

AMENDMENT NO. \_\_\_\_\_ Calendar No. \_\_\_\_\_

Purpose: In the nature of a substitute.

**IN THE SENATE OF THE UNITED STATES—116th Cong., 1st Sess.**

**S. 440**

To amend title 35, United States Code, to provide that a patent owner may not assert sovereign immunity as a defense in certain actions before the United States Patent and Trademark Office, and for other purposes.

Referred to the Committee on \_\_\_\_\_ and  
ordered to be printed

Ordered to lie on the table and to be printed

AMENDMENT IN THE NATURE OF A SUBSTITUTE intended  
to be proposed by Ms. ERNST

Viz:

1 Strike all after the enacting clause and insert the fol-  
2 lowing:

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Preserving Access to  
5 Cost Effective Drugs Act” or the “PACED Act”.

6 **SEC. 2. ABROGATION OF SOVEREIGN IMMUNITY.**

7 (a) IN GENERAL.—Title 35, United States Code, is  
8 amended—

9 (1) in section 135, by adding at the end the fol-  
10 lowing:

11 “(g) SOVEREIGN IMMUNITY.—

1 “(1) DEFINITIONS.—In this subsection—

2 “(A) the term ‘foreign state’ has the mean-  
3 ing given the term in section 1603(a) of title  
4 28; and

5 “(B) the term ‘Indian tribe’ has the mean-  
6 ing given the term in section 4(e) of the Indian  
7 Self-Determination and Education Assistance  
8 Act (25 U.S.C. 5304(e)).

9 “(2) ABROGATION OF SOVEREIGN IMMUNITY.—  
10 Except as provided in paragraph (3), and subject to  
11 paragraph (4), a patent owner may not assert sov-  
12 ereign immunity, including the sovereign immunity  
13 accorded to an Indian tribe, as a defense in—

14 “(A) a derivation proceeding instituted  
15 under subsection (a); or

16 “(B) a review by a court of the United  
17 States with respect to a decision reached in a  
18 proceeding described in subparagraph (A).

19 “(3) IMMUNITY OF FOREIGN STATES.—If a pat-  
20 ent owner is a foreign state, for the purposes of any  
21 proceeding described in paragraph (2)(A), the Pat-  
22 ent Trial and Appeal Board shall determine whether  
23 the patent owner is immune from the jurisdiction of  
24 the Patent Trial and Appeal Board, in accordance

1 with chapter 97 of title 28 as if the Patent Trial and  
2 Appeal Board were a court of the United States.

3 “(4) LIMITATION.—This subsection—

4 “(A) shall apply only to the extent per-  
5 mitted under the 11th amendment to the Con-  
6 stitution of the United States; and

7 “(B) shall not apply with respect to—

8 “(i) any State of the United States; or

9 “(ii) any institution of higher edu-  
10 cation, as defined in section 101 of the  
11 Higher Education Act of 1965 (20 U.S.C.  
12 1001), that is a public institution in a  
13 State of the United States.”;

14 (2) in section 296—

15 (A) in the section heading, by striking  
16 “**and State officials**” and inserting “,  
17 **State officials, and Indian tribes**”; and

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

19 “(c) ABROGATION OF TRIBAL SOVEREIGN IMMUN-  
20 NITY.—

21 “(1) DEFINITIONS.—In this subsection—

22 “(A) the term ‘covered claim’ means any  
23 claim, counterclaim, or third-party claim that  
24 arises under—

1 “(i) this title relating to infringement  
2 of a patent; or

3 “(ii) section 351 of the Public Health  
4 Service Act (42 U.S.C. 262); and

5 “(B) the term ‘Indian tribe’ has the mean-  
6 ing given the term in section 4(e) of the Indian  
7 Self-Determination and Education Assistance  
8 Act (25 U.S.C. 5304(e)).

9 “(2) ABROGATION.—In any action that involves  
10 a covered claim that is otherwise within the jurisdic-  
11 tion of a court of the United States, an Indian tribe  
12 may not assert sovereign immunity as a defense.”;

13 (3) in section 305—

14 (A) in the first sentence, by striking “After  
15 the” and inserting the following:

16 “(a) IN GENERAL.—After the”; and

17 (B) by adding at the end the following:

18 “(b) SOVEREIGN IMMUNITY.—

19 “(1) DEFINITIONS.—In this subsection—

20 “(A) the term ‘foreign state’ has the mean-  
21 ing given the term in section 1603(a) of title  
22 28; and

23 “(B) the term ‘Indian tribe’ has the mean-  
24 ing given the term in section 4(e) of the Indian

1 Self-Determination and Education Assistance  
2 Act (25 U.S.C. 5304(e)).

3 “(2) ABROGATION OF SOVEREIGN IMMUNITY.—  
4 Except as provided in paragraph (3), and subject to  
5 paragraph (4), a patent owner may not assert sov-  
6 ereign immunity, including the sovereign immunity  
7 accorded to an Indian tribe, as a defense in—

8 “(A) any reexamination proceeding under  
9 this section, including any appeal to the Patent  
10 Trial and Appeal Board; or

11 “(B) a review by a court of the United  
12 States with respect to a decision reached in a  
13 proceeding described in subparagraph (A).

14 “(3) IMMUNITY OF FOREIGN STATES.—If a pat-  
15 ent owner is a foreign state, for the purposes of any  
16 proceeding described in paragraph (2)(A), the Office  
17 or the Patent Trial and Appeal Board, as applicable,  
18 shall determine whether the patent owner is immune  
19 from the jurisdiction of the Office or the Patent  
20 Trial and Appeal Board, as applicable, in accordance  
21 with chapter 97 of title 28 as if the Office or the  
22 Patent Trial and Appeal Board, as applicable, were  
23 a court of the United States.

