

Calendar No. 528

119TH CONGRESS
2D SESSION**S. 2658**

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

AUGUST 1, 2025

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

JULY 28, 2026

Reported by Mr. CASSIDY, with an amendment

[Strike out all after the enacting clause and insert the part printed in *italic*]

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,*

1 **SECTION 1. SHORT TITLE.**

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

4 **SEC. 2. DISCLOSURE OF INFORMATION.**

5 (a) IN GENERAL.—

6 (1) IN GENERAL.—Section 505(b) of the Fed-
7 eral Food, Drug, and Cosmetic Act (21 U.S.C.
8 355(b)) is amended by adding at the end the fol-
9 lowing:

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

14 “(i) certify to the Food and Drug Administra-
15 tion that the information described in subparagraph
16 (B) that is submitted to the Secretary is, to the best
17 knowledge of the sponsor or holder, consistent with
18 the information such sponsor or holder provided to
19 the United States Patent and Trademark Office and
20 any communications such sponsor or holder had with
21 the United States Patent and Trademark Office;
22 and

23 “(ii)(I) submit to the United States Patent and
24 Trademark Office any information material to pat-
25 entability with respect to such applicable patent that
26 the sponsor or holder submits to the Food and Drug

1 Administration, and any information the Food and
2 Drug Administration provided in response; and

3 “(H) certify to the United States Patent and
4 Trademark Office that the submission under sub-
5 clause (I), to the best knowledge of the sponsor or
6 holder, includes all information material to patent-
7 ability, and is consistent with the information such
8 sponsor or holder provided to the Food and Drug
9 Administration and any communications such spon-
10 sor or holder had with the Food and Drug Adminis-
11 tration.

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

16 “(i) any statement or characterization of ana-
17 lytical data set forth in the chemistry, manufac-
18 turing, and controls section of a new drug applica-
19 tion disclosed by the sponsor of the application or
20 holder of the approved application under this section
21 to the United States Patent and Trademark Office
22 that has been, or will be, submitted to the Food and
23 Drug Administration to support the approval of an
24 application under this section;

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

7 “(iii) other information, as the Secretary or the
8 Secretary of Commerce may by regulation require.

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

11 “(i) a patent that—

12 “(I) claims a drug that is the subject of an
13 application described in subparagraph (A), in-
14 cluding any patent that claims, with respect to
15 such a drug, a formulation or composition,
16 method of use, or method of manufacturing;
17 and

18 “(II) is issued, assigned, or licensed to the
19 sponsor of the application or holder of the ap-
20 proved application described in subparagraph
21 (A);

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

1 “(iii) such other patent or application for a pat-
2 ent as the Secretary or the Secretary of Commerce
3 may by regulation require.

4 “(D)(i) Except as provided in clause (ii), subpara-
5 graph (A) shall apply with respect to any original applica-
6 tion submitted under this subsection on or after the date
7 of enactment of the Medication Affordability and Patent
8 Integrity Act and to any amendments or supplements to
9 such original application.

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

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

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

21 “(E) The United States Patent and Trademark Of-
22 fice shall, as necessary, update its applicable regulations
23 or establish new procedures to ensure that any informa-
24 tion that the sponsor or holder of the application has sub-
25 mitted to or received from the Food and Drug Administra-

tion and that is submitted to the United States Patent and Trademark Office to fulfill the requirements of subparagraph (A), and that would not otherwise be submitted to the United States Patent and Trademark Office, shall remain subject to application protections for trade secret or confidential information or financial information as if the information were held by the Food and Drug Administration.”.

(2) INCLUSION OF CERTIFICATIONS IN APPLICATION.—Section 505(b)(1)(A) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)(1)(A)) is amended—

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

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

(C) by adding at the end the following:

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

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

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

5 “(I) certify to the Food and Drug Administra-
6 tion that the information described in clause (ii) that
7 is submitted to the Secretary is, to the best knowl-
8 edge of the sponsor or holder, consistent with the in-
9 formation such sponsor or holder provided to the
10 United States Patent and Trademark Office and any
11 communications such sponsor or holder had with the
12 United States Patent and Trademark Office; and

13 “(H)(aa) submit to the United States Patent
14 and Trademark Office any information material to
15 patentability with respect to such applicable patent
16 that the sponsor or holder submits to the Food and
17 Drug Administration provided in response; and

18 “(bb) certify to the United States Patent and
19 Trademark Office that the submission under item
20 (aa), to the best knowledge of the sponsor or holder,
21 includes all information material to patentability and
22 is consistent with the information such sponsor or
23 holder provided to the Food and Drug Administra-
24 tion and any communications such sponsor or holder
25 had with the Food and Drug Administration.

