I

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.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Medication Affordability and Patent Integrity Act''.

SEC. 2. DISCLOSURE OF INFORMATION.

(a) IN GENERAL.—

(1) IN GENERAL.—Section 505(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)) is amended by adding at the end the following:

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

''(i) certify to the Food and Drug Administration that the information described in subparagraph (B) that is submitted to the Secretary is complete and consistent with the information such sponsor or holder provided to the United States Patent and Trademark Office and any communications such sponsor or holder had with the United States Patent and Trademark Office; and

''(ii)(I) submit to the United States Patent and Trademark Office any information material to patentability with respect to such applicable patent that the sponsor or holder submits to the Food and Drug Administration, and any communications with the Food and Drug Administration that are related to such submissions; and

''(II) certify to the United States Patent and Trademark Office that the information provided under subclause (I) is complete and consistent with the information such sponsor or holder provided to the Food and Drug Administration and any communications such sponsor or holder had with the Food and Drug Administration.

''(B) The information described in this subparagraph is—

''(i) any statement or characterization of analytical or clinical data disclosed by the sponsor of the application or holder of the approved application under this section to the United States Patent and Trademark Office that has been, or will be, submitted to the Food and Drug Administration to support the approval of an application under this section;

''(ii) any statement or characterization with respect to an applicable patent, including any statement or characterization of prior art, submitted by the sponsor of the application or holder of the approved application to the United States Patent and Trademark Office in support of patentability; and

''(iii) other information, as the Secretary or the Secretary of Commerce may require.

"(C) In this paragraph, the term 'applicable patent' means—

"(i) a patent that—

"(I) claims a drug that is the subject of an application described in subparagraph (A), including any patent that claims, with respect to such a drug, a formulation or composition, method of use, or method of manufacturing; and

"(II) is issued, assigned, or licensed to the sponsor of the application or holder of the approved application described in subparagraph (A);

"(ii) an application for a patent described in clause (i)(I) that is sought by the sponsor of the application or holder of the approved application described in subparagraph (A); or

"(iii) such other patent or application for a patent as the Secretary determines appropriate.

"(D)(i) Except as provided in clause (ii), subparagraph (A) shall apply with respect to any original application submitted under this subsection on or after the date of enactment of the Medication Affordability and Patent Integrity Act and to any amendments or supplements to such original application.

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

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

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

(2) CONDITION FOR APPROVAL.—Section 505(d)(6) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 505(d)(6)) is amended by inserting '', or the sponsor failed to comply with a requirement of subsection (b)(7)(A)(i)'' after ''subsection (b)''.

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

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

''(I) certify to the Food and Drug Administration that the information described in clause (ii) that is submitted to the Secretary is complete and consistent with the information such sponsor or holder provided to the United States Patent and Trademark Office and any communications such sponsor or holder had with the United States Patent and Trademark Office; and

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

''(bb) certify to the United States Patent and Trademark Office that the information provided under item (aa) is complete and consistent with the information such sponsor or holder provided to the Food and Drug Administration and any communications such sponsor or holder had with the Food and Drug Administration.

''(ii) The information described in this clause is—

''(I) any statement or characterization of analytical or clinical data disclosed by the sponsor of the

application or holder of the approved application under this section to the United States Patent and Trademark Office that has been, or will be, submitted to the Food and Drug Administration to support the approval of an application under this section;

''(II) any statement or characterization with respect to an applicable patent, including any statement or characterization of prior art, submitted by the sponsor of the application or holder of the approved application to the United States Patent and Trademark Office in support of patentability; and

''(III) other information, as the Secretary or the Secretary of Commerce may require.

''(iii) In this subparagraph, the term 'applicable patent' means—

''(I) a patent—

''(aa) with respect to which a reference product sponsor could reasonably assert a claim of patent infringement, if a person not licensed by the reference product sponsor engaged in the making, using, offering to sell, selling, or importing into the United States of a biological product that relies on such patent; and

''(bb) that is issued, assigned, or exclusively licensed to the sponsor of the application or holder of the licensure described in clause (i);

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

''(III) such other patent or application for a patent as the Secretary determines appropriate.

''(iv)(I) Except as provided in subclause (II), clause (i) shall apply with respect to any original application submitted under this subsection on or after the date of enactment of the Medication Affordability and Patent Integrity Act and to any amendments or supplements to such original application.

''(II) In the case of an application submitted under this subsection before the date of enactment of the Medication Affordability and Patent Integrity Act, the requirements of clause (i) apply with respect to—

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

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

(II) of clause (i) made on or after such date of enactment.

''(v) Notwithstanding subparagraph (C), the Secretary may not approve an application for a biological product if the sponsor of such application is out of compliance with the requirements of clause (i)(I) with respect to such application.''.

(c) ENFORCEMENT.—

(1) FDA ENFORCEMENT.—Section 301 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331) is amended by adding at the end the following:

''(jjj) A failure to comply with a requirement of section 505(b)(7) of this Act or section 351(a)(2)(F) of the Public Health Service Act.''.

(2) DEFENSE AGAINST PATENT INFRINGEMENT ACTIONS.—

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

''§ 274. Non-disclosure defense to infringement of drug patent

''A person shall be entitled to a defense under section 282(b) in an action asserting infringement of an applicable patent (as defined in paragraph (7)(B) of section 505(b) of the Federal Food, Drug, and Cosmetic Act (21

U.S.C. 355(b)) or subparagraph (F)(ii) of section 351(a)(2) of the Public Health Service Act (42 U.S.C. 262(a)(2))) if the owner or predecessor owner of the applicable patent violated paragraph (7)(A) of such section 505(b) or subparagraph (F)(i) of such section 351(a)(2) with respect to the applicable patent by negligently or intentionally failing to disclose any information required to be disclosed pursuant to such paragraph (7)(A) or such subparagraph (F)(i).''.

(B) TECHNICAL AND CONFORMING AMENDMENT.—The table of sections for chapter 28 of title 35, United States Code, is amended by adding at the end the following:

''274. Non-disclosure defense to infringement of drug patent.''.

○