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116TH CONGRESS
1ST SESSION

H. R. 4850

To provide for certain additional requirements with respect to patent disclosures.

IN THE HOUSE OF REPRESENTATIVES

OCTOBER 23, 2019

Ms. SPANBERGER (for herself and Mr. REED) 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

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A BILL

To provide for certain additional requirements with respect to patent disclosures.

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 ''Biologic Patent Transparency Act''.

SEC. 2. PATENT DISCLOSURE REQUIREMENTS.

(a) IN GENERAL.—Section 351 of the Public Health Service Act (42 U.S.C. 262) is amended by adding at the end the following:

''(o) ADDITIONAL REQUIREMENTS WITH RESPECT TO PATENTS.—

''(1) APPROVED APPLICATION HOLDER LISTING REQUIREMENTS.—

''(A) IN GENERAL.—Beginning on the date of enactment of the Biologic Patent Transparency Act, within 30 days of approval of an application under subsection (a) or (k), the holder of such approved application shall submit to the Secretary a list of each patent required to be disclosed (as described in paragraph (3)).

''(B) PREVIOUSLY APPROVED OR LICENSED BIOLOGICAL PRODUCTS.—

''(i) PRODUCTS APPROVED UNDER SECTION 351 OF THE PHSA.—Not later than 30 days after the date of enactment of the Biologic Patent Transparency Act, the holder of a biological product license that was approved under subsection (a) or (k) before the date of enactment of such Act shall submit to the Secretary a list of each patent required to be disclosed (as described in paragraph (3)).

"(ii) PRODUCTS APPROVED UNDER SECTION 505 OF THE FFDCA.—Not later than 30 days after March 23, 2020, the holder of an approved application for a biological product under section 505 of the Federal Food, Drug, and Cosmetic Act that is deemed to be a license for the biological product under this section on March 23, 2020, shall submit a list of each patent required to be disclosed (as described in paragraph (3)).

"(C) UPDATES.—The holder of a biological product license approved under subsection (a) or (k) shall submit to the Secretary a list that includes—

"(i) any patent first required to be disclosed (as described in paragraph (3)) after the submission under subparagraph (A) or (B), as applicable, within 30 days of the earlier of—

"(I) the date of issuance of such patent by the United States Patent and Trademark Office; or

"(II) the date of approval of a supplemental application for the biological product; and

"(ii) any patent, or any claim with respect to a patent, included on the list pursuant to this paragraph with respect to the biological product subsequently determined to be invalid or unenforceable, within 30 days of a determination of patent invalidity.

"(2) PUBLICATION OF INFORMATION.—

"(A) IN GENERAL.—Within 1 year of the date of enactment of the Biologic Patent Transparency Act, the Secretary shall publish and make available to the public a single, easily searchable, list that includes—

"(i) the official and proprietary name of each biological product licensed under subsection (a) or (k), and of each biological product application approved under section 505 of the Federal Food, Drug, and Cosmetic Act and deemed to be a license for the biological product under this section on March 23, 2020;

''(ii) with respect to each biological product described in clause (i), each patent submitted in accordance with paragraph (1);

''(iii) the date of licensure and application number for each such biological product;

''(iv) the marketing status, dosage form, route of administration, strength, and, if applicable, reference product, for each such biological product;

''(v) the licensure status for each such biological product, including whether the license at the time of listing is approved, withdrawn, or revoked;

''(vi) any period of any exclusivity under subsection (k)(7)(A) or subsection (k)(7)(B) of this section or section 527 of the Federal Food, Drug, and Cosmetic Act, and any extension of such period in accordance with subsection (m) of this section with respect to each such biological product, and the date on which such exclusivity expires;

"(vii) information regarding any determination related to biosimilarity or interchangeability for each such biological product; and

"(viii) information regarding approved indications for each such biological product, in such manner as the Secretary determines appropriate.

"(B) UPDATES.—Every 30 days after the publication of the first list under subparagraph (A), the Secretary shall revise the list to include—

"(i)(I) each biological product licensed under subsection (a) or (k) during the 30-day period; and

"(II) with respect to each biological product described in subclause (I), the information described in clauses (i) through (viii) of subparagraph (A); and

"(ii) any updates to information previously published in accordance with subparagraph (A).

"(3) PATENTS REQUIRED TO BE DISCLOSED.—In this section, a 'patent required to be disclosed' is any patent for which the holder of a biological prod-

uct license approved under subsection (a) or (k), or a biological product application approved under section 505 of the Federal Food, Drug, and Cosmetic Act and deemed to be a license for a biological product under this section on March 23, 2020, believes a claim of patent infringement could reasonably be asserted by the holder, or by a patent owner that has granted an exclusive license to the holder with respect to the biological product that is the subject of such license, if a person not licensed by the holder engaged in the making, using, offering to sell, selling, or importing into the United States of the biological product that is the subject of such license.''.

(b) DISCLOSURE OF PATENTS.—Section 351(l)(3)(A)(i) of the Public Health Service Act (42 U.S.C. 262(l)(3)(A)(i)) is amended by inserting ''included in the list provided by the reference product sponsor under subsection (o)(1)'' after ''a list of patents''.

(c) RESTRICTION ON CLAIMS OF PATENT INFRINGEMENT.—Section 271(e) of title 35, United States Code, is amended by adding at the end the following:

''(7) The owner of a patent that should have been included in the list described in section 351(o)(1) of the Public Health Service Act (42 U.S.C. 262(o)(1)), including any updates required

under subparagraph (C) of that section, but was not timely included in such list, may not bring an action under this section for infringement of the patent.''.

(d) REGULATIONS.—The Secretary of Health and Human Services may promulgate regulations to carry out subsection (o) of section 351 of the Public Health Service Act (42 U.S.C. 262), as added by subsection (a).

(e) RULE OF CONSTRUCTION.—Nothing in this Act, including an amendment made by this Act, shall be construed to require or allow the Secretary of Health and Human Services to delay the licensing of a biological product under section 351 of the Public Health Service Act (42 U.S.C. 262).

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