1 “(ii) The information described in this clause is lim-
2 ited to information that is material to patentability, as de-
3 fined in regulations promulgated by the United States
4 Patent and Trademark Office, and that is—

5 “(I) any statement or characterization of ana-
6 lytical data set forth in the chemistry, manufac-
7 turing, and controls section in a biological product
8 license application disclosed by the sponsor of the
9 application or holder of the approved application
10 under this section to the United States Patent and
11 Trademark Office that has been, or will be, sub-
12 mitted to the Food and Drug Administration to sup-
13 port the approval of an application under this sec-
14 tion;

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

21 “(III) other information, as the Secretary or
22 the Secretary of Commerce may by regulation re-
23 quire.

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

1 “(I) a patent that—

2 “(aa) claims a biological product that is
3 the subject of an application described in clause
4 (i); including any patent that claims, with re-
5 spect to such biological product, a formulation
6 or composition, method of use, or method of
7 manufacturing; and

8 “(bb) is issued, assigned, or exclusively li-
9 censed to the sponsor of the application or hold-
10 er of the licensure described in clause (i);

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

15 “(III) such other patent or application for a
16 patent as the Secretary or Secretary of Commerce
17 may by regulation require.

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

24 “(II) In the case of an application submitted under
25 this subsection before the date of enactment of the Medi-

1 cation Affordability and Patent Integrity Act, the require-
 2 ments of clause (i) apply only with respect to—

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

5 “(bb) in the case of an applicable patent issued
 6 before such date of enactment, only to submissions
 7 and communications described in subclauses (I) and
 8 (II) of clause (i) made on or after such date of en-
 9 actment.

10 “(v)(I) Any information that the sponsor of the appli-
 11 cation or holder of the licensure has submitted to or re-
 12 ceived from the Food and Drug Administration that is
 13 submitted to the United States Patent and Trademark Of-
 14 fice to fulfill the requirements of clause (i) shall remain
 15 subject to application protections for trade secret or con-
 16 fidential information or financial information as if the in-
 17 formation were held by the Food and Drug Administra-
 18 tion.

19 “(II) The United States Patent and Trademark Of-
 20 fice shall, as necessary, update its applicable regulations
 21 or create new procedures to ensure compliance with sub-
 22 clause (I) for information submitted under this subpara-
 23 graph.”.

24 (c) ENFORCEMENT.—

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

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

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

8 (C) by adding at the end the following:

9 “(D) to submit the certification required under
 10 section 505(b)(7) of this Act or section 351(a)(2)(F)
 11 of the Public Health Service Act.”.

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

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

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

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

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

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

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

11 **SECTION 1. SHORT TITLE.**

12 *This Act may be cited as the “Medication Affordability*
 13 *and Patent Integrity Act”.*

14 **SEC. 2. DISCLOSURE OF INFORMATION.**

15 (a) *IN GENERAL.*—

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

19 “(8)(A) *With respect to any application submitted*
 20 *under this subsection or approved under subsection (c), the*
 21 *sponsor of the application or holder of the approved appli-*
 22 *cation shall, for any applicable patent—*

23 “(i) *certify to the Food and Drug Administra-*
 24 *tion that the information described in subparagraph*
 25 *(B) that is submitted to the Secretary is, to the best*

1 *knowledge of the sponsor or holder, consistent with the*
2 *information such sponsor or holder provided to the*
3 *United States Patent and Trademark Office and any*
4 *communications such sponsor or holder had with the*
5 *United States Patent and Trademark Office; and*

6 *“(ii)(I) submit to the United States Patent and*
7 *Trademark Office any information material to pat-*
8 *entability, with respect to such applicable patent that*
9 *the sponsor or holder submits to the Food and Drug*
10 *Administration, and any information the Food and*
11 *Drug Administration provided in response; and*

12 *“(II) certify to the United States Patent and*
13 *Trademark Office that the submission under subclause*
14 *(I), to the best knowledge of the sponsor or holder, in-*
15 *cludes all information material to patentability and*
16 *is consistent with the information such sponsor or*
17 *holder provided to the Food and Drug Administration*
18 *and any communications such sponsor or holder had*
19 *with the Food and Drug Administration.*

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

24 *“(i) any statement or characterization of analyt-*
25 *ical data set forth in the chemistry, manufacturing,*

1 *and controls section of a new drug application dis-*
2 *closed by the sponsor of the application or holder of*
3 *the approved application under this section to the*
4 *United States Patent and Trademark Office that has*
5 *been, or will be, submitted to the Food and Drug Ad-*
6 *ministration to support the approval of an applica-*
7 *tion under this section;*

