a) should be released not less frequently than biennially
17 and contain the summaries and all related appendixes sup-
18 porting the judgeship recommendations of the Judicial
19 Conference of the United States, including—

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

22 (2) any caseload and methodology changes;

23 (3) judgeship surveys with recommendations;

24 and

1 (4) specific information about each court for
2 which the Judicial Conference recommends addi-
3 tional judgeships.

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

Passed the Senate August 1, 2024.

Attest:

Secretary.

118TH CONGRESS
2^D 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

A BILL

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

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Patent Eligibility Res-
5 toration Act of 2023”.

6 **SEC. 2. FINDINGS.**

7 Congress finds the following:

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

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

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

9 (3) Efforts by judges of district courts and
10 courts of appeals of the United States to apply the
11 exceptions described in paragraph (2) to specific cir-
12 cumstances have led to extensive confusion and a
13 lack of consistency—

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

16 (B) among patent practitioners.

17 (4) Many judges of the United States Court of
18 Appeals for the Federal Circuit and of various dis-
19 trict courts of the United States have explicitly ex-
20 pressed the need for more guidance with respect to
21 the meaning of section 101 of title 35, United States
22 Code, and many patent owners, and persons that en-
23 gage with patent owners, complain that the interpre-
24 tation of that section is extremely confusing and dif-
25 ficult to discern and apply with any confidence.

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

3 (A) All judicial exceptions to patent eligi-
4 bility are eliminated.

5 (B) Any invention or discovery that can be
6 claimed as a useful process, machine, manufac-
7 ture, or composition of matter, or any useful
8 improvement thereof, is eligible for patent pro-
9 tection, except as explicitly provided in section
10 101 of title 35, United States Code, as amend-
11 ed by this Act, as described in subparagraphs
12 (D) and (E) of this paragraph.

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

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

20 (i) A mathematical formula that is
21 not part of an invention that is in a cat-
22 egory described in subparagraph (B).

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

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

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

5 (v) A process that is substantially eco-
6 nomic, financial, business, social, cultural,
7 or artistic.

8 (E) Under the exception described in sub-
9 paragraph (D)(v)—

10 (i) process claims drawn solely to the
11 steps undertaken by human beings in
12 methods of doing business, performing
13 dance moves, offering marriage proposals,
14 and the like shall not be eligible for patent
15 coverage, and adding a non-essential ref-
16 erence to a computer by merely stating, for
17 example, “do it on a computer” shall not
18 establish such eligibility; and

19 (ii) any process that cannot be prac-
20 tically performed without the use of a ma-
21 chine (including a computer) or manufac-
22 ture shall be eligible for patent coverage.

23 SEC. 3. PATENT ELIGIBILITY.

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

1 (1) in section 100—

2 (A) in subsection (b), by striking “includes
3 a new use of a known process” and
inserting
4 “includes a use, application, or method of man-
5 ufacture of a known or naturally-occurring
6 process”; and

7 (B) by adding at the end the following:

8 “(k) The term ‘useful’ means, with respect to an in-
9 vention or discovery, that the invention or discovery has
10 a specific and practical utility from the perspective of a
11 person of ordinary skill in the art to which the invention
12 or discovery pertains.”; and

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

14 **“§ 101. Patent eligibility**

15 “(a) IN GENERAL.—Whoever invents or discovers
16 any useful process, machine, manufacture, or composition
17 of matter, or any useful improvement thereof, may obtain
18 a patent therefor, subject only to the exclusions in sub-
19 section (b) and to the further conditions and requirements
20 of this title.

21 “(b) ELIGIBILITY EXCLUSIONS.—

22 “(1) IN GENERAL.—Subject to paragraph (2), a
23 person may not obtain a patent for any of the fol-
24 lowing, if claimed as such:

1 “(A) A mathematical formula that is not
2 part of a claimed invention in a category de-
3 scribed in subsection (a).

4 “(B)(i) Subject to clause (ii), a process
5 that is substantially economic, financial, busi-
6 ness, social, cultural, or artistic, even though
7 not less than 1 step in the process refers to a
8 machine or manufacture.

9 “(ii) The process described in clause (i)
10 shall not be excluded from eligibility for a pat-
11 ent if the process cannot practically be per-
12 formed without the use of a machine or manu-
13 facture.

14 “(C) A process that—

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

17 “(ii) occurs in nature wholly inde-
18 pendent of, and prior to, any human activ-
19 ity.

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

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

24 “(2) CONDITIONS.—For the purposes of sub-
25 paragraphs (D) and (E) of paragraph (1), a human

1 gene or natural material shall not be considered to
2 be unmodified if the gene or material, as applicable,
3 is—

4 “(A) isolated, purified, enriched, or other-
5 wise altered by human activity; or

6 “(B) otherwise employed in a useful inven-
7 tion or discovery.

8 “(c) ELIGIBILITY.—

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

12 “(A) by considering the claimed invention
13 as a whole and without discounting or dis-
14 regarding any claim element; and

15 “(B) without regard to—

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

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

21 “(iii) the state of the applicable art,
22 as of the date on which the claimed inven-
23 tion is invented; or

24 “(iv) any other consideration in sec-
25 tion 102, 103, or 112.

1 “(2) INFRINGEMENT ACTION.—

2 “(A) IN GENERAL.—In an action brought
3 for infringement under this title, the court, at
4 any time, may determine whether an invention
5 or discovery that is a subject of the action is el-
6 igible for a patent under this section, including
7 on motion of a party when there are no genuine
8 issues of material fact.

9 “(B) LIMITED DISCOVERY.—With respect
10 to a determination described in subparagraph
11 (A), the court may consider limited discovery
12 relevant only to the eligibility described in that
13 subparagraph before ruling on a motion de-
14 scribed in that subparagraph.”.

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

“101. Patent eligibility.”.

Æ

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

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.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Promoting and Re-
5 specting Economically Vital American Innovation Leader-
6 ship Act” or the “PREVAIL Act”.

1 SEC. 2. FINDINGS.

2 Congress finds the following:

3 (1) The patent property rights enshrined in the
4 Constitution of the United States provide the foun-
5 dation for the exceptional innovation environment in
6 the United States.

7 (2) Reliable and effective patent protection en-
8 courages United States inventors to invest their re-
9 sources in creating new inventions.

10 (3) United States inventors have made discov-
11 eries leading to patient cures, positive changes to the
12 standard of living for all people in the United
13 States, and improvements to the agricultural, tele-
14 communications, and electronics industries, among
15 others.

16 (4) The United States patent system is an es-
17 sential part of the economic success of the United
18 States.

