

118TH CONGRESS
1ST SESSION

H. R. 5429

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 HOUSE OF REPRESENTATIVES

SEPTEMBER 13, 2023

Ms. KUSTER (for herself and Mrs. HARSHBARGER) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on the Judiciary, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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”.

1 **SEC. 2. DISCLOSURE OF INFORMATION.**

2 (a) IN GENERAL.—

3 (1) IN GENERAL.—Section 505(b) of the Fed-
4 eral Food, Drug, and Cosmetic Act (21 U.S.C.
5 355(b)) is amended by adding at the end the fol-
6 lowing:

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

11 “(i) certify to the Food and Drug Administra-
12 tion that the information described in subparagraph
13 (B) that is submitted to the Secretary is complete
14 and consistent with the information such sponsor or
15 holder provided to the United States Patent and
16 Trademark Office and any communications such
17 sponsor or holder had with the United States Patent
18 and Trademark Office; and

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

1 “(II) certify to the United States Patent and
2 Trademark Office that the information provided
3 under subclause (I) is complete and consistent with
4 the information such sponsor or holder provided to
5 the Food and Drug Administration and any commu-
6 nications such sponsor or holder had with the Food
7 and Drug Administration.

8 “(B) The information described in this subparagraph
9 is—

10 “(i) any statement or characterization of ana-
11 lytical or clinical data disclosed by the sponsor of the
12 application or holder of the approved application
13 under this section to the United States Patent and
14 Trademark Office that has been, or will be, sub-
15 mitted to the Food and Drug Administration to sup-
16 port the approval of an application under this sec-
17 tion;

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

24 “(iii) other information, as the Secretary or the
25 Secretary of Commerce may 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 determines appropriate.

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

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

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

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

12 (2) CONDITION FOR APPROVAL.—Section
13 505(d)(6) of the Federal Food, Drug, and Cosmetic
14 Act (21 U.S.C. 505(d)(6)) is amended by inserting
15 “, or the sponsor failed to comply with a require-
16 ment of subsection (b)(7)(A)(i)” after “subsection
17 (b)”.

18 (b) BIOLOGICAL PRODUCT APPLICATIONS.—Section
19 351(a)(2) of the Public Health Service Act (42 U.S.C.
20 262(a)(2)) is amended by adding at the end the following:

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

1 “(I) certify to the Food and Drug Administra-
2 tion that the information described in clause (ii) that
3 is submitted to the Secretary is complete and con-
4 sistent with the information such sponsor or holder
5 provided to the United States Patent and Trade-
6 mark Office and any communications such sponsor
7 or holder had with the United States Patent and
8 Trademark Office; and

9 “(II)(aa) submit to the United States Patent
10 and Trademark Office any information material to
11 patentability with respect to such applicable patent
12 that the sponsor or holder submits to the Food and
13 Drug Administration, and any communications with
14 the Food and Drug Administration that are related
15 to such submissions; and

16 “(bb) certify to the United States Patent and
17 Trademark Office that the information provided
18 under item (aa) is complete and consistent with the
19 information such sponsor or holder provided to the
20 Food and Drug Administration and any communica-
21 tions such sponsor or holder had with the Food and
22 Drug Administration.

23 “(ii) The information described in this clause is—

24 “(I) any statement or characterization of ana-
25 lytical or clinical data 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; and

13 “(III) other information, as the Secretary or
14 the Secretary of Commerce may require.

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

17 “(I) a patent—

18 “(aa) with respect to which a reference
19 product sponsor could reasonably assert a claim
20 of patent infringement, if a person not licensed
21 by the reference product sponsor engaged in the
22 making, using, offering to sell, selling, or im-
23 porting into the United States of a biological
24 product that relies on such patent; 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 determines appropriate.

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

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

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

23 “(bb) in the case of an applicable patent issued
24 before such date of enactment, only to submissions
25 and communications described in subclauses (I) and

1 (II) of clause (i) made on or after such date of en-
 2 actment.

3 “(v) Notwithstanding subparagraph (C), the Sec-
 4 retary may not approve an application for a biological
 5 product if the sponsor of such application is out of compli-
 6 ance with the requirements of clause (i)(I) with respect
 7 to such application.”.

8 (c) ENFORCEMENT.—

9 (1) FDA ENFORCEMENT.—Section 301 of the
 10 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
 11 331) is amended by adding at the end the following:
 12 “(jjj) A failure to comply with a requirement of sec-
 13 tion 505(b)(7) of this Act or section 351(a)(2)(F) of the
 14 Public Health Service Act.”.

15 (2) DEFENSE AGAINST PATENT INFRINGEMENT
 16 ACTIONS.—

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

20 **“§ 274. Non-disclosure defense to infringement of**
 21 **drug patent**

22 “A person shall be entitled to a defense under section
 23 282(b) in an action asserting infringement of an applica-
 24 ble patent (as defined in paragraph (7)(B) of section
 25 505(b) of the Federal Food, Drug, and Cosmetic Act (21

1 U.S.C. 355(b)) or subparagraph (F)(ii) of section
2 351(a)(2) of the Public Health Service Act (42 U.S.C.
3 262(a)(2))) if the owner or predecessor owner of the appli-
4 cable patent violated paragraph (7)(A) of such section
5 505(b) or subparagraph (F)(i) of such section 351(a)(2)
6 with respect to the applicable patent by negligently or in-
7 tentiously failing to disclose any information required to
8 be disclosed pursuant to such paragraph (7)(A) or such
9 subparagraph (F)(i).”.

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

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

