

Calendar No. 130116TH CONGRESS
1ST SESSION**S. 1224**

To enable the Federal Trade Commission to deter filing of sham citizen petitions to cover an attempt to interfere with approval of a competing generic drug or biosimilar, to foster competition, and facilitate the efficient review of petitions filed in good faith to raise legitimate public health concerns, and for other purposes.

IN THE SENATE OF THE UNITED STATES

APRIL 29, 2019

Ms. KLOBUCHAR (for herself and Mr. GRASSLEY) 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 and an amendment to the title
[Strike out all after the enacting clause and insert the part printed in *italic*]

A BILL

To enable the Federal Trade Commission to deter filing of sham citizen petitions to cover an attempt to interfere with approval of a competing generic drug or biosimilar, to foster competition, and facilitate the efficient review of petitions filed in good faith to raise legitimate public health concerns, 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 “Stop Significant and
3 Time-wasting Abuse Limiting Legitimate Innovation of
4 New Generics Act” or the “Stop STALLING Act”.

5 **SEC. 2. FEDERAL TRADE COMMISSION ENFORCEMENT**
6 **AGAINST SHAM PETITIONS.**

7 (a) DEFINITIONS.—In this section:

8 (1) COMMISSION.—The term “Commission”
9 means the Federal Trade Commission.

10 (2) COVERED APPLICATION.—The term “cov-
11 ered application” means an application filed pursu-
12 ant to subsection (b)(2) or (j) of section 505 of the
13 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
14 355) or section 351(k) of the Public Health Service
15 Act (42 U.S.C. 262(k)).

16 (3) COVERED PETITION.—The term “covered
17 petition” means a petition, or a supplement to a pe-
18 tition, filed under section 505(q) of the Federal
19 Food, Drug, and Cosmetic Act (21 U.S.C. 355(q)).

20 (4) PERSON.—The term “person”—

21 (A) means an individual or entity; and

22 (B) includes—

23 (i) a director, officer, employee, agent,
24 representative, successor, and assign of an
25 entity;

1 (ii) a joint venture, subsidiary, part-
 2 nership, division, group, and affiliate con-
 3 trolled by an entity; and

4 (iii) a director, officer, employee,
 5 agent, representative, successor, and assign
 6 of a joint venture, subsidiary, partnership,
 7 division, group, and affiliate controlled by
 8 an entity.

9 (5) SERIES OF COVERED PETITIONS.—The
 10 term “series of covered petitions” means any group
 11 of more than 1 covered petition.

12 (6) SHAM.—The term “sham” means a covered
 13 petition that is objectively baseless and that at-
 14 tempts to use a governmental process, as opposed to
 15 the outcome of that process, to interfere with the
 16 business of a competitor, or a series of covered peti-
 17 tions that attempts to use a governmental process,
 18 as opposed to the outcome of that process, to inter-
 19 fere with the business of a competitor.

20 (b) VIOLATION.—A person submitting or causing the
 21 submission of a covered petition or a series of covered peti-
 22 tions that is a sham shall be liable for engaging in an
 23 unfair method of competition under section 5(a)(1) of the
 24 Federal Trade Commission Act (15 U.S.C. 45(a)(1)).

25 (c) CIVIL ACTION.—

1 (1) IN GENERAL.—If the Commission has rea-
2 son to believe that the submission of a covered peti-
3 tion or a series of covered petitions constitutes a vio-
4 lation of section 5(a)(1) of the Federal Trade Com-
5 mission Act (15 U.S.C. 45(a)(1)), the Commission
6 may commence a civil action to recover a civil pen-
7 alty and seek other appropriate relief in a district
8 court of the United States against any person that
9 submitted or caused to be submitted such covered
10 petition or such series of covered petitions, including
11 successors or assigns.

12 (2) PRESUMPTION.—In a civil action under
13 paragraph (1), a covered petition shall be presumed
14 to be part of a series of covered petitions that is a
15 sham under subsection (b) of this section if the Sec-
16 retary of Health and Human Services has deter-
17 mined that the covered petition was submitted with
18 the primary purpose of delaying the approval of a
19 covered application and was part of a series of cov-
20 ered petitions, and has referred such determination
21 to the Federal Trade Commission in writing, with a
22 reasoned basis for the determination.

23 (3) EXCEPTION.—The presumption in para-
24 graph (2) shall not apply if the defendant estab-
25 lishes, by a preponderance of the evidence, that the

1 series of covered petitions that includes the covered
2 petition referred to the Commission by the Secretary
3 of Health and Human Services is not a sham.

