116TH CONGRESS
1ST SESSION

S. 1617

To amend the Federal Food, Drug, and Cosmetic Act with respect to the listing of patents in the Orange Book.

IN THE SENATE OF THE UNITED STATES

MAY 22, 2019

Mrs. MURRAY (for herself and Mr. CORNYN) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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A BILL

To amend the Federal Food, Drug, and Cosmetic Act with respect to the listing of patents in the Orange Book.

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 ''Second Look at Drug Patents Act of 2019''.

SEC. 2. AMENDMENTS.

(a) IN GENERAL.—Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) is amended—

(1) in subsection (b)(1), at the end of the fifth sentence, by inserting ''subject to subsection (j)(7)(A)(iii)(II)'' before the period; and

(2) in subsection (j)(7)(A)(iii)—

(A) by striking ''When patent'' and inserting ''(I) When patent'';

(B) by inserting '', subject to subclauses (II) and (III),'' after '', include''; and

(C) by adding at the end the following:

''(II) The Secretary shall include patent information on the list pursuant to subclause (I) if the following conditions are met:

''(aa) If the patent has been issued as of the date on which the application is approved under subsection (c), the sponsor, within 30 days of the date of such approval, shall submit to the Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office (referred to in this clause as the 'Director') a notification that the sponsor has included in its application information about the patent as required under subsection (b)(1).

''(bb) If the patent is issued after the date on which the application is approved under sub-

section (c), the sponsor, not later than 30 days after the date on which the patent is issued, shall submit to the Director the notification described in item (aa).

''(cc) Upon receipt of a notification under item (aa) or (bb), as applicable, the Director shall publish, not later than 30 days of such receipt, in the Official Gazette of the United States Patent and Trademark Office, and on an internet website that the Director shall establish, maintain, and operate, a notification with respect to the patent, requesting that any person that is eligible to file a request described in section 311(b) of title 35, United States Code, file such a request.

''(III) A patent included on the list as described in subclause (II) shall be designated as being provisionally included on such list until either of the following conditions is met:

''(aa) The Patent Trial and Appeal Board of the United States Patent and Trademark Office (referred to in this clause as the 'Board') issues a final written decision with respect to an inter partes review of all claims of the patent conducted under chapter 31 of title 35, United

States Code, and the Director issues and publishes a certificate confirming those claims to be patentable.

''(bb) Notwithstanding the filing deadlines provided under section 321(c) of title 35, United States Code, no person files a petition for inter partes review of any claim of the patent, with respect to a patent described in subclause (II)(aa), not later than 300 days after the date on which the application is approved under subsection (c), or, with respect to a patent described in subclause (II)(bb), not later than 15 months after the date on which the application is so approved.

''(IV) With respect to a patent that is included on the list as described in subclause (II), is designated as provisionally included on such list under subclause (III), and, after an inter partes review of the patent conducted under chapter 31 of title 35, United States Code, is subject to a final written decision of the Board and a certificate issued and published by the Director canceling one or more claims of the patent finally determined to be unpatentable, the holder of the approved application, not later than 30 days after the date on which the Director

publishes the certificate, shall submit to the Secretary—

"(aa) if that decision and certificate relate to all claims of the patent, a request to remove the patent from the list; and

"(bb) if that decision and certificate do not relate to all claims of the patent, a request to remove the patent information relating to the claim or claims to which that decision and certificate relate from the list.

"(V) If, as of the date on which a drug is approved under subsection (c), a complaint has been filed in a district court of the United States challenging the validity of a patent, a patent submitted under subsection (b) or (c) respecting such drug included on the list shall be included on the list until the date on which the court invalidates the patent, if applicable.

"(VI) Nothing in this clause shall affect the availability to a first applicant of an exclusivity period pursuant to clause (iv) or (v) of paragraph (5)(B), provided that, at the time that the first applicant submits an application under this subsection containing a certification described in paragraph (2)(A)(vii)(IV), information about the patent is in-

cluded on the list or is included on the list on a provisional basis.''.

(b) EFFECTIVE DATE.—The amendments made by subsection (a) shall apply only with respect to patents issued after the date of enactment of this Act.

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