19 (5) Reliable and effective patent protection im-
20 proves the chances of success for individual inven-
21 tors and small companies and increases the chances
22 of securing investments for those inventors and com-
23 panies.

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

1 (A) generate tens of millions of jobs for in-
2 dividuals in the United States; and

3 (B) account for more than $\frac{1}{3}$ of the gross
4 domestic product of the United States.

5 (7) The National Security Commission on Arti-
6 ficial Intelligence has emphasized that—

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

11 (B) the United States has failed to simi-
12 larly recognize the importance of intellectual
13 property in securing its own national security,
14 economic interests, and technological competi-
15 tiveness.

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

21 (9) Congress last enacted comprehensive re-
22 forms of the patent system in 2011.

23 (10) Unintended consequences of the com-
24 prehensive 2011 reform of patent laws have become
25 evident during the decade preceding the date of en-

1 actment of this Act, including the strategic filing of
2 post-grant review proceedings to depress stock prices
3 and extort settlements, the filing of repetitive peti-
4 tions for inter partes and post-grant reviews that
5 have the effect of harassing patent owners, and the
6 unnecessary duplication of work by the district
7 courts of the United States and the Patent Trial
8 and Appeal Board, all of which drive down invest-
9 ment in innovation and frustrate the purpose of
10 those patent reform laws.

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

16 (A) disincentivizing United States compa-
17 nies from innovating; and

18 (B) weakening the economy of the United
19 States.

20 SEC. 3. PATENT TRIAL AND APPEAL BOARD.

21 Section 6 of title 35, United States Code, is amend-
22 ed—

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

1 (2) by inserting after subsection (a) the fol-
2 lowing:

3 “(b) CODE OF CONDUCT.—

4 “(1) IN GENERAL.—The Director shall pre-
5 scribe regulations establishing a code of conduct for
6 the members of the Patent Trial and Appeal Board.

7 “(2) CONSIDERATIONS.—In prescribing regula-
8 tions under paragraph (1), the Director shall con-
9 sider the Code of Conduct for United States Judges
10 and how the provisions of that Code of Conduct may
11 apply to the Patent Trial and Appeal Board.”;

12 (3) by striking subsection (d), as so redesign-
13 nated, and inserting the following:

14 “(d) 3-MEMBER PANELS.—

15 “(1) IN GENERAL.—Each appeal, derivation
16 proceeding, post-grant review, and inter partes re-
17 view shall be heard by at least 3 members of the
18 Patent Trial and Appeal Board, who shall be des-
19 ignated by the Director. The Patent Trial and Ap-
20 peal Board may grant rehearings.

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

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

3 “(3) NO DIRECTION OR INFLUENCE.—An offi-
4 cer who has supervisory authority or disciplinary au-
5 thority with respect to an administrative patent
6 judge of the Patent Trial and Appeal Board (or a
7 delegate of such an officer), and who is not a mem-
8 ber of a panel described in this subsection, shall re-
9 frain from communications with the panel that di-
10 rect or otherwise influence any merits decision of the
11 panel.

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

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

18 (A) in the first sentence—

19 (i) by striking “this subsection” and
20 inserting “the date of enactment of the
21 Promoting and Respecting Economically
22 Vital American Innovation Leadership
23 Act”;

1 (ii) by striking “by the Director” and
2 inserting “by the Director or the Sec-
3 retary”; and

4 (iii) by inserting “or the Secretary, as
5 applicable,” after “on which the Director”;
6 and

7 (B) in the second sentence—

8 (i) by inserting after “by the Direc-
9 tor” the following: “, or, before the date of
10 enactment of the Promoting and Respect-
11 ing Economically Vital American Innova-
12 tion Leadership Act, having performed du-
13 ties no longer performed by administrative
14 patent judges,”; and

15 (ii) by striking “that the administra-
16 tive patent judge so appointed” and insert-
17 ing “that the applicable administrative pat-
18 ent judge”.

19 SEC. 4. INTER PARTES REVIEW.

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

23 “(d) **PERSONS THAT MAY PETITION.**—

24 “(1) **DEFINITION.**—In this subsection, the term
25 ‘charged with infringement’ means a real and sub-

1 stantial controversy regarding infringement of a pat-
2 ent exists such that the person would have standing
3 to bring a declaratory judgment action in Federal
4 court.

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

10 “(A) sued for infringement of the
 patent;

11 or

12 “(B) charged with infringement of the pat-
13 ent.

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

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

23 “(e) REHEARING.—Not later than 45 days after the
24 date on which a request for rehearing from a determina-
25 tion by the Director under subsection (b) is filed, the Di-

1 rector shall finally decide any request for reconsideration,
2 rehearing, or review with respect to the determination, ex-
3 cept that the Director may, for good cause shown, extend
4 that 45-day period by not more than 30 days.”.

5 (c) ELIMINATING REPETITIVE PROCEEDINGS.—

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

8 (A) in subsection (b), by amending the sec-
9 ond sentence to read as follows: “The time limi-
10 tation set forth in the preceding sentence shall
11 not bar a request for joinder under subsection
12 (d), but shall establish a rebuttable presump-
13 tion against joinder for the requesting person.”;

14 (B) by redesignating subsections (c), (d),
15 and (e) as subsections (d), (e), and (f), respec-
16 tively;

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

19 “(c) SINGLE FORUM.—

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

1 Trade Commission under section 337 of the Tariff
2 Act of 1930 (19 U.S.C. 1337), a claim, a counter-
3 claim, or an affirmative defense challenging the va-
4 lidity of any claim of the patent on any ground de-
5 scribed in section 311(b).

6 “(2) CONSIDERATIONS.—In determining wheth-
7 er to institute a proceeding under this chapter, sub-
8 ject to the provisions of subsections (a)(1) and (g),
9 the Director may not reject a petition requesting an
10 inter partes review on the basis of the petitioner, a
11 real party in interest, or a privy of the petitioner fil-
12 ing or maintaining a claim, a counterclaim, or an af-
13 firmative defense challenging the validity of the ap-
14 plicable patent in any civil action arising in whole or
15 in part under section 1338 of title 28, or in a pro-
16 ceeding before the International Trade Commission
17 under section 337 of the Tariff Act of 1930 (19
18 U.S.C. 1337).”;

19 (D) by amending subsection (d), as so re-
20 designated, to read as follows:

21 “(d) JOINDER.—

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

1 quest to join the inter partes review and a petition
2 under section 311 that the Director, after receiving
3 a preliminary response under section 313 or the ex-
4 piration of the time for filing such a response, deter-
5 mines warrants the institution of an inter partes re-
6 view under section 314.

