

119TH CONGRESS
1ST 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

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, to the best
12 knowledge of the sponsor or holder, consistent with
13 the information such sponsor or holder provided to
14 the United States Patent and Trademark Office and
15 any communications such sponsor or holder had with
16 the United States Patent and Trademark Office;
17 and

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

24 “(II) certify to the United States Patent and
25 Trademark Office that the submission under sub-

1 clause (I), to the best knowledge of the sponsor or
2 holder, includes all information material to patent-
3 ability, and is consistent with the information such
4 sponsor or holder provided to the Food and Drug
5 Administration and any communications such spon-
6 sor or holder had with the Food and Drug Adminis-
7 tration.

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

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

21 “(ii) any statement or characterization with re-
22 spect to an applicable patent, including any state-
23 ment or characterization of prior art, submitted by
24 the sponsor of the application or holder of the ap-

1 proved application to the United States Patent and
2 Trademark Office in support of patentability; or

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

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

7 “(i) a patent that—

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

14 “(II) is issued, assigned, or licensed to the
15 sponsor of the application or holder of the ap-
16 proved application described in subparagraph
17 (A);

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

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

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

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

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

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

18 “(E) The United States Patent and Trademark Of-
19 fice shall, as necessary, update its applicable regulations
20 or establish new procedures to ensure that any informa-
21 tion that the sponsor or holder of the application has sub-
22 mitted to or received from the Food and Drug Administra-
23 tion and that is submitted to the United States Patent
24 and Trademark Office to fulfill the requirements of sub-
25 paragraph (A), and that would not otherwise be submitted

1 to the United States Patent and Trademark Office, shall
 2 remain subject to application protections for trade secret
 3 or confidential information or financial information as if
 4 the information were held by the Food and Drug Adminis-
 5 tration.”.

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

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

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

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

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

20 (b) BIOLOGICAL PRODUCT APPLICATIONS.—Section
 21 351(a)(2) of the Public Health Service Act (42 U.S.C.
 22 262(a)(2)) is amended by adding at the end the following:

23 “(F)(i) With respect to any application submitted
 24 under this subsection or biological product licensed under

1 this subsection, the sponsor of the application or holder
2 of the licensure shall, for any applicable patent—

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

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

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

24 “(ii) The information described in this clause is lim-
25 ited to information that is material to patentability, as de-

1 fined in regulations promulgated by the United States
2 Patent and Trademark Office, and that is—

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

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

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

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

24 “(I) a patent that—

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

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

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

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

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

23 “(II) In the case of an application submitted under
24 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.”.