4 (4) CIVIL PENALTY.—In an action under para-
5 graph (1), any person that has been found liable for
6 a violation of section 5(a)(1) of the Federal Trade
7 Commission Act (15 U.S.C. 45(a)(1)) shall be sub-
8 ject to a civil penalty for each violation of not more
9 than the greater of—

10 (A) any revenue earned from the sale by
11 such person of any drug product, referenced in
12 a covered application that was the subject of a
13 covered petition or a series of covered petitions
14 that is a sham, during the period in which the
15 covered petition or series of covered petitions
16 was under review by the Secretary of Health
17 and Human Services; or

18 (B) \$50,000 for each calendar day that
19 each covered petition that is a sham or that was
20 part of a series of covered petitions that is a
21 sham was under review by the Secretary of
22 Health and Human Services.

23 (5) ANTITRUST LAWS.—Nothing in this section
24 shall modify, impair, limit, or supersede the applica-
25 bility of the antitrust laws as defined in subsection

1 (a) of the first section of the Clayton Act (15 U.S.C.
2 12(a)), and of section 5 of the Federal Trade Com-
3 mission Act (15 U.S.C. 45) to the extent that it ap-
4 plies to unfair methods of competition.

5 (6) RULE OF CONSTRUCTION.—The civil pen-
6 alty provided in this subsection is in addition to, and
7 not in lieu of, any other remedies provided by Fed-
8 eral law, including under section 16 of the Clayton
9 Act (15 U.S.C. 26) or under section 13(b) of the
10 Federal Trade Commission Act (15 U.S.C. 53(b)).
11 Nothing in this paragraph shall be construed to af-
12 fect any authority of the Commission under any
13 other provision of law.

14 (d) APPLICABILITY.—This section shall apply to any
15 covered petition submitted on or after the date of enact-
16 ment of this Act.

17 **SEC. 3. SEVERABILITY.**

18 If any provision of this Act or the application of such
19 provision to any person or circumstance is held to be un-
20 constitutional, the remainder of this Act and the applica-
21 tion of the provisions of such Act to any person or cir-
22 cumstance shall not be affected.

1 **SECTION 1. SHORT TITLE.**

2 *This Act may be cited as the “Stop Significant and*
 3 *Time-wasting Abuse Limiting Legitimate Innovation of*
 4 *New Generics Act” or the “Stop STALLING Act”.*

5 **SEC. 2. FEDERAL TRADE COMMISSION ENFORCEMENT**
 6 **AGAINST SHAM PETITIONS.**

7 (a) *DEFINITIONS.—In this section:*

8 (1) *COMMISSION.—The term “Commission”*
 9 *means the Federal Trade Commission.*

10 (2) *COVERED APPLICATION.—The term “covered*
 11 *application” means an application filed pursuant to*
 12 *subsection (b)(2) or (j) of section 505 of the Federal*
 13 *Food, Drug, and Cosmetic Act (21 U.S.C. 355) or sec-*
 14 *tion 351(k) of the Public Health Service Act (42*
 15 *U.S.C. 262(k)).*

16 (3) *COVERED PETITION.—The term “covered pe-*
 17 *tition” means a petition, or a supplement to a peti-*
 18 *tion, filed under section 505(q) of the Federal Food,*
 19 *Drug, and Cosmetic Act (21 U.S.C. 355(q)).*

20 (4) *PERSON.—The term “person”—*

21 *(A) means an individual or entity; and*

22 *(B) includes—*

23 *(i) a successor and an assign of an en-*
 24 *tity; and*

1 (ii) a joint venture, subsidiary, part-
2 nership, division, group, and affiliate con-
3 trolled by an entity, and

4 (iii) a successor and an assign of a
5 joint venture, subsidiary, partnership, divi-
6 sion, group, and affiliate controlled by an
7 entity.

8 (5) *SERIES OF COVERED PETITIONS.*—The term
9 “series of covered petitions” means any group of more
10 than 1 covered petition relating to the same covered
11 application.

12 (6) *SHAM.*—The term “sham” means a covered
13 petition that is objectively baseless and that attempts
14 to use a governmental process, as opposed to the out-
15 come of that process, to interfere with the business of
16 a competitor, or a series of covered petitions that at-
17 tempts to use a governmental process, as opposed to
18 the outcome of that process, to interfere with the busi-
19 ness of a competitor.