8 “(ii) *any statement or characterization with re-*
9 *spect to an applicable patent, including any state-*
10 *ment or characterization of prior art, submitted by*
11 *the sponsor of the application or holder of the ap-*
12 *proved application to the United States Patent and*
13 *Trademark Office in support of patentability; or*

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

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

18 “(i) *a patent that—*

19 “(I) *claims a drug that is the subject of an*
20 *application described in subparagraph (A), in-*
21 *cluding any patent that claims, with respect to*
22 *such a drug, a formulation or composition,*
23 *method of use, or method of manufacturing; and*

24 “(II) *is issued, assigned, or exclusively li-*
25 *censed to the sponsor of the application or holder*

1 *of the approved application described in sub-*
2 *paragraph (A);*

3 *“(ii) an application for a patent described in*
4 *clause (i)(I) that is sought by the sponsor of the ap-*
5 *plication or holder of the approved application de-*
6 *scribed in subparagraph (A); or*

7 *“(iii) such other patent or application for a pat-*
8 *ent as the Secretary or the Secretary of Commerce*
9 *may by regulation require.*

10 *“(D)(i) Except as provided in clause (ii), subpara-*
11 *graph (A) shall apply with respect to any original applica-*
12 *tion submitted under this subsection on or after the date*
13 *of enactment of the Medication Affordability and Patent In-*
14 *tegrity Act and to any amendments or supplements to such*
15 *original application.*

16 *“(ii) In the case of an application submitted under*
17 *this subsection before the date of enactment of the Medica-*
18 *tion Affordability and Patent Integrity Act, the require-*
19 *ments of subparagraph (A) apply only with respect to—*

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

22 *“(II) in the case of an applicable patent issued*
23 *before such date of enactment, only to submissions*
24 *and communications described in clauses (i) and (ii)*

1 of subparagraph (A) made on or after such date of en-
 2 actment.

3 “(E)(i) Any information that the sponsor of the appli-
 4 cation or holder of the approved application has submitted
 5 to or received from the Food and Drug Administration that
 6 is submitted to the United States Patent and Trademark
 7 Office to fulfill the requirements of subparagraph (A), and
 8 that would not otherwise be submitted to the United States
 9 Patent and Trademark Office, shall remain subject to pro-
 10 tections for trade secret or confidential information or fi-
 11 nancial information applicable to such application as if the
 12 information were held by the Food and Drug Administra-
 13 tion, except that such protections shall not apply to infor-
 14 mation that the United States Patent and Trademark Of-
 15 fice determines necessary for the public to understand the
 16 scope of patent claims granted.

17 “(ii) The United States Patent and Trademark Office
 18 shall, as necessary, update its applicable regulations or es-
 19 tablish new procedures to ensure compliance with clause (i)
 20 for information submitted under this paragraph.”.

21 (2) INCLUSION OF CERTIFICATIONS IN APPLICA-
 22 TION.—Section 505(b)(1)(A) of the Federal Food,
 23 Drug, and Cosmetic Act (21 U.S.C. 355(b)(1)(A)) is
 24 amended—

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

3 (B) in clause (viii)(II), by striking the pe-
4 riod and inserting “; and”; and

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

6 “(ix) with respect to each patent listed in the ap-
7 plication pursuant to clause (viii) that is an applica-
8 ble patent (as defined in paragraph (8)(C)), the cer-
9 tifications required under clauses (i) and (ii)(II) of
10 paragraph (8)(A).”.

11 (b) *BIOLOGICAL PRODUCT APPLICATIONS.*—Section
12 351(a)(2) of the Public Health Service Act (42 U.S.C.
13 262(a)(2)) is amended by adding at the end the following:

14 “(F)(i) With respect to any application submitted
15 under this subsection or biological product licensed under
16 this subsection, the sponsor of the application or holder of
17 the license shall, for any applicable patent—

18 “(I) certify to the Food and Drug Administra-
19 tion that the information described in clause (ii) that
20 is submitted to the Secretary is, to the best knowledge
21 of the sponsor or holder, consistent with the informa-
22 tion such sponsor or holder provided to the United
23 States Patent and Trademark Office and any commu-
24 nications such sponsor or holder had with the United
25 States Patent and Trademark Office; and

1 “(II)(aa) submit to the United States Patent and
2 Trademark Office any information material to pat-
3 entability with respect to such applicable patent that
4 the sponsor or holder submits to the Food and Drug
5 Administration, and any information the Food and
6 Drug Administration provided in response; and

7 “(bb) certify to the United States Patent and
8 Trademark Office that the submission under item
9 (aa), to the best knowledge of the sponsor or holder,
10 includes all information material to patentability
11 and is consistent with the information such sponsor
12 or holder provided to the Food and Drug Administra-
13 tion and any communications such sponsor or holder
14 had with the Food and Drug Administration.