7 “(2) TIME-BARRED PERSON.—Pursuant to
8 paragraph (1), the Director, in the discretion of the
9 Director, may join as a party to an inter partes re-
10 view a person that did not satisfy the time limitation
11 under subsection (b) that rebuts the presumption
12 against joinder, except that any such person shall
13 not be permitted to serve as the lead petitioner and
14 shall not be permitted to maintain the inter partes
15 review unless a petitioner that satisfied the time lim-
16 itation under subsection (b) remains in the inter
17 partes review.”;

18 (E) by amending subsection (e), as so re-
19 designated, to read as follows:

20 “(e) MULTIPLE PROCEEDINGS.—

21 “(1) IN GENERAL.—Notwithstanding sections
22 135(a), 251, and 252, and chapter 30, after a peti-
23 tion to institute an inter partes review is filed, if an-
24 other proceeding or matter involving the patent is
25 before the Office—

1 “(A) the parties shall notify the Director
2 of that other proceeding or matter—

3 “(i) not later than 30 days after the
4 date of entry of the notice of filing date ac-
5 corded to the petition; or

6 “(ii) if the other proceeding or matter
7 is filed after the date on which the petition
8 to institute an inter partes review is filed,
9 not later than 30 days after the date on
10 which the other proceeding or matter is
11 filed; and

12 “(B) the Director shall issue a decision de-
13 termining the manner in which the inter partes
14 review or other proceeding or matter may pro-
15 ceed, including providing for stay, transfer, con-
16 solidation, or termination of any such matter or
17 proceeding.

18 “(2) CONSIDERATIONS.—In determining wheth-
19 er to institute a proceeding under this chapter, the
20 Director shall, unless the Director determines that
21 the petitioner has demonstrated exceptional cir-
22 cumstances, reject any petition that presents prior
23 art or an argument that is the same or substantially
24 the same as prior art or an argument that previously
25 was presented to the Office.”;

1 (F) by amending subsection (f), as so re-
2 designated, to read as follows:

3 “(f) ESTOPPEL.—

4 “(1) IN GENERAL.—A petitioner that has pre-
5 viously requested an inter partes review of a claim
6 in a patent under this chapter, or a real party in in-
7 terest or a privy of such a petitioner, may not re-
8 quest or maintain another proceeding before the Of-
9 fice with respect to that patent on any ground that
10 the petitioner raised or reasonably could have raised
11 in the petition requesting or during the prior inter
12 partes review, unless—

13 “(A) after the filing of the initial petition,
14 the petitioner, or a real party in interest or a
15 privy of the petitioner, is charged with infringe-
16 ment of additional claims of the patent;

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

22 “(C) that subsequent petition is accom-
23 panied by a request for joinder to the prior
24 inter partes review, which overcomes the rebut-
25 table presumption against joinder set forth in

1 subsection (b), and which the Director shall
2 grant if the Director authorizes an inter partes
3 review to be instituted on the subsequent peti-
4 tion under section 314.

5 “(2) JOINED PARTY.—Any person joined as a
6 party to an inter partes review, and any real party
7 in interest or any privy of such person, shall be es-
8 topped under this subsection and subsections (c)(1)
9 and (e)(2) to the same extent as if that person, real
10 party in interest, or privy had been the first peti-
11 tioner in that inter partes review.”; and

12 (G) by adding at the end the following:

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

1 (2) TECHNICAL AND CONFORMING AMEND-
2 MENTS.—Section 316(a) of title 35, United States
3 Code, is amended—

4 (A) in paragraph (11), by striking “section
5 315(c)” and inserting “section 315(d)”; and

6 (B) in paragraph (12), by striking “section
7 315(c)” and inserting “section 315(d)”.

8 (d) CONDUCT OF INTER PARTES REVIEW.—Section
9 316 of title 35, United States Code, is amended—

10 (1) in subsection (a)—

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

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

16 “(A) the deposition of witnesses submitting
17 affidavits or declarations;

18 “(B) evidence identifying the real parties
19 in interest of the petitioner; and

20 “(C) what is otherwise necessary in the in-
21 terest of justice;”;

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

24 “(9) setting forth standards and procedures
25 for—

1 “(A) allowing the patent owner to move to
2 amend the patent under subsection (d) to can-
3 cel a challenged claim or propose a reasonable
4 number of substitute claims;

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

8 “(C) allowing the patent owner to further
9 revise proposed substitute claims after the
10 issuance of guidance described in subparagraph
11 (B); and

12 “(D) ensuring that any information sub-
13 mitted by the patent owner in support of any
14 amendment entered under subsection (d), and
15 any guidance issued by the Patent Trial and
16 Appeal Board, is made available to the public
17 as part of the prosecution history of the pat-
18 ent;”;

19 (C) in paragraph (12), by striking “and”
20 at the end;

21 (D) in paragraph (13), by striking the pe-
22 riod at the end and inserting “; and”; and

23 (E) by adding at the end the following:

1 “(14) setting forth the standards for dem-
2 onstrating exceptional circumstances under sections
3 303(e)(1) and 315(e)(2).”;

4 (2) by amending subsection (e) to read as fol-
5 lows:

6 “(e) EVIDENTIARY STANDARDS.—

7 “(1) PRESUMPTION OF VALIDITY.—The pre-
8 sumption of validity under section 282(a) shall apply
9 to previously issued claims of a patent that is chal-
10 lenged in an inter partes review under this chapter.

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

13 “(A) the petitioner shall have the burden
14 of proving a proposition of unpatentability of a
15 previously issued claim of a patent by clear and
16 convincing evidence; and

17 “(B) the petitioner shall have the burden
18 of persuasion, by a preponderance of the evi-
19 dence, with respect to a proposition of
20 unpatentability for any substitute claim pro-
21 posed by the patent owner.”; and

22 (3) by adding at the end the following:

23 “(f) CLAIM CONSTRUCTION.—For the purposes of
24 this chapter—

1 “(1) each challenged claim of a patent, and
2 each substitute claim proposed in a motion to
3 amend, shall be construed as the claim would be
4 construed under section 282(b) in an action to inval-
5 idate a patent, including by construing each such
6 claim in accordance with—

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

11 “(B) the prosecution history pertaining to
12 the patent; and

13 “(2) if a court has previously construed a chal-
14 lenged claim of a patent or a challenged claim term
15 in a civil action to which the patent owner was a
16 party, the Office shall consider that claim construc-
17 tion.”.

