

AMENDMENT NO. _____ Calendar No. _____

Purpose: In the nature of a substitute.

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

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.

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. KLOBUCHAR (for herself and Mr. GRASSLEY)

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 “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:

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

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

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

13 (4) PERSON.—The term “person”—

14 (A) means an individual or entity; and

15 (B) includes—

16 (i) a successor and an assign of an
17 entity; and

18 (ii) a joint venture, subsidiary, part-
19 nership, division, group, and affiliate con-
20 trolled by an entity, and

21 (iii) a successor and an assign of a
22 joint venture, subsidiary, partnership, divi-
23 sion, group, and affiliate controlled by an
24 entity.

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

5 (6) SHAM.—The term “sham” means a covered
6 petition that is objectively baseless and that at-
7 tempts to use a governmental process, as opposed to
8 the outcome of that process, to interfere with the
9 business of a competitor, or a series of covered peti-
10 tions that attempts to use a governmental process,
11 as opposed to the outcome of that process, to inter-
12 fere with the business of a competitor.

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

18 (c) CIVIL ACTION.—

19 (1) IN GENERAL.—If the Commission has rea-
20 son to believe that the submission of a covered peti-
21 tion or a series of covered petitions constitutes a vio-
22 lation of section 5(a)(1) of the Federal Trade Com-
23 mission Act (15 U.S.C. 45(a)(1)), the Commission
24 may commence a civil action to recover a civil pen-
25 alty and seek other appropriate relief in a district

1 court of the United States against any person that
2 submitted or caused to be submitted such covered
3 petition or such series of covered petitions, including
4 successors or assigns.

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

9 (A) the Secretary of Health and Human
10 Services—

11 (i) has determined that the covered
12 petition was submitted with the primary
13 purpose of delaying the approval of a cov-
14 ered application; and

15 (ii) has referred such determination to
16 the Federal Trade Commission in writing,
17 including a reasoned basis for the deter-
18 mination; and

19 (B) the covered petition was part of a se-
20 ries of covered petitions.

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

1 petition referred to the Commission by the Secretary
2 of Health and Human Services is not a sham.

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

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

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

22 (5) ANTITRUST LAWS.—Nothing in this section
23 shall modify, impair, limit, or supersede the applica-
24 bility of the antitrust laws as defined in subsection
25 (a) of the first section of the Clayton Act (15 U.S.C.

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

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

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

16 **SEC. 3. SEVERABILITY.**

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