

**Calendar No. 129**116<sup>TH</sup> CONGRESS  
1<sup>ST</sup> SESSION**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.

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**IN THE SENATE OF THE UNITED STATES**

FEBRUARY 12, 2019

Mr. COTTON (for himself, Ms. ERNST, and Mr. TOOMEY) introduced the following bill; which was read twice and referred to the Committee on the Judiciary

JUNE 28 (legislative day, JUNE 27), 2019

Reported by Mr. GRAHAM, with an amendment

[Strike out all after the enacting clause and insert the part printed in italic]

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**A BILL**

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.

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

1 **SECTION 1. SHORT TITLE.**

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

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

5 (a) IN GENERAL.—Title 35, United States Code, is  
6 amended—

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

9 “(g) SOVEREIGN IMMUNITY.—

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

11 “(A) the term ‘foreign state’ has the mean-  
12 ing given the term in section 1603(a) of title  
13 28; and

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

18 “(2) ABROGATION OF SOVEREIGN IMMUNITY.—

19 Except as provided in paragraph (3), and subject to  
20 paragraph (4), a patent owner may not assert sov-  
21 ereign immunity, including the sovereign immunity  
22 accorded to an Indian tribe, as a defense in—

23 “(A) a derivation proceeding instituted  
24 under subsection (a); or

1           “(B) a review by a court of the United  
2           States with respect to a decision reached in a  
3           proceeding described in subparagraph (A).

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

12          “(4) LIMITATION.—This subsection shall apply  
13          only to the extent permitted under the 11th amend-  
14          ment to the Constitution of the United States.”;

15          (2) in section 296—

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

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

20                 “(e) ABROGATION OF TRIBAL SOVEREIGN IMMU-  
21                 NITY.—

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

23                         “(A) the term ‘covered claim’ means any  
24                         claim, counterclaim, or third-party claim that  
25                         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.~~

1           “(4) LIMITATION.—This subsection shall apply  
2 only to the extent permitted under the 11th amend-  
3 ment to the Constitution of the United States.”;

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

6           “(f) SOVEREIGN IMMUNITY.—

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

8           “(A) the term ‘foreign state’ has the mean-  
9 ing given the term in section 1603(a) of title  
10 28; and

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

15           “(2) ABROGATION OF SOVEREIGN IMMUNITY.—

16 Except as provided in paragraph (3), and subject to  
17 paragraph (4), a patent owner may not assert sov-  
18 ereign immunity, including the sovereign immunity  
19 accorded to an Indian tribe, as a defense in—

20           “(A) an inter partes review instituted  
21 under this chapter; or

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

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

9           “(4) LIMITATION.—This subsection shall apply  
 10          only to the extent permitted under the 11th amend-  
 11          ment to the Constitution of the United States.”; and

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

14          “(f) SOVEREIGN IMMUNITY.—

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

16                         “(A) the term ‘foreign state’ has the mean-  
 17                         ing given the term in section 1603(a) of title  
 18                         28; and

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

23                 “(2) ABROGATION OF SOVEREIGN IMMUNITY.—  
 24                 Except as provided in paragraph (3), and subject to  
 25                 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) a post-grant review instituted under  
4 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 shall apply  
17 only to the extent permitted under the 11th amend-  
18 ment to the Constitution of the United States.”.

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

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

22 “(o) ABROGATION OF TRIBAL SOVEREIGN IMMU-  
23 NITY.—

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

25 “(A) the term ‘covered person’—



1 “(i) means a person; and

2 “(ii) includes—

3 “(I) an Indian tribe; and

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

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

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

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

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

20 **SECTION 1. SHORT TITLE.**

21 *This Act may be cited as the “Preserving Access to Cost*  
22 *Effective Drugs Act” or the “PACED Act”.*

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

2 (a) *IN GENERAL.*—*Title 35, United States Code, is*  
3 *amended—*

4 (1) *in section 135, by adding at the end the fol-*  
5 *lowing:*

6 “(g) *SOVEREIGN IMMUNITY.*—

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

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

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

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

20 “(A) *a derivation proceeding instituted*  
21 *under subsection (a); or*

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

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

1       *proceeding 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               (2) *in section 296—*

19                       (A) *in the section heading, by striking*  
 20                       “**and State officials**” *and inserting “,*  
 21                       **State officials, and Indian tribes**”; *and*

22                       (B) *by adding at the end the following:*

23               “(c) *ABROGATION OF TRIBAL SOVEREIGN IMMU-*  
 24       *NITY.—*

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

1           “(A) the term ‘covered claim’ means any  
2 claim, counterclaim, or third-party claim that  
3 arises under—

4                   “(i) this title relating to infringement  
5 of a patent; or

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

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

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

16           (3) in section 305—

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

19                   “(a) *IN GENERAL*.—After the”; and

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

21                   “(b) *SOVEREIGN IMMUNITY*.—

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

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

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

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

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

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

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

1           “(4) *LIMITATION.*—*This subsection—*

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

5                   “(B) *shall not apply with respect to—*

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

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

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

14           “(f) *SOVEREIGN IMMUNITY.*—

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

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

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

23                   “(2) *ABROGATION OF SOVEREIGN IMMUNITY.*—

24                   *Except as provided in paragraph (3), and subject to*  
25 *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 under*  
4 *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 28;  
9                   and

10                   “(B) the term ‘Indian tribe’ has the mean-  
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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.—Sec-  
 19 tion 337 of the Tariff Act of 1930 (19 U.S.C. 1337) is  
 20 amended by adding at the end the following:

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

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

24 “(A) the term ‘covered person’—

25 “(i) means a person; and





**Calendar No. 129**

116<sup>TH</sup> CONGRESS  
1<sup>ST</sup> Session  
**S. 440**

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**A BILL**

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.

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JUNE 28 (legislative day, JUNE 27), 2019  
Reported with an amendment