

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:

1 After section 4, add the following:

2 **SEC. 5. PREVENTING THE INTER PARTES REVIEW PROCESS**

3 **FOR CHALLENGING PATENTS FROM DIMIN-**

4 **ISHING COMPETITION IN THE PHARMA-**

5 **CEUTICAL INDUSTRY AND WITH RESPECT TO**

6 **DRUG INNOVATION; PREVENTING THE MA-**

7 **NIPULATIVE AND DECEPTIVE USE OF INTER**

8 **PARTES REVIEW.**

9 (a) SHORT TITLE.—This section may be cited as the

10 “Hatch-Waxman Integrity Act of 2018”.

1 (b) BRAND NAME DRUGS.—Section 505(b)(2) of the  
2 Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
3 355(b)(2)) is amended—

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

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

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

9 “(C) in each certification required under sub-  
10 subparagraph (A) with respect to a patent, a certifi-  
11 cation that—

12 “(i) neither the applicant nor any party in  
13 privity with the applicant has filed, or will file,  
14 a petition to institute inter partes review or  
15 post-grant review of that patent under chapter  
16 31 or 32, respectively, of title 35, United States  
17 Code; and

18 “(ii) in making the certification required  
19 under subparagraph (A), the applicant is not  
20 relying in whole or in part on any decision  
21 issued by the Patent Trial and Appeal Board in  
22 an inter partes review or post-grant review  
23 under chapter 31 or 32, respectively, of title 35,  
24 United States Code.”.

1 (c) GENERIC DRUGS.—Section 505(j)(2)(A) of the  
2 Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
3 355(j)(2)(A)) is amended—

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

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

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

10 “(ix) in each certification required under  
11 clause (vii) with respect to a patent, a certifi-  
12 cation that—

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

20 “(II) in making the certification re-  
21 quired under clause (vii), the applicant is  
22 not relying in whole or in part on any deci-  
23 sion issued by the Patent Trial and Appeal  
24 Board in an inter partes review or post-  
25 grant review under chapter 31 or 32, re-

1                   spectively, of title 35, United States  
2                   Code.”; and

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

6                   (d) BIOSIMILAR DRUGS; EVALUATION BY THE SEC-  
7                   RETARY.—Section 351(k) of the Public Health Service Act  
8                   (42 U.S.C. 262(k)) is amended—

9                   (1) in paragraph (2)(A)(iii)—

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

12                   (B) in subclause (II), by striking the pe-  
13                   riod at the end and inserting “; and”; and

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

15                   “**(III)** with respect to any patent  
16                   that is, or that could be, included on  
17                   a list of patents under subsection  
18                   (l)(3)(A)(i), shall include a certifi-  
19                   cation that neither the applicant nor  
20                   any party in privity with the applicant  
21                   has filed, or will file, a petition to in-  
22                   stitute inter partes review or post-  
23                   grant review of that patent under  
24                   chapter 31 or 32, respectively, of title  
25                   35, United States Code.”; and

1 (2) in paragraph (3)—

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

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

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

7 “(C) the Secretary determines that the ap-  
8 plication fully complies with the requirements  
9 under paragraph (2)(A)(iii).”.

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

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

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

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

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

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

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