

118TH CONGRESS
1ST SESSION

S. _____

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

Ms. HASSAN (for herself and Mr. BRAUN) introduced the following bill; which was read twice and referred to the Committee on _____

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 tentiously 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.”.