

Bill Cassidy, M.D.

AMENDMENT NO. _____ Calendar No. _____

Purpose: In the nature of a substitute.

IN THE SENATE OF THE UNITED STATES—119th Cong., 2d Sess.

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.

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 “(8)(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
17 that the sponsor or holder submits to the Food and
18 Drug Administration, and any information the Food
19 and 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 exclusively li-
11 censed to the sponsor of the application or hold-
12 er of the approved application described in sub-
13 paragraph (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 under
4 this subsection before the date of enactment of the Medi-
5 cation Affordability and Patent Integrity Act, the require-
6 ments of subparagraph (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 of the ap-
15 plication or holder of the approved application has sub-
16 mitted to or received from the Food and Drug Administra-
17 tion that is submitted to the United States Patent and
18 Trademark Office to fulfill the requirements of subpara-
19 graph (A), and that would not otherwise be submitted to
20 the United States Patent and Trademark Office, shall re-
21 main subject to protections for trade secret or confidential
22 information or financial information applicable to such ap-
23 plication as if the information were held by the Food and
24 Drug Administration, except that such protections shall
25 not apply to information that the United States Patent

1 and Trademark Office determines necessary for the public
2 to understand the scope of patent claims granted.

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

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

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

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

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

16 “(ix) with respect to each patent listed in the
17 application pursuant to clause (viii) that is an appli-
18 cable patent (as defined in paragraph (8)(C)), the
19 certifications required under clauses (i) and (ii)(II)
20 of paragraph (8)(A).”

21 (b) BIOLOGICAL PRODUCT APPLICATIONS.—Section
22 351(a)(2) of the Public Health Service Act (42 U.S.C.
23 262(a)(2)) is amended by adding at the end the following:

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

1 this subsection, the sponsor of the application or holder
2 of the license 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, and any information the Food
16 and Drug Administration provided in response; and

17 “(bb) certify to the United States Patent and
18 Trademark Office that the submission under item
19 (aa), to the best knowledge of the sponsor or holder,
20 includes all information material to patentability and
21 is consistent with the information such sponsor or
22 holder provided to the Food and Drug Administra-
23 tion and any communications such sponsor or holder
24 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 of 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 license 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 license described in
14 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 license has submitted to or received
12 from the Food and Drug Administration that is submitted
13 to the United States Patent and Trademark office to fulfill
14 the requirements of clause (i), and that would not other-
15 wise be submitted to the United States Patent and Trade-
16 mark Office, shall remain subject to protections for trade
17 secret or confidential information or financial information
18 applicable to such application or license as if the informa-
19 tion were held by the Food and Drug Administration, ex-
20 cept that such protections shall not apply to information
21 that the United States Patent and Trademark Office de-
22 termines necessary for the public to understand the scope
23 of patent claims granted.

24 “(II) The United States Patent and Trademark Of-
25 fice shall, as necessary, update its applicable regulations

1 or establish new procedures to ensure compliance with
2 subclause (I) for information submitted under this sub-
3 paragraph.”.

4 (c) ENFORCEMENT.—

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

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

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

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

13 “(D) to submit the certification required under
14 section 505(b)(8)(A)(i) of this Act or section
15 351(a)(2)(F)(i)(I) of the Public Health Service
16 Act.”.

17 (2) DEFENSE AGAINST PATENT INFRINGEMENT
18 ACTIONS.—

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

22 **“§ 274. Non-disclosure defense to infringement of**
23 **drug patent**

24 “A person shall be entitled to a defense under
25 section 282(b) in an action asserting infringement of

1 an applicable patent (as defined in paragraph (8)(C)
2 of section 505(b) of the Federal Food, Drug, and
3 Cosmetic Act (21 U.S.C. 355(b)) or subparagraph
4 (F)(iii) of section 351(a)(2) of the Public Health
5 Service Act (42 U.S.C. 262(a)(2))) if the owner or
6 predecessor owner of the applicable patent violated
7 paragraph (8)(A) of such section 505(b) or subpara-
8 graph (F)(i) of such section 351(a)(2) with respect
9 to the applicable patent by negligently or inten-
10 tionally failing to disclose any information required
11 to be disclosed pursuant to such paragraph (8)(A) or
12 such subparagraph (F)(i).”.

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

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