24 “(4) LIMITATION.—This subsection—

1           “(A) shall apply only to the extent per-  
2           mitted under the 11th amendment to the Con-  
3           stitution of the United States; and

4           “(B) shall not apply with respect to—

5                   “(i) any State of the United States; or

6                   “(ii) any institution of higher edu-  
7           cation, as defined in section 101 of the  
8           Higher Education Act of 1965 (20 U.S.C.  
9           1001), that is a public institution in a  
10          State of the United States.”;

11          (4) in section 316, by adding at the end the fol-  
12          lowing:

13          “(f) SOVEREIGN IMMUNITY.—

14               “(1) DEFINITIONS.—In this subsection—

15                   “(A) the term ‘foreign state’ has the mean-  
16           ing given the term in section 1603(a) of title  
17           28; and

18                   “(B) the term ‘Indian tribe’ has the mean-  
19           ing given the term in section 4(e) of the Indian  
20           Self-Determination and Education Assistance  
21           Act (25 U.S.C. 5304(e)).

22               “(2) ABROGATION OF SOVEREIGN IMMUNITY.—

23          Except as provided in paragraph (3), and subject to  
24          paragraph (4), a patent owner may not assert sov-

1 foreign immunity, including the sovereign immunity  
2 accorded to an Indian tribe, as a defense in—

3 “(A) an inter partes review instituted  
4 under this chapter; or

5 “(B) a review by a court of the United  
6 States with respect to a decision reached in a  
7 proceeding described in subparagraph (A).

8 “(3) IMMUNITY OF FOREIGN STATES.—If a pat-  
9 ent owner is a foreign state, for the purposes of any  
10 review described in paragraph (2)(A), the Patent  
11 Trial and Appeal Board shall determine whether the  
12 patent owner is immune from the jurisdiction of the  
13 Patent Trial and Appeal Board, in accordance with  
14 chapter 97 of title 28 as if the Patent Trial and Ap-  
15 peal Board were a court of the United States.

16 “(4) LIMITATION.—This subsection—

17 “(A) shall apply only to the extent per-  
18 mitted under the 11th amendment to the Con-  
19 stitution of the United States; and

20 “(B) shall not apply with respect to—

21 “(i) any State of the United States; or

22 “(ii) any institution of higher edu-  
23 cation, as defined in section 101 of the  
24 Higher Education Act of 1965 (20 U.S.C.

1                   1001), that is a public institution in a  
2                   State of the United States.”; and

3                   (5) in section 326, by adding at the end the fol-  
4                   lowing:

5                   “(f) SOVEREIGN IMMUNITY.—

6                   “(1) DEFINITIONS.—In this subsection—

7                   “(A) the term ‘foreign state’ has the mean-  
8                   ing given the term in section 1603(a) of title  
9                   28; and

10                  “(B) the term ‘Indian tribe’ has the mean-  
11                  ing given the term in section 4(e) of the Indian  
12                  Self-Determination and Education Assistance  
13                  Act (25 U.S.C. 5304(e)).

14                  “(2) ABROGATION OF SOVEREIGN IMMUNITY.—  
15                  Except as provided in paragraph (3), and subject to  
16                  paragraph (4), a patent owner may not assert sov-  
17                  ereign immunity, including the sovereign immunity  
18                  accorded to an Indian tribe, as a defense in—

19                  “(A) a post-grant review instituted under  
20                  this chapter; or

21                  “(B) a review by a court of the United  
22                  States with respect to a decision reached in a  
23                  proceeding described in subparagraph (A).

24                  “(3) IMMUNITY OF FOREIGN STATES.—If a pat-  
25                  ent owner is a foreign state, for the purposes of any



1 review described in paragraph (2)(A), the Patent  
2 Trial and Appeal Board shall determine whether the  
3 patent owner is immune from the jurisdiction of the  
4 Patent Trial and Appeal Board, in accordance with  
5 chapter 97 of title 28 as if the Patent Trial and Ap-  
6 peal Board were a court of the United States.

7 “(4) LIMITATION.—This subsection—

8 “(A) shall apply only to the extent per-  
9 mitted under the 11th amendment to the Con-  
10 stitution of the United States; and

11 “(B) shall not apply with respect to—

12 “(i) any State of the United States; or

13 “(ii) any institution of higher edu-  
14 cation, as defined in section 101 of the  
15 Higher Education Act of 1965 (20 U.S.C.  
16 1001), that is a public institution in a  
17 State of the United States.”.

18 (b) AMENDMENTS TO THE TARIFF ACT OF 1930.—

19 Section 337 of the Tariff Act of 1930 (19 U.S.C. 1337)  
20 is amended by adding at the end the following:

21 “(o) ABROGATION OF TRIBAL SOVEREIGN IMMUN-  
22 NITY.—

23 “(1) DEFINITIONS.—In this subsection—

24 “(A) the term ‘covered person’—

25 “(i) means a person; and

1 “(ii) includes—

2 “(I) an Indian tribe; and

3 “(II) any other person that  
4 claims immunity on account of the  
5 sovereign status of an Indian tribe;  
6 and

7 “(B) the term ‘Indian tribe’ has the mean-  
8 ing given the term in section 4(e) of the Indian  
9 Self-Determination and Education Assistance  
10 Act (25 U.S.C. 5304(e)).

11 “(2) ABROGATION.—In any proceeding under  
12 this section, no covered person may assert as a de-  
13 fense the sovereign immunity that is accorded to an  
14 Indian tribe.”.

15 (c) TECHNICAL AND CONFORMING AMENDMENT.—  
16 The table of sections for chapter 29 of title 35, United  
17 States Code, is amended by striking the item relating to  
18 section 296 and inserting the following:

“296. Liability of States, instrumentalities of States, State officials, and Indian  
tribes for infringement of patents.”.