AMENDMENT NO. Calendar No.

Purpose: To prevent the inter partes review process for challenging patents from diminishing competition in the pharmaceutical industry and with respect to drug innovation.

IN THE SENATE OF THE UNITED STATES—115th Cong., 2d Sess.

S. 974

To promote competition in the market for drugs and biological products by facilitating the timely entry of lower-cost generic and biosimilar versions of those drugs and biological products.

Referred to the Committee on and ordered to be printed

Ordered to lie on the table and to be printed

AMENDMENT intended to be proposed by Mr. HATCH

Viz:

After section 4, add the following:

SEC. 5. PREVENTING THE INTER PARTES REVIEW PROCESS FOR CHALLENGING PATENTS FROM DIMINISHING COMPETITION IN THE PHARMACEUTICAL INDUSTRY AND WITH RESPECT TO DRUG INNOVATION; PREVENTING THE MANIPULATIVE AND DECEPTIVE USE OF INTER PARTES REVIEW.

(a) SHORT TITLE.—This section may be cited as the ''Hatch-Waxman Integrity Act of 2018''.

(b) 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 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.''.

(c) 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 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 decision issued by the Patent Trial and Appeal Board in an inter partes review or post-grant review under chapter 31 or 32, re-

spectively, 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)''.

(d) 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) in subclause (I), by striking ''and'' at the end;

(B) in subclause (II), by striking the period at the end and inserting ''; and''; and

(C) by adding at the end the following:

''(III) with respect to any patent that is, or that could be, included on a list of patents under subsection (l)(3)(A)(i), shall include a certification that neither the applicant nor any party in privity 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

(2) in paragraph (3)—

(A) in subparagraph (A)(ii), by striking ''and'' at the end;

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

(C) by adding at the end the following:

''(C) the Secretary determines that the application fully complies with the requirements under paragraph (2)(A)(iii).''.

(e) PREVENTING THE MANIPULATIVE AND DECEPTIVE USE OF INTER PARTES REVIEW.—Section 10(b) of the Securities Exchange Act of 1934 (15 U.S.C. 78j(b)) is amended—

(1) by inserting ''(1)'' after ''(b)''; and

(2) by adding at the end the following:

''(2) For purposes of paragraph (1), a person shall be considered to be using a manipulative or deceptive device if—

''(A) the person, or an affiliate of the person, files a petition to institute an inter partes review under chapter 31 of title 35, United States Code, with respect to a patent; and

''(B) the person, or an affiliate of the person, during the 180-day period beginning on the date that is 90 days before the date on which the person

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