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

20 (f) TIMING TO ISSUE TRIAL CERTIFICATE AND DE-
21 CISIONS ON REHEARING.—Section 318 of title 35, United
22 States Code, is amended—

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

1 that the time for appeal has expired or any appeal
2 has terminated,” after “the Director shall”; and

3 (2) by adding at the end the following:

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

12 “(f) REVIEW BY DIRECTOR.—

13 “(1) IN GENERAL.—The Director may grant re-
14 hearing, reconsideration, or review of a decision by
15 the Patent Trial and Appeal Board issued under this
16 chapter.

17 “(2) REQUIREMENTS.—Any reconsideration, re-
18 hearing, or review by the Director, as described in
19 paragraph (1), shall be issued in a separate written
20 opinion that—

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

22 “(B) sets forth the reasons for the recon-
23 sideration, rehearing, or review of the applicable
24 decision by the Patent Trial and Appeal Board.

1 “(g) RULE OF CONSTRUCTION.—For the purposes of
2 an appeal permitted under section 141, any decision on
3 rehearing, reconsideration, or review of a final written de-
4 cision of the Patent Trial and Appeal Board under sub-
5 section (a) of this section that is issued by the Director
6 shall be deemed to be a final written decision of the Patent
7 Trial and Appeal Board.”.

8 (g) TIMING TO ISSUE DECISIONS ON REMAND.—Sec-
9 tion 319 of title 35, United States Code, is amended—
10 (1) by striking “A party” and inserting the fol-
11 lowing:

12 “(a) IN GENERAL.—A party”; and

13 (2) by adding at the end the following:

14 “(b) TIMING ON REMAND AFTER APPEAL.—Not
15 later than 120 days after the date on which a
 mandate

16 issues from the court remanding to the Patent Trial and
17 Appeal Board after an appeal under subsection (a), the
18 Board or the Director shall finally decide any issue on re-
19 mand, except that the Director may, for good cause
20 shown, extend that 120-day period by not more than 60
21 days.”.

22 SEC. 5. POST-GRANT REVIEW.

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

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

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

10 “(f) REHEARING.—Not later than 45 days after the
11 date on which a request for rehearing from a determina-
12 tion by the Director under subsection (c) is filed, the Di-
13 rector shall finally decide any request for reconsideration,
14 rehearing, or review with respect to the determination, ex-
15 cept that the Director may, for good cause shown, extend
16 that 45-day period by not more than 30 days.”.

17 (c) ELIMINATING REPETITIVE PROCEEDINGS.—Sec-
18 tion 325 of title 35, United States Code, is amended—

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

21 (2) by inserting after subsection (b) the fol-
22 lowing:

23 “(c) SINGLE FORUM.—

24 “(1) IN GENERAL.—If a post-grant review is in-
25 stituted challenging the validity of a patent, the peti-

1 tioner, a real party in interest, or a privy of the peti-
2 tioner may not file or maintain, in a civil action aris-
3 ing in whole or in part under section 1338 of title
4 28, or in a proceeding before the International
5 Trade Commission under section 337 of the Tariff
6 Act of 1930 (19 U.S.C. 1337), a claim, a counter-
7 claim, or an affirmative defense challenging the va-
8 lidity of any claim of the patent.

9 “(2) CONSIDERATIONS.—In determining wheth-
10 er to institute a proceeding under this chapter, sub-
11 ject to the provisions of subsections (a)(1) and (h),
12 the Director may not reject a petition requesting a
13 post-grant review on the basis of the petitioner, a
14 real party in interest, or a privy of the petitioner fil-
15 ing or maintaining a claim, a counterclaim, or an af-
16 firmative defense challenging the validity of the pat-
17 ent in any civil action arising in whole or in part
18 under section 1338 of title 28, or in a proceeding be-
19 fore the International Trade Commission under sec-
20 tion 337 of the Tariff Act of 1930 (19 U.S.C.
21 1337).”;

22 (3) by amending subsection (e), as so redesign-
23 nated, to read as follows:

24 “(e) MULTIPLE PROCEEDINGS.—

1 “(1) IN GENERAL.—Notwithstanding sections
2 135(a), 251, and 252, and chapter 30, after a peti-
3 tion to institute a post-grant review is filed, if an-
4 other proceeding or matter involving the patent is
5 before the Office—

6 “(A) the parties shall notify the Director
7 of that other proceeding or matter—

8 “(i) not later than 30 days after the
9 date of entry of the notice of filing date ac-
10 corded to the petition; or

11 “(ii) if the other proceeding or matter
12 is filed after the date on which the petition
13 to institute an inter partes review is filed,
14 not later than 30 days after the date on
15 which the other proceeding or matter is
16 filed; and

17 “(B) the Director shall issue a decision de-
18 termining the manner in which the post-grant
19 review or other proceeding or matter may pro-
20 ceed, including providing for stay, transfer, con-
21 solidation, or termination of any such matter or
22 proceeding.

23 “(2) CONSIDERATIONS.—In determining wheth-
24 er to institute a proceeding under this chapter, the
25 Director shall, unless the Director determines that

1 the petitioner has demonstrated exceptional cir-
2 cumstances, reject any petition that presents prior
3 art or an argument that is the same or substantially
4 the same as prior art or an argument that previously
5 was presented to the Office.”;

6 (4) by amending subsection (f), as so redesign-
7 nated, to read as follows:

8 “(f) ESTOPPEL.—

9 “(1) IN GENERAL.—A petitioner that has pre-
10 viously requested a post-grant review of a claim in
11 a patent under this chapter, or a real party in inter-
12 est or a privy of a petitioner, may not request or
13 maintain another proceeding before the Office with
14 respect to that patent on any ground that the peti-
15 tioner raised or reasonably could have raised in the
16 petition requesting or during the prior post-grant re-
17 view, unless—

18 “(A) after the filing of the initial petition,
19 the petitioner, or a real party in interest or a
20 privy of the petitioner, is charged with infringe-
21 ment of additional claims of the patent;

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

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

3 “(C) that subsequent petition is accom-
4 panied by a request for joinder to the prior
5 post-grant review, which the Director shall
6 grant if the Director authorizes a post-grant re-
7 view to be instituted on the subsequent petition
8 under section 324.

9 “(2) JOINED PARTY.—Any person joined as a
10 party to a post-grant review, and any real party in
11 interest or any privy of such person, shall be es-
12 topped under this subsection and subsections (c)(1)
13 and (e)(2) to the same extent as if that person, real
14 party in interest, or privy had been the first peti-
15 tioner in that post-grant review.”; and

16 (5) by adding at the end the following:

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

1 sion, as applicable, has entered a final judgment that de-
2 cides a challenge to the validity of the patent claim.”.

