

115TH CONGRESS
2D SESSION

S. 3738

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

DECEMBER 11, 2018

Mr. HATCH (for himself and Mr. TILLIS) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Hatch-Waxman Integ-
5 rity Act of 2018”.

1 **SEC. 2. PREVENTING THE INTER PARTES REVIEW PROCESS**
2 **FOR CHALLENGING PATENTS FROM DIMIN-**
3 **ISHING COMPETITION IN THE PHARMA-**
4 **CEUTICAL INDUSTRY AND WITH RESPECT TO**
5 **DRUG INNOVATION.**

6 (a) BRAND NAME DRUGS.—Section 505(b)(2) of the
7 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
8 355(b)(2)) is amended—

9 (1) in subparagraph (A)(iv), by striking “and”
10 at the end;

11 (2) in subparagraph (B), by striking the period
12 at the end and inserting “; and”; and

13 (3) by adding at the end the following:

14 “(C) in each certification required under sub-
15 paragraph (A) with respect to a patent, a certifi-
16 cation that—

17 “(i) neither the applicant nor any party in
18 privity with, related to, or cooperating with the
19 applicant has filed, or will file, a petition to in-
20 stitute inter partes review or post-grant review
21 of that patent under chapter 31 or 32, respec-
22 tively, of title 35, United States Code; and

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

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

4 (b) GENERIC DRUGS.—Section 505(j)(2)(A) of the
5 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
6 355(j)(2)(A)) is amended—

7 (1) in clause (vii)(IV), by striking “and” at the
8 end;

9 (2) in clause (viii), by striking the period at the
10 end and inserting “; and”;

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

13 “(ix) in each certification required under
14 clause (vii) with respect to a patent, a certifi-
15 cation that—

16 “(I) neither the applicant nor any
17 party in privity with, related to, or cooper-
18 ating with the applicant has filed, or will
19 file, a petition to institute inter partes re-
20 view or post-grant review of that patent
21 under chapter 31 or 32, respectively, of
22 title 35, United States Code; and

23 “(II) in making the certification re-
24 quired under clause (vii), the applicant is
25 not relying in whole or in part on any deci-

1 sion issued by the Patent Trial and Appeal
2 Board in an inter partes review or post-
3 grant review under chapter 31 or 32, re-
4 spectively, of title 35, United States
5 Code.”; and

6 (4) in the flush text following clause (ix), as
7 added by paragraph (3), by striking “(viii)” and in-
8 serting “(ix)”.

9 (c) BIOSIMILAR DRUGS; EVALUATION BY THE SEC-
10 RETARY.—Section 351(k) of the Public Health Service Act
11 (42 U.S.C. 262(k)) is amended—

12 (1) in paragraph (2)(A)(iii)—

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

16 (B) in the matter preceding item (aa), as
17 so redesignated, by striking “An application”
18 and inserting the following:

19 “(I) IN GENERAL.—An applica-
20 tion”;

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

22 (i) in item (aa), as so redesignated, by
23 striking “and” at the end;

1 (ii) in item (bb), as so redesignated,
2 by striking the period at the end and in-
3 serting “; and”; and

4 (iii) by adding at the end the fol-
5 lowing:

6 “(cc) shall, with respect to a
7 patent described in subclause
8 (II), include a certification that
9 neither the applicant nor any
10 party in privity with, related to,
11 or cooperating with the applicant
12 has filed, or will file, a petition to
13 institute inter partes review or
14 post-grant review of the patent
15 under chapter 31 or 32, respec-
16 tively, of title 35, United States
17 Code.”; and

18 (D) by adding at the end the following:

19 “(II) PATENT DESCRIBED.—A
20 patent is described in this subclause
21 if—

22 “(aa) the patent covers the
23 reference product or a method
24 for using the reference product;
25 and

1 “(bb)(AA) the reference
2 product described in item (aa) is
3 marked under section 287(a) of
4 title 35, United States Code; or

5 “(BB) there is otherwise
6 public notice regarding the appli-
7 cability of the reference product
8 described in item (aa).”; and

9 (2) in paragraph (3)—

10 (A) in subparagraph (A)(ii), by striking
11 “and” at the end;

12 (B) in subparagraph (B), by striking the
13 period at the end and inserting “; and”; and

14 (C) by adding at the end the following:

15 “(C) the Secretary determines that the ap-
16 plication fully complies with the requirements
17 under paragraph (2)(A)(iii).”.

18 **SEC. 3. PREVENTING THE MANIPULATIVE AND DECEPTIVE**

19 **USE OF INTER PARTES REVIEW.**

20 Section 10(b) of the Securities Exchange Act of 1934
21 (15 U.S.C. 78j(b)) is amended—

22 (1) by inserting “(1)” after “(b)”; and

23 (2) by adding at the end the following:

1 “(2) For purposes of paragraph (1), a person shall
2 be considered to be using a manipulative or deceptive de-
3 vice if—

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

8 “(B) the person, or an affiliate of the person,
9 during the 180-day period beginning on the date
10 that is 90 days before the date on which the person
11 files the petition described in subparagraph (A), en-
12 gages in a short sale of any publicly traded security
13 of the owner of the patent that is the subject of the
14 petition.”.

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