15 “(ii) The information described in this clause is lim-
16 ited to information that is material to patentability, as de-
17 fined in regulations promulgated by the United States Pat-
18 ent and Trademark Office, and that is—

19 “(I) any statement or characterization of analyt-
20 ical data set forth in the chemistry, manufacturing,
21 and controls section of a biological product license ap-
22 plication disclosed by the sponsor of the application
23 or holder of the approved application under this sec-
24 tion to the United States Patent and Trademark Of-
25 fice that has been, or will be, submitted to the Food

1 *and Drug Administration to support the approval of*
 2 *an application under this section;*

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

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

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

13 “(I) *a patent that—*

14 “(aa) *claims a biological product that is the*
 15 *subject of an application described in clause (i),*
 16 *including any patent that claims, with respect to*
 17 *such biological product, a formulation or com-*
 18 *position, method of use, or method of manufac-*
 19 *turing; and*

20 “(bb) *is issued, assigned, or exclusively li-*
 21 *censed to the sponsor of the application or holder*
 22 *of the license described in clause (i);*

23 “(II) *an application for a patent described in*
 24 *subclause (I)(aa) that is sought by the sponsor of the*

1 *application or holder of the license described in clause*
 2 *(i); or*

3 *“(III) such other patent or application for a pat-*
 4 *ent as the Secretary or Secretary of Commerce may*
 5 *by regulation require.*

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

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

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

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

23 *“(v)(I) Any information that the sponsor of the appli-*
 24 *cation or holder of the license has submitted to or received*
 25 *from the Food and Drug Administration that is submitted*

1 *to the United States Patent and Trademark Office to fulfill*
 2 *the requirements of clause (i), and that would not otherwise*
 3 *be submitted to the United States Patent and Trademark*
 4 *Office, shall remain subject to protections for trade secret*
 5 *or confidential information or financial information appli-*
 6 *cable to such application or license as if the information*
 7 *were held by the Food and Drug Administration, except*
 8 *that such protections shall not apply to information that*
 9 *the United States Patent and Trademark Office determines*
 10 *necessary for the public to understand the scope of patent*
 11 *claims granted.*

12 “(II) *The United States Patent and Trademark Office*
 13 *shall, as necessary, update its applicable regulations or es-*
 14 *tablish new procedures to ensure compliance with subclause*
 15 *(I) for information submitted under this subparagraph.”.*

16 (c) *ENFORCEMENT.*—

17 (1) *FDA ENFORCEMENT.*—*Section 301(q)(1) of*
 18 *the Federal Food, Drug, and Cosmetic Act (21 U.S.C.*
 19 *331(q)(1)) is amended—*

20 (A) *in clause (B), by striking “; or” and in-*
 21 *serting a semicolon;*

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

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

1 “(D) to submit the certification required under
 2 section 505(b)(8)(A)(i) of this Act or section
 3 351(a)(2)(F)(i)(I) of the Public Health Service Act.”.

4 (2) *DEFENSE AGAINST PATENT INFRINGEMENT*
 5 *ACTIONS.*—

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

9 **“§ 274. Non-disclosure defense to infringement of drug**
 10 **patent**

11 “A person shall be entitled to a defense under
 12 section 282(b) in an action asserting infringement of
 13 an applicable patent (as defined in paragraph (8)(C)
 14 of section 505(b) of the Federal Food, Drug, and Cos-
 15 metic Act (21 U.S.C. 355(b)) or subparagraph
 16 (F)(iii) of section 351(a)(2) of the Public Health
 17 Service Act (42 U.S.C. 262(a)(2))) if the owner or
 18 predecessor owner of the applicable patent violated
 19 paragraph (8)(A) of such section 505(b) or subpara-
 20 graph (F)(i) of such section 351(a)(2) with respect to
 21 the applicable patent by negligently or intentionally
 22 failing to disclose any information required to be dis-
 23 closed pursuant to such paragraph (8)(A) or such
 24 subparagraph (F)(i), on the condition that such a de-
 25 fense shall not be available if the person asserting

1 *such a defense is a covered foreign person (as defined*
2 *in section 809 of the Defense Production Act of 1950*
3 *(50 U.S.C. 4589)).”.*

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

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

Calendar No. 528

119TH CONGRESS
2D Session

S. 2658

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.

JULY 28, 2026

Reported with an amendment