

AMENDMENT NO. _____ Calendar No. _____

Purpose: In the nature of a substitute.

IN THE SENATE OF THE UNITED STATES—118th Cong., 2d Sess.

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.

Referred to the Committee on _____ and
ordered to be printed

Ordered to lie on the table and to be printed

AMENDMENT IN THE NATURE OF A SUBSTITUTE intended
to be proposed by _____

Viz:

1 Strike all after the enacting clause and insert the fol-
2 lowing:

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.—

8 (1) IN GENERAL.—Section 505(b) of the Fed-
9 eral Food, Drug, and Cosmetic Act (21 U.S.C.
10 355(b)) is amended by adding at the end the fol-
11 lowing:

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

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

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

20 “(II) certify to the United States Patent and
21 Trademark Office that the submission under sub-
22 clause (I), to the best knowledge of the sponsor or
23 holder, includes all information material to patent-
24 ability, and is consistent with the information such
25 sponsor or holder provided to the Food and Drug

1 Administration and any communications such spon-
2 sor or holder had with the Food and Drug Adminis-
3 tration.

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

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

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

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

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

3 “(i) a patent that—

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

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

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

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

21 “(D)(i) Except as provided in clause (ii), subpara-
22 graph (A) shall apply with respect to any original applica-
23 tion submitted under this subsection on or after the date
24 of enactment of the Medication Affordability and Patent

1 Integrity Act and to any amendments or supplements to
2 such original application.

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

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

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

14 “(E)(i) Any information that the sponsor or holder
15 of the application has submitted to or received from the
16 Food and Drug Administration that is submitted to the
17 United States Patent and Trademark office to fulfill the
18 requirements of subparagraph (A) shall remain subject to
19 application protections for trade secret or confidential in-
20 formation or financial information as if the information
21 were held by the Food and Drug Administration.

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

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

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

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

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

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

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

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

22 “(I) certify to the Food and Drug Administra-
23 tion that the information described in clause (ii) that
24 is submitted to the Secretary is, to the best knowl-
25 edge of the sponsor or holder, consistent with the in-

1 formation such sponsor or holder provided to the
2 United States Patent and Trademark Office and any
3 communications such sponsor or holder had with the
4 United States Patent and Trademark Office; and

5 “(II)(aa) submit to the United States Patent
6 and Trademark Office any information material to
7 patentability with respect to such applicable patent
8 that the sponsor or holder submits to the Food and
9 Drug Administration provided in response; and

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

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

22 “(I) any statement or characterization of ana-
23 lytical data set forth in the chemistry, manufac-
24 turing, and controls section in a biological product
25 license application disclosed by the sponsor of the

1 application or holder of the approved application
2 under this section to the United States Patent and
3 Trademark Office that has been, or will be, sub-
4 mitted to the Food and Drug Administration to sup-
5 port the approval of an application under this sec-
6 tion;

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

13 “(III) other information, as the Secretary or
14 the Secretary of Commerce may by regulation re-
15 quire.

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

18 “(I) a patent—

19 “(aa) claims a biological product that is
20 the subject of an application described in clause
21 (i), including any patent that claims, with re-
22 spect to such biological product, a formulation
23 or composition, method of use, or method of
24 manufacturing; and

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

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

9 “(III) such other patent or application for a
10 patent as the Secretary or Secretary of Commerce
11 may by regulation require.

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

18 “(II) In the case of an application submitted under
19 this subsection before the date of enactment of the Medi-
20 cation Affordability and Patent Integrity Act, the require-
21 ments of clause (i) apply only with respect to—

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

24 “(bb) in the case of an applicable patent issued
25 before such date of enactment, only to submissions

1 and communications described in subclauses (I) and
2 (II) of clause (i) made on or after such date of en-
3 actment.

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

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

18 (c) ENFORCEMENT.—

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

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

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

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

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

5 (2) DEFENSE AGAINST PATENT INFRINGEMENT
6 ACTIONS.—

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

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

12 “A person shall be entitled to a defense under section
13 282(b) in an action asserting infringement of an applica-
14 ble patent (as defined in paragraph (7)(B) of section
15 505(b) of the Federal Food, Drug, and Cosmetic Act (21
16 U.S.C. 355(b)) or subparagraph (F)(ii) of section
17 351(a)(2) of the Public Health Service Act (42 U.S.C.
18 262(a)(2)) if the owner or predecessor owner of the appli-
19 cable patent violated paragraph (7)(A) of such section
20 505(b) or subparagraph (F)(i) of such section 351(a)(2)
21 with respect to the applicable patent by negligently or in-
22 tentiously failing to disclose any information required to
23 be disclosed pursuant to such paragraph (7)(A) or such
24 subparagraph (F)(i).”.

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

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