3 (d) CONDUCT OF POST-GRANT REVIEW.—Section
4 326 of title 35, United States Code, is amended—

5 (1) in subsection (a)—

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

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

11 “(A) the deposition of witnesses submitting
12 affidavits or declarations;

13 “(B) evidence identifying the real parties
14 in interest of the petitioner; and

15 “(C) what is otherwise necessary in the in-
16 terest of justice;”;

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

19 “(9) setting forth standards and procedures
20 for—

21 “(A) allowing the patent owner to move to
22 amend the patent under subsection (d) to can-
23 cel a challenged claim or propose a reasonable
24 number of substitute claims;

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

4 “(C) allowing the patent owner to further
5 revise proposed substitute claims after the
6 issuance of guidance described in subparagraph
7 (B); and

8 “(D) ensuring that any information sub-
9 mitted by the patent owner in support of any
10 amendment entered under subsection (d), and
11 any guidance issued by the Patent Trial and
12 Appeal Board, is made available to the public
13 as part of the prosecution history of the pat-
14 ent;”;

15 (C) in paragraph (11), by striking “section
16 325(c)” and inserting “section 325(d)”;

17 (D) in paragraph (12), by striking the pe-
18 riod at the end and inserting “; and”;

19 (E) by adding at the end the following:

20 “(13) setting forth the standards for dem-
21 onstrating exceptional circumstances under section
22 325(e)(2).”;

23 (2) by amending subsection (e) to read as fol-
24 lows:

25 “(e) EVIDENTIARY STANDARDS.—

1 “(1) PRESUMPTION OF VALIDITY.—The pre-
2 sumption of validity under section 282(a) shall apply
3 to previously issued claims of a patent that is chal-
4 lenged in a post-grant review under this chapter.

5 “(2) BURDEN OF PROOF.—In a post-grant re-
6 view under this chapter—

7 “(A) the petitioner shall have the burden
8 of proving a proposition of unpatentability of a
9 previously issued claim of a patent by clear and
10 convincing evidence; and

11 “(B) the petitioner shall have the burden
12 of persuasion, by a preponderance of the evi-
13 dence, with respect to a proposition of
14 unpatentability for any substitute claim pro-
15 posed by the patent owner.”; and

16 (3) by adding at the end the following:

17 “(f) CLAIM CONSTRUCTION.—For the purposes of
18 this chapter—

19 “(1) each challenged claim of a patent, and
20 each substitute claim proposed in a motion to
21 amend, shall be construed as the claim would be
22 construed under section 282(b) in an action to inval-
23 idate a patent, including by construing each such
24 claim in accordance with—

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

5 “(B) the prosecution history pertaining to
6 the patent; and

7 “(2) if a court has previously construed a chal-
8 lenged claim of a patent or a challenged claim term
9 in a civil action to which the patent owner was a
10 party, the Office shall consider that claim construc-
11 tion.”.

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

14 (f) TIMING TO ISSUE TRIAL CERTIFICATES AND DE-
15 CISIONS ON REHEARING.—Section 328 of title 35, United
16 States Code, is amended—

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

22 (2) by adding at the end the following:

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

1 under subsection (a) is filed, the Board or the Director
2 shall finally decide any request for reconsideration, rehear-
3 ing, or review that is submitted with respect to the deci-
4 sion, except that the Director may, for good cause shown,
5 extend that 90-day period by not more than 60 days.

6 “(f) REVIEW BY DIRECTOR.—

7 “(1) IN GENERAL.—The Director may grant re-
8 hearing, reconsideration, or review of a decision by
9 the Patent Trial and Appeal Board issued under this
10 chapter.

11 “(2) REQUIREMENTS.—Any reconsideration, re-
12 hearing, or review by the Director, as described in
13 paragraph (1), shall be issued in a separate written
14 opinion that—

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

16 “(B) sets forth the reasons for the recon-
17 sideration, rehearing, or review of the decision
18 by the Patent Trial and Appeal Board.

19 “(g) RULE OF CONSTRUCTION.—For the purposes of
20 an appeal permitted under section 141, any decision on
21 rehearing, reconsideration, or review of a final written de-
22 cision of the Patent Trial and Appeal Board under sub-
23 section (a) of this section that is issued by the Director
24 shall be deemed to be a final written decision of the Patent
25 Trial and Appeal Board.”.

1 (g) TIMING TO ISSUE DECISIONS ON REMAND.—Sec-
2 tion 329 of title 35, United States Code, is amended—

3 (1) by striking “A party” and inserting the fol-
4 lowing:

5 “(a) IN GENERAL.—A party”; and

6 (2) by adding at the end the following:

7 “(b) TIMING ON REMAND AFTER APPEAL.—Not
8 later than 120 days after the date on which a
mandate

9 issues from the court remanding to the Patent Trial and
10 Appeal Board after an appeal under subsection (a), the
11 Board or the Director shall finally decide any issue on re-
12 mand, except that the Director may, for good cause
13 shown, extend that 120-day period by not more than 60
14 days.”.

15 **SEC. 6. REEXAMINATION OF PATENTS.**

16 (a) REQUEST FOR REEXAMINATION.—Section 302 of
17 title 35, United States Code, is amended by inserting after
18 the second sentence the following: “The request must
19 identify all real parties in interest and certify that reexam-
20 ination is not barred under section 303(d).”.

21 (b) REEXAMINATION BARRED.—Section 303 of title
22 35, United States Code, is amended—

23 (1) in subsection (a), by striking the third sen-
24 tence; and

25 (2) by adding at the end the following:

1 “(d) An ex parte reexamination may not be ordered
2 if the request for reexamination is filed more than 1 year
3 after the date on which the requester or a real party in
4 interest or a privy of the requester is served with a com-
5 plaint alleging infringement of the patent. For purposes
6 of this chapter, a person that directly or through an affil-
7 iate, subsidiary, or proxy makes a financial contribution
8 to the preparation for, or conduct during, an ex parte re-
9 examination on behalf of a requester shall be considered
10 a real party in interest of the requester.

11 “(e) In determining whether to order an ex parte re-
12 examination, the Director—

13 “(1) shall, unless the Director determines that
14 the requestor has demonstrated exceptional cir-
15 cumstances, reject any request that presents prior
16 art or an argument that is the same or substantially
17 the same as prior art or an argument that previously
18 was presented to the Office; and

19 “(2) may reject any request that the Director
20 determines has used a prior Office decision as a
21 guide to correct or bolster a previous deficient re-
22 quest filed under this chapter or a previous deficient
23 petition filed under chapter 31 or 32.”.