20 (b) *VIOLATION.*—A person submitting or causing the
21 submission of a covered petition or a series of covered peti-
22 tions that is a sham shall be liable for engaging in an un-
23 fair method of competition under section 5(a)(1) of the Fed-
24 eral Trade Commission Act (15 U.S.C. 45(a)(1)).

25 (c) *CIVIL ACTION.*—

1 (1) *IN GENERAL.*—*If the Commission has reason*
2 *to believe that the submission of a covered petition or*
3 *a series of covered petitions constitutes a violation of*
4 *section 5(a)(1) of the Federal Trade Commission Act*
5 *(15 U.S.C. 45(a)(1)), the Commission may commence*
6 *a civil action to recover a civil penalty and seek other*
7 *appropriate relief in a district court of the United*
8 *States against any person that submitted or caused to*
9 *be submitted such covered petition or such series of*
10 *covered petitions, including successors or assigns.*

11 (2) *PRESUMPTION.*—*In a civil action under*
12 *paragraph (1), a covered petition shall be presumed*
13 *to be part of a series of covered petitions that is a*
14 *sham under subsection (b) of this section if—*

15 (A) *the Secretary of Health and Human*
16 *Services—*

17 (i) *has determined that the covered pe-*
18 *tition was submitted with the primary pur-*
19 *pose of delaying the approval of a covered*
20 *application; and*

21 (ii) *has referred such determination to*
22 *the Federal Trade Commission in writing,*
23 *including a reasoned basis for the deter-*
24 *mination; and*

1 (B) the covered petition was part of a series
2 of covered petitions.

3 (3) *EXCEPTION.*—The presumption in paragraph
4 (2) shall not apply if the defendant establishes, by a
5 preponderance of the evidence, that the series of cov-
6 ered petitions that includes the covered petition re-
7 ferred to the Commission by the Secretary of Health
8 and Human Services is not a sham.

9 (4) *CIVIL PENALTY.*—In an action under para-
10 graph (1), any person that has been found liable for
11 a violation of section 5(a)(1) of the Federal Trade
12 Commission Act (15 U.S.C. 45(a)(1)) shall be subject
13 to a civil penalty for each violation of not more than
14 the greater of—

15 (A) any revenue earned from the sale by
16 such person of any drug product, referenced in
17 a covered application that was the subject of a
18 covered petition or a series of covered petitions
19 that is a sham, during the period in which the
20 covered petition or series of covered petitions was
21 under review by the Secretary of Health and
22 Human Services; or

23 (B) \$50,000 for each calendar day that each
24 covered petition that is a sham or that was part
25 of a series of covered petitions that is a sham

1 *was under review by the Secretary of Health and*
2 *Human Services.*

3 (5) *ANTITRUST LAWS.*—*Nothing in this section*
4 *shall modify, impair, limit, or supersede the applica-*
5 *bility of the antitrust laws as defined in subsection*
6 *(a) of the first section of the Clayton Act (15 U.S.C.*
7 *12(a)), and of section 5 of the Federal Trade Commis-*
8 *sion Act (15 U.S.C. 45) to the extent that it applies*
9 *to unfair methods of competition.*

10 (6) *RULE OF CONSTRUCTION.*—*The civil penalty*
11 *provided in this subsection is in addition to, and not*
12 *in lieu of, any other remedies provided by Federal*
13 *law, including under section 16 of the Clayton Act*
14 *(15 U.S.C. 26) or under section 13(b) of the Federal*
15 *Trade Commission Act (15 U.S.C. 53(b)). Nothing in*
16 *this paragraph shall be construed to affect any au-*
17 *thority of the Commission under any other provision*
18 *of law.*

19 (d) *APPLICABILITY.*—*This section shall apply to any*
20 *covered petition submitted on or after the date of enactment*
21 *of this Act.*

22 **SEC. 3. SEVERABILITY.**

23 *If any provision of this Act or the application of such*
24 *provision to any person or circumstance is held to be uncon-*
25 *stitutional, the remainder of this Act and the application*

- 1 *of the provisions of such Act to any person or circumstance*
- 2 *shall not be affected.*

Amend the title so as to read: “A bill to enable the Federal Trade Commission to deter filing of sham citizen petitions to cover an attempt to interfere with approval of a competing generic drug or biosimilar, to foster competition, and facilitate the efficient review of petitions filed in good faith to raise legitimate public health concerns, and for other purposes.”.

Calendar No. 130

116TH CONGRESS
1ST Session
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A BILL

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JUNE 28 (legislative day, JUNE 27), 2019

Reported with an amendment and an amendment to the title