

117TH CONGRESS
1ST SESSION

S. 1425

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 28, 2021

Ms. KLOBUCHAR (for herself, Mr. GRASSLEY, Mr. BLUMENTHAL, Ms. ERNST, and Mr. LEAHY) introduced the following bill; which was read twice and referred to the Committee on the Judiciary

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 successor and an assign of an
24 entity;

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
9 term “series of covered petitions” means any group
10 of more than 1 covered petition relating to the same
11 covered application.

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—

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

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

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

1 (B) the covered petition was part of a se-
2 ries of covered petitions.

3 (3) EXCEPTION.—The presumption in para-
4 graph (2) shall not apply if the defendant estab-
5 lishes, by a preponderance of the evidence, that the
6 series of covered petitions that includes the covered
7 petition referred to the Commission by the Secretary
8 of Health 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 sub-
13 ject to a civil penalty for each violation of not more
14 than 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
21 was under review by the Secretary of Health
22 and Human Services; or

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

1 sham was under review by the Secretary of
2 Health and 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 Com-
8 mission Act (15 U.S.C. 45) to the extent that it ap-
9 plies to unfair methods of competition.

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

19 (d) APPLICABILITY.—This section shall apply to any
20 covered petition submitted on or after the date of enact-
21 ment 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 un-
25 constitutional, the remainder of this Act and the applica-

1 tion of the provisions of such Act to any person or cir-
2 cumstance shall not be affected.

○