24 (c) REEXAMINATION ORDER BY DIRECTOR.—Section
25 304 of title 35, United States Code, is amended, in the

1 first sentence, by inserting after “resolution of the ques-
2 tion” the following: “, unless the Director determines that
3 the request for reexamination should be rejected under
4 subsection (d) or (e) of section 303, in which case the Di-
5 rector shall issue an order denying reexamination”.

6 SEC. 7. ELIMINATION OF USPTO FEE DIVERSION.

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

9 (1) in subsection (a), by striking “All fees” and
10 inserting the following:

11 “(a) FEES FOR SERVICE BY PTO.—All fees”;

12 (2) in subsection (b)—

13 (A) by striking “All fees paid to the Direc-
14 tor and all appropriations” and inserting the
15 following:

16 “(b) INNOVATION PROMOTION FUND.—All fees paid
17 to the Director”; and

18 (B) by striking “Patent and Trademark
19 Office Appropriation Account” and inserting
20 “United States Patent and Trademark Office
21 Innovation Promotion Fund”;

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

24 “(c) COLLECTION OF FUNDS FOR PTO ACTIVI-
25 TIES.—

1 “(1) IN GENERAL.—Fees authorized in this
2 title or any other Act to be charged or established
3 by the Director shall be collected by the Director
4 and shall be available to the Director until expended
5 to carry out the activities of the Patent and Trade-
6 mark Office.

7 “(2) USE OF FEES.—

8 “(A) PATENT FEES.—Any fees that are
9 collected under this title, and any surcharges on
10 such fees, may only be used for expenses of the
11 Office relating to the processing of patent appli-
12 cations and for other activities, services, and
13 materials relating to patents and to cover a pro-
14 portionate share of the administrative costs of
15 the Office.

16 “(B) TRADEMARK FEES.—Any fees that
17 are collected under section 31 of the Trademark
18 Act of 1946 (as defined in subsection (d)(1))
19 (15 U.S.C. 1113), and any surcharges on such
20 fees, may only be used for expenses of the Of-
21 fice relating to the processing of trademark reg-
22 istrations and for other activities, services, and
23 materials relating to trademarks and to cover a
24 proportionate share of the administrative costs
25 of the Office.”;

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

3 (5) by inserting after subsection (c) the fol-
4 lowing:

5 “(d) REVOLVING FUND.—

6 “(1) DEFINITIONS.—In this subsection—

7 “(A) the term ‘Fund’ means the United
8 States Patent and Trademark Office Innovation
9 Promotion Fund established under paragraph
10 (2); and

11 “(B) the term ‘Trademark Act of 1946’
12 means the Act entitled ‘An Act to provide for
13 the registration and protection of trademarks
14 used in commerce, to carry out the provisions
15 of certain international conventions, and for
16 other purposes’, approved July 5, 1946 (15
17 U.S.C. 1051 et seq.) (commonly referred to as
18 the ‘Trademark Act of 1946’ or the ‘Lanham
19 Act’).

20 “(2) ESTABLISHMENT.—There is established in
21 the Treasury a revolving fund to be known as the
22 ‘United States Patent and Trademark Office Inno-
23 vation Promotion Fund’.

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

4 “(A) this title; or

5 “(B) the Trademark Act of 1946.

6 “(4) EXPENSES.—Amounts deposited into the
7 Fund under paragraph (3) shall be available, with-
8 out fiscal year limitation, to cover—

9 “(A) to the extent consistent with the limi-
10 tation on the use of fees under subsection (c),
11 all expenses, including all administrative and
12 operating expenses, determined by the Director
13 to be ordinary and reasonable, incurred by the
14 Director for the continued operation of all serv-
15 ices, programs, activities, and duties of the Of-
16 fice relating to patents and trademarks, as such
17 services, programs, activities, and duties are de-
18 scribed under—

19 “(i) this title; and

20 “(ii) the Trademark Act of 1946; and

21 “(B) all expenses incurred pursuant to any
22 obligation, representation, or other commitment
23 of the Office.”;

24 (6) in subsection (e), as so redesignated, by
25 striking “The Director” and inserting the following:

1 “(e) REFUNDS.—The Director”; and

2 (7) in subsection (f), as so redesignated, by
3 striking “The Secretary” and inserting the fol-
4 lowing:

5 “(f) REPORT.—The Secretary”.

6 (b) EFFECTIVE DATE; TRANSFER FROM AND TERMI-
7 NATION OF OBSOLETE FUNDS.—

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

12 (2) REMAINING BALANCES.—On the effective
13 date described in paragraph (1), there shall be de-
14 posited in the United States Patent and
15 Office Innovation Promotion Fund established under
16 section 42(d)(2) of title 35, United States Code (as
17 added by subsection (a)), any available unobligated
18 balances remaining in the Patent and
19 Office Appropriation Account, and in the Patent and
20 Trademark Fee Reserve Fund established under sec-
21 tion 42(c)(2) of title 35, United States Code, as in
22 effect on the day before that effective date.

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

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

3 **SEC. 8. INSTITUTIONS OF HIGHER EDUCATION.**

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

6 “(d) INSTITUTIONS OF HIGHER EDUCATION.—

7 “(1) DEFINITION.—In this subsection, the term
8 ‘institution of higher education’ has the meaning
9 given the term in section 101(a) of the Higher Edu-
10 cation Act of 1965 (20 U.S.C. 1001(a)).

11 “(2) INCLUSIONS.—For purposes of this sec-
12 tion, a micro entity shall include an applicant who
13 certifies that—

14 “(A) the applicant’s employer, from which
15 the applicant obtains the majority of the appli-
16 cant’s income, is an institution of higher edu-
17 cation;

18 “(B) the applicant has assigned, granted,
19 conveyed, or is under an obligation by contract
20 or law to assign, grant, or convey, a license or
21 other ownership interest in the particular appli-
22 cations to an institution of higher education;

23 “(C) the applicant is an institution of
24 higher education; or

1 “(D) the applicant is an organization de-
2 scribed in section 501(c)(3) of the Internal Rev-
3 enue Code of 1986 and exempt from taxation
4 under section 501(a) of such Code that holds
5 title to patents and patent applications on be-
6 half of an institution of higher education for the
7 purpose of facilitating commercialization of the
8 technologies of the patents and patent applica-
9 tions.”.

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

12 (a) **DEFINITION.**—In this section, the term “small
13 business concern” has the meaning given the term in sec-
14 tion 3 of the Small Business Act (15 U.S.C. 632).

