115TH CONGRESS
2D SESSION

S. _____

To amend the Federal Food, Drug, and Cosmetic Act and the Securities Exchange Act of 1934 to prevent the inter partes review process for challenging patents from diminishing competition in the pharmaceutical industry and with respect to drug innovation, and for other purposes.

IN THE SENATE OF THE UNITED STATES

Mr. HATCH (for himself and Mr. TILLIS) introduced the following bill; which was read twice and referred to the Committee on _____

A BILL

To amend the Federal Food, Drug, and Cosmetic Act and the Securities Exchange Act of 1934 to prevent the inter partes review process for challenging patents from diminishing competition in the pharmaceutical industry and with respect to drug innovation, and for other purposes.

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 "Hatch-Waxman Integrity Act of 2018".

SEC. 2. PREVENTING THE INTER PARTES REVIEW PROCESS FOR CHALLENGING PATENTS FROM DIMINISHING COMPETITION IN THE PHARMACEUTICAL INDUSTRY AND WITH RESPECT TO DRUG INNOVATION.

(a) BRAND NAME DRUGS.—Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)(2)) is amended—

(1) in subparagraph (A)(iv), by striking "and" at the end;

(2) in subparagraph (B), by striking the period at the end and inserting "; and"; and

(3) by adding at the end the following:

"(C) in each certification required under subparagraph (A) with respect to a patent, a certification that—

"(i) neither the applicant nor any party in privity with, related to, or cooperating with the applicant has filed, or will file, a petition to institute inter partes review or post-grant review of that patent under chapter 31 or 32, respectively, of title 35, United States Code; and

"(ii) in making the certification required under subparagraph (A), the applicant is not relying in whole or in part on any decision issued by the Patent Trial and Appeal Board in

an inter partes review or post-grant review under chapter 31 or 32, respectively, of title 35, United States Code.".

(b) GENERIC DRUGS.—Section 505(j)(2)(A) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(2)(A)) is amended—

(1) in clause (vii)(IV), by striking "and" at the end;

(2) in clause (viii), by striking the period at the end and inserting "; and";

(3) by inserting after clause (viii), as amended by paragraph (2), the following:

"(ix) in each certification required under clause (vii) with respect to a patent, a certification that—

"(I) neither the applicant nor any party in privity with, related to, or cooperating with the applicant has filed, or will file, a petition to institute inter partes review or post-grant review of that patent under chapter 31 or 32, respectively, of title 35, United States Code; and

"(II) in making the certification required under clause (vii), the applicant is not relying in whole or in part on any deci-

sion issued by the Patent Trial and Appeal Board in an inter partes review or post-grant review under chapter 31 or 32, respectively, of title 35, United States Code.''; and

(4) in the flush text following clause (ix), as added by paragraph (3), by striking ''(viii)'' and inserting ''(ix)''.

(c) BIOSIMILAR DRUGS; EVALUATION BY THE SECRETARY.—Section 351(k) of the Public Health Service Act (42 U.S.C. 262(k)) is amended—

(1) in paragraph (2)(A)(iii)—

(A) by redesignating subclauses (I) and (II) as items (aa) and (bb), respectively, and adjusting the margins accordingly;

(B) in the matter preceding item (aa), as so redesignated, by striking ''An application'' and inserting the following:

''(I) IN GENERAL.—An application'';

(C) in subclause (I), as so designated—

(i) in item (aa), as so redesignated, by striking ''and'' at the end;

(ii) in item (bb), as so redesignated, by striking the period at the end and inserting "; and"; and

(iii) by adding at the end the following:

"(cc) shall, with respect to a patent described in subclause (II), include a certification that neither the applicant nor any party in privity with, related to, or cooperating with the applicant has filed, or will file, a petition to institute inter partes review or post-grant review of the patent under chapter 31 or 32, respectively, of title 35, United States Code."; and

(D) by adding at the end the following:

"(II) PATENT DESCRIBED.—A patent is described in this subclause if—

"(aa) the patent covers the reference product or a method for using the reference product; and

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