

Calendar No. 21118TH CONGRESS
1ST SESSION**S. 148**

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

JANUARY 30, 2023

Ms. KLOBUCHAR (for herself, Mr. GRASSLEY, Mr. DURBIN, Mr. BRAUN, Mr. BLUMENTHAL, Mr. CRUZ, Mr. BOOKER, Mr. OSSOFF, and Mr. WELCH) introduced the following bill; which was read twice and referred to the Committee on the Judiciary

MARCH 1, 2023

Reported by Mr. DURBIN, with an amendment

[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,*

3 **SECTION 1. SHORT TITLE.**

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

7 **SEC. 2. FEDERAL TRADE COMMISSION ENFORCEMENT**
 8 **AGAINST SHAM PETITIONS.**

9 (a) **DEFINITIONS.**—In this section:

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

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

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

22 (4) **PERSON.**—The term “person”—

23 (A) means an individual or entity; and

24 (B) includes—

1 (i) a successor and an assign of an
2 entity;

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

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

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

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

22 (b) VIOLATION.—A person submitting or causing the
23 submission of a covered petition or a series of covered peti-
24 tions that is a sham shall be liable for engaging in an

1 unfair method of competition under section 5(a)(1) of the
2 Federal Trade Commission Act (15 U.S.C. 45(a)(1)).

3 (c) CIVIL ACTION.—

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

15 (2) PRESUMPTION.—In a civil action under
16 paragraph (1), a covered petition shall be presumed
17 to be part of a series of covered petitions that is a
18 sham under subsection (b) of this section if—

19 (A) the Secretary of Health and Human
20 Services—

21 (i) has determined that the covered
22 petition was submitted with the primary
23 purpose of delaying the approval of a cov-
24 ered application; and

1 (ii) has referred such determination to
2 the Commission in writing, including a rea-
3 soned basis for the determination; and

4 (B) the covered petition was part of a se-
5 ries of covered petitions.

6 (3) EXCEPTION.—The presumption in para-
7 graph (2) shall not apply if the defendant estab-
8 lishes, by a preponderance of the evidence, that the
9 series of covered petitions that includes the covered
10 petition referred to the Commission by the Secretary
11 of Health and Human Services is not a sham.

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

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

1 (B) \$50,000 for each calendar day that
2 each covered petition that is a sham or that was
3 part of a series of covered petitions that is a
4 sham was under review by the Secretary of
5 Health and Human Services.

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

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

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

1 **SEC. 3. SEVERABILITY.**

2 If any provision of this Act or the application of such
 3 provision to any person or circumstance is held to be un-
 4 constitutional, the remainder of this Act and the applica-
 5 tion of the provisions of such Act to any person or cir-
 6 cumstance shall not be affected.

7 **SECTION 1. SHORT TITLE.**

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

11 **SEC. 2. FEDERAL TRADE COMMISSION ENFORCEMENT**
 12 **AGAINST SHAM PETITIONS.**

13 (a) *DEFINITIONS.—In this section:*

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

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

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

26 (4) *PERSON.—The term “person”—*

1 (A) means an individual or entity; and

2 (B) includes—

3 (i) a successor or an assign of an enti-
4 ty;

5 (ii) a joint venture, subsidiary, part-
6 nership, division, group, or affiliate con-
7 trolled by an entity; and

8 (iii) a successor or an assign of a joint
9 venture, subsidiary, partnership, division,
10 group, or affiliate controlled by an entity.

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

15 (6) *SHAM.*—The term “sham” means—

16 (A) a covered petition that—

17 (i) is objectively baseless; and

18 (ii) attempts to use a governmental
19 process, as opposed to the outcome of that
20 process, to interfere with the business of a
21 competitor; or

22 (B) a series of covered petitions that at-
23 tempts to use a governmental process, as opposed
24 to the outcome of that process, to interfere with
25 the business of a competitor.

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

6 (c) *CIVIL ACTION.*—

7 (1) *IN GENERAL.*—If the Commission has reason
8 to believe that the submission of a covered petition or
9 a series of covered petitions constitutes a violation of
10 section 5(a)(1) of the Federal Trade Commission Act
11 (15 U.S.C. 45(a)(1)), the Commission may commence
12 a civil action to recover a civil penalty and seek other
13 appropriate relief in a district court of the United
14 States against any person that submitted or caused to
15 be submitted such covered petition or such series of
16 covered petitions.

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

21 (A) the Secretary of Health and Human
22 Services—

23 (i) has determined that the covered pe-
24 tition was submitted with the primary pur-

1 *pose of delaying the approval of a covered*
2 *application; and*

3 *(ii) has referred such determination to*
4 *the Commission in writing, including a*
5 *reasoned basis for the determination; and*

6 *(B) the covered petition was part of a series*
7 *of covered petitions.*

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

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

20 *(A) any revenue earned from the sale by*
21 *such person of any drug product, referenced in*
22 *a covered application that was the subject of a*
23 *covered petition or a series of covered petitions*
24 *that is a sham, during the period during which*
25 *the covered petition or series of covered petitions*

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

3 *(B) \$50,000 for each calendar day that each*
4 *covered petition that is a sham or that was part*
5 *of a series of covered petitions that is a sham*
6 *was under review by the Secretary of Health and*
7 *Human Services.*

8 *(5) REVIEW OF REFERRAL.—No referral by the*
9 *Secretary of Health and Human Services under para-*
10 *graph (2)(A) shall be subject to judicial review, except*
11 *as a third-party claim asserted by the defendant*
12 *under section 706(2)(A) of title 5, United States Code,*
13 *against the Secretary of Health and Human Services*
14 *or the Department of Health and Human Services, as*
15 *part of a civil action commenced under paragraph*
16 *(1).*

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

24 *(7) RULE OF CONSTRUCTION.—The civil penalty*
25 *provided in this subsection is in addition to, and not*

1 *in lieu of, any other remedies provided by Federal*
2 *law, including under section 16 of the Clayton Act*
3 *(15 U.S.C. 26) or under section 13(b) of the Federal*
4 *Trade Commission Act (15 U.S.C. 53(b)).*

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

8 *(e) RULE OF CONSTRUCTION.—Nothing in this Act*
9 *shall be construed to limit any authority of the Commission*
10 *under any other provision of law.*

11 **SEC. 3. SEVERABILITY.**

12 *If any provision of this Act or the application of such*
13 *provision to any person or circumstance is held to be uncon-*
14 *stitutional, the remainder of this Act and the application*
15 *of the provisions of such Act to any person or circumstance*
16 *shall not be affected.*

Calendar No. 21

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