15 (b) **SMALL BUSINESS ADMINISTRATION REPORT.**—
16 Not later than 1 year after the date of the enactment of
17 this Act, the Administrator of the Small Business Admin-
18 istration, using existing resources, shall submit to the
19 Committee on Small Business and Entrepreneurship of
20 the Senate and the Committee on Small Business of the
21 House of Representatives a report analyzing the impact
22 of—

23 (1) patent ownership by small business con-
24 cerns; and

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

4 (c) FREE ONLINE AVAILABILITY OF PUBLIC SEARCH
5 FACILITY MATERIALS.—Section 41(i) of title 35, United
6 States Code, is amended by adding at the end the fol-
7 lowing:

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

16 “(A) search tools and databases;

17 “(B) informational materials; and

18 “(C) training classes and materials.”.

Æ

118TH CONGRESS
2D SESSION

S. I I

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

| | | | | | | | | |

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

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.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Realizing Engineering,
5 Science, and Technology Opportunities by Restoring Ex-
6 clusive Patent Rights Act of 2024” or the “RESTORE
7 Patent Rights Act of 2024”.

1 SEC. 2. FINDINGS.

2 Congress finds the following:

3 (1) Securing effective and reliable patent pro-
4 tection for new technologies is critical to maintaining
5 the competitive advantage of the United States in
6 the global innovation economy.

7 (2) The Constitution of the United States em-
8 powers Congress to grant inventors the “exclusive
9 Right” to their inventions in order to “promote the
10 Progress of Science and the useful Arts”.

11 (3) The right to prevent others from making,
12 using, offering to sell, selling, or importing a pat-
13 ented invention without authority from the inventor
14 is the core of the patent right, ensuring that an in-
15 ventor enjoys, for a limited time, the sole benefit of
16 the inventor’s invention or discovery.

17 (4) Congress and the courts of the United
18 States have long secured the constitutionally pro-
19 tected patent right through the traditional equitable
20 remedy of an injunction.

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

1 (6) Recently, courts have ended the approach
2 described in paragraph (5), which contradicts the
3 traditional, historical practice governing the equi-
4 table remedy described in that paragraph.

5 (7) Eliminating the traditional, historical equi-
6 table practice of applying a rebuttable presumption
7 of injunctive relief in the case of continuing acts of
8 infringement or willful infringement of a patent
9 has—

10 (A) substantially reduced the ability of pat-
11 ent owners to obtain injunctions to stop con-
12 tinuing or willful infringement of patents; and

13 (B) created incentives for large, multi-
14 national companies to commit predatory acts of
15 infringement, especially with respect to patents
16 owned by undercapitalized entities, such as in-
17 dividual inventors, institutions of higher edu-
18 cation, startups, and small or medium-sized en-
19 terprises.

20 **SEC. 3. REBUTTABLE PRESUMPTION THAT INJUNCTIVE RE-**
21 **LIEF IS WARRANTED.**

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

24 (1) by striking “The several” and inserting the
25 following:

1 “(a) IN GENERAL.—The several”; and

2 (2) by adding at the end the following:

3 “(b) REBUTTABLE PRESUMPTION.—If, in a case
4 under this title, the court enters a final judgment finding
5 infringement of a right secured by patent, the patent
6 owner shall be entitled to a rebuttable presumption that
7 the court should grant a permanent injunction with re-
8 spect 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

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.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Medication Afford-
5 ability and Patent Integrity Act”.

6 **SEC. 2. DISCLOSURE OF INFORMATION.**

7 (a) **IN GENERAL.**—

1 (1) IN GENERAL.—Section 505(b) of the Fed-
2 eral Food, Drug, and Cosmetic Act (21 U.S.C.
3 355(b)) is amended by adding at the end the fol-
4 lowing:

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

9 “(i) certify to the Food and Drug Administra-
10 tion that the information described in subparagraph
11 (B) that is submitted to the Secretary is complete
12 and consistent with the information such sponsor or
13 holder provided to the United States Patent and
14 Trademark Office and any communications such
15 sponsor or holder had with the United States Patent
16 and Trademark Office; and

17 “(ii)(I) submit to the United States Patent and
18 Trademark Office any information material to pat-
19 entability with respect to such applicable patent that
20 the sponsor or holder submits to the Food and Drug
21 Administration, and any communications with the
22 Food and Drug Administration that are related to
23 such submissions; and

24 “(II) certify to the United States Patent and
25 Trademark Office that the information provided

1 under subclause (I) is complete and consistent with
2 the information such sponsor or holder provided to
3 the Food and Drug Administration and any commu-
4 nications such sponsor or holder had with the Food
5 and Drug Administration.

6 “(B) The information described in this subparagraph
7 is—

8 “(i) any statement or characterization of ana-
9 lytical or clinical data disclosed by the sponsor of the
10 application or holder of the approved application
11 under this section to the United States Patent and
12 Trademark Office that has been, or will be, sub-
13 mitted to the Food and Drug Administration to sup-
14 port the approval of an application under this sec-
15 tion;

16 “(ii) any statement or characterization with re-
17 spect to an applicable patent, including any state-
18 ment or characterization of prior art, submitted by
19 the sponsor of the application or holder of the ap-
20 proved application to the United States Patent and
21 Trademark Office in support of patentability; and

22 “(iii) other information, as the Secretary or the
23 Secretary of Commerce may require.

24 “(C) In this paragraph, the term ‘applicable patent’
25 means—

1 “(i) a patent that—

2 “(I) claims a drug that is the subject of an
3 application described in subparagraph (A), in-
4 cluding any patent that claims, with respect to
5 such a drug, a formulation or composition,
6 method of use, or method of manufacturing;
7 and

8 “(II) is issued, assigned, or licensed to the
9 sponsor of the application or holder of the ap-
10 proved application described in subparagraph
11 (A);

12 “(ii) an application for a patent described in
13 clause (i)(I) that is sought by the sponsor of the ap-
14 plication or holder of the approved application de-
15 scribed in subparagraph (A); or

16 “(iii) such other patent or application for a pat-
17 ent as the Secretary determines appropriate.

18 “(D)(i) Except as provided in clause (ii), subpara-
19 graph (A) shall apply with respect to any original applica-
20 tion submitted under this subsection on or after the date
21 of enactment of the Medication Affordability and Patent
22 Integrity Act and to any amendments or supplements to
23 such original application.

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

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

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

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

10 (2) CONDITION FOR APPROVAL.—Section
11 505(d)(6) of the Federal Food, Drug, and Cosmetic
12 Act (21 U.S.C. 505(d)(6)) is amended by
inserting

13 “, or the sponsor failed to comply with a require-
14 ment of subsection (b)(7)(A)(i)” after “subsection
15 (b)”.

