

Union Calendar No. 577

116TH CONGRESS
2^D SESSION

H. R. 2374

[Report No. 116-694]

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 HOUSE OF REPRESENTATIVES

APRIL 29, 2019

Mr. JEFFRIES (for himself, Mr. SENSENBRENNER, Mr. NADLER, Mr. COLLINS of Georgia, Mr. CICILLINE, and Mr. WELCH) introduced the following bill; which was referred to the Committee on the Judiciary

DECEMBER 24, 2020

Additional sponsors: Mr. COHEN and Mr. POSEY

DECEMBER 24, 2020

Reported from the Committee on the Judiciary; committed to the Committee of the Whole House on the State of the Union and ordered to be printed

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” means—
23 (A) an individual or entity;

1 (B) its directors, officers, employees,
2 agents, representatives, successors, and assigns;
3 and

4 (C) the joint ventures, subsidiaries, part-
5 nerships, divisions, groups, and affiliates it con-
6 trols, and the respective directors, officers, em-
7 ployees, agents, representatives, successors, and
8 assigns of each.

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

21 (1) IN GENERAL.—A person submitting or
22 causing the submission of a covered petition or a se-
23 ries of covered petitions that is a sham shall be lia-
24 ble for engaging in an unfair method of competition

1 under section 5(a)(1) of the Federal Trade Commis-
2 sion 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 the Sec-
19 retary of Health and Human Services has deter-
20 mined that the covered petition was submitted with
21 the primary purpose of delaying the approval of a
22 covered application, was part of a series of covered
23 petitions, and has referred such determination to the
24 Federal Trade Commission in writing, with a rea-
25 soned basis for the determination.

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

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

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

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

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

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

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

20 **SEC. 3. SEVERABILITY.**

21 If any provision of this Act, an amendment made by
22 this Act, or the application of such provision or amend-
23 ment to any person or circumstance is held to be unconsti-
24 tutional, the remainder of this Act, the amendments made
25 by this Act, and the application of the provisions of such

- 1 Act or amendments to any person or circumstance shall
- 2 not be affected.

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