16 (b) BIOLOGICAL PRODUCT APPLICATIONS.—Section
17 351(a)(2) of the Public Health Service Act (42 U.S.C.
18 262(a)(2)) is amended by adding at the end the following:

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

23 “(I) certify to the Food and Drug Administra-
24 tion that the information described in clause (ii) that
25 is submitted to the Secretary is complete and con-

1 sistent with the information such sponsor or holder
2 provided to the United States Patent and Trade-
3 mark Office and any communications such sponsor
4 or holder had with the United States Patent and
5 Trademark Office; and

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

13 “(bb) certify to the United States Patent and
14 Trademark Office that the information provided
15 under item (aa) is complete and consistent with the
16 information such sponsor or holder provided to the
17 Food and Drug Administration and any communica-
18 tions such sponsor or holder had with the Food and
19 Drug Administration.

20 “(ii) The information described in this clause is—

21 “(I) any statement or characterization of ana-
22 lytical or clinical data disclosed by the sponsor of the
23 application or holder of the approved application
24 under this section to the United States Patent and
25 Trademark Office that has been, or will be, sub-

1 mitted to the Food and Drug Administration to sup-
2 port the approval of an application under this sec-
3 tion;

4 “(II) any statement or characterization with re-
5 spect to an applicable patent, including any state-
6 ment or characterization of prior art, submitted by
7 the sponsor of the application or holder of the ap-
8 proved application to the United States Patent and
9 Trademark Office in support of patentability; and

10 “(III) other information, as the Secretary or
11 the Secretary of Commerce may require.

12 “(iii) In this subparagraph, the term ‘applicable pat-
13 ent’ means—

14 “(I) a patent—

15 “(aa) with respect to which a reference
16 product sponsor could reasonably assert a claim
17 of patent infringement, if a person not licensed
18 by the reference product sponsor engaged in the
19 making, using, offering to sell, selling, or im-
20 porting into the United States of a biological
21 product that relies on such patent; and

22 “(bb) that is issued, assigned, or exclu-
23 sively licensed to the sponsor of the application
24 or holder of the licensure described in clause
25 (i);

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

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

7 “(iv)(I) Except as provided in subclause (II), clause
8 (i) shall apply with respect to any original application sub-
9 mitted under this subsection on or after the date of enact-
10 ment of the Medication Affordability and Patent Integrity
11 Act and to any amendments or supplements to such origi-
12 nal application.

13 “(II) In the case of an application submitted under
14 this subsection before the date of enactment of the Medi-
15 cation Affordability and Patent Integrity Act, the require-
16 ments of clause (i) apply with respect to—

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

19 “(bb) in the case of an applicable patent issued
20 before such date of enactment, only to submissions
21 and communications described in subclauses (I) and
22 (II) of clause (i) made on or after such date of en-
23 actment.

24 “(v) Notwithstanding subparagraph (C), the Sec-
25 retary may not approve an application for a biological

1 product if the sponsor of such application is out of compli-
2 ance with the requirements of clause (i)(I) with respect
3 to such application.”.

4 (c) ENFORCEMENT.—

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

8 “(jjj) A failure to comply with a requirement of sec-
9 tion 505(b)(7) of this Act or section 351(a)(2)(F) of the
10 Public Health Service Act.”.

11 (2) DEFENSE AGAINST PATENT INFRINGEMENT
12 ACTIONS.—

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

16 **“§ 274. Non-disclosure defense to infringement of**
17 **drug patent**

18 “A person shall be entitled to a defense under section
19 282(b) in an action asserting infringement of an applica-
20 ble patent (as defined in paragraph (7)(B) of section
21 505(b) of the Federal Food, Drug, and Cosmetic Act (21
22 U.S.C. 355(b)) or subparagraph (F)(ii) of section
23 351(a)(2) of the Public Health Service Act (42 U.S.C.
24 262(a)(2))) if the owner or predecessor owner of the appli-
25 cable patent violated paragraph (7)(A) of such section

1 505(b) or subparagraph (F)(i) of such section 351(a)(2)
2 with respect to the applicable patent by negligently or in-
3 tentionally failing to disclose any information required to
4 be disclosed pursuant to such paragraph (7)(A) or such
5 subparagraph (F)(i).”.

6 (B) TECHNICAL AND CONFORMING AMEND-
7 MENT.—The table of sections for chapter 28 of
8 title 35, United States Code, is amended by
9 adding at the end the following:

“274. Non-disclosure defense to infringement of drug patent.”.

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S 2780 IS

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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.

1 This Act may be cited as the “Medication Affordability and Patent Integrity Act”.

2 SEC. 2. DISCLOSURE OF INFORMATION.

3 (a) In General.—

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

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

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

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

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

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

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

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

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

38 “(C) In this paragraph, the term ‘applicable patent’ means—

39 “(i) a patent that—

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

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

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

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

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

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

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

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

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

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

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

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

33 **(A) in clause (vii), by striking “and” at the end;**

34 **(B) in clause (viii)(II), by striking the period and inserting “; and”; and**

35 **(C) by adding at the end the following:**

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

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

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

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

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

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

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

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

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

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

34 “(iii) In this subparagraph, the term ‘applicable patent’ means—

35 “(I) a patent—

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

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

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

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

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

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

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

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

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

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

29 (c) Enforcement.—

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

32 **(A) in clause (B), by striking “; or” and inserting a semicolon;**

33 **(B) in clause (C), by striking the period and inserting “; or”; and**

34 **(C) by adding at the end the following:**

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

38 (2) DEFENSE AGAINST PATENT INFRINGEMENT ACTIONS.—

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

1 “274. Non-disclosure defense to infringement of drug patent

2 “A person shall be entitled to a defense under section 282(b) in an action asserting
3 infringement of an applicable patent (as defined in paragraph (7)(B) of section 505(b) of the
4 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)) or subparagraph (F)(ii) of section
5 351(a)(2) of the Public Health Service Act (42 U.S.C. 262(a)(2))) if the owner or predecessor
6 owner of the applicable patent violated paragraph (7)(A) of such section 505(b) or subparagraph
7 (F)(i) of such section 351(a)(2) with respect to the applicable patent by negligently or
8 intentionally failing to disclose any information required to be disclosed pursuant to such
9 paragraph (7)(A) or such subparagraph (F)(i).”.

10 (B) TECHNICAL AND CONFORMING AMENDMENT.—The table of sections for chapter
11 28 of title 35, United States Code, is amended by adding at the end the following:

12 “274. Non-disclosure defense to infringement of drug patent.”.