Union Calendar No. 577

116TH CONGRESS
2D 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 heath 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 heath concerns, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Stop Significant and Time-wasting Abuse Limiting Legitimate Innovation of New Generics Act'' or the ''Stop STALLING Act''.

SEC. 2. FEDERAL TRADE COMMISSION ENFORCEMENT AGAINST SHAM PETITIONS.

(a) DEFINITIONS.—In this section:

(1) COMMISSION.—The term ''Commission'' means the Federal Trade Commission.

(2) COVERED APPLICATION.—The term ''covered application'' means an application filed pursuant to subsection (b)(2) or (j) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) or section 351(k) of the Public Health Service Act (42 U.S.C. 262(k)).

(3) COVERED PETITION.—The term ''covered petition'' means a petition, or a supplement to a petition, filed under section 505(q) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(q)).

(4) PERSON.—The term ''person'' means—

(A) an individual or entity;

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

(C) the joint ventures, subsidiaries, partnerships, divisions, groups, and affiliates it controls, and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.

(5) SERIES OF COVERED PETITIONS.—The term ''series of covered petitions'' means any group of more than one covered petition.

(6) SHAM.—The term ''sham'' means a covered petition that is objectively baseless and that attempts to use a governmental process, as opposed to the outcome of that process, to interfere with the business of a competitor, or a series of covered petitions, that attempts to use a governmental process, as opposed to the outcome of that process, to interfere with the business of a competitor.

(b) VIOLATION.—

(1) IN GENERAL.—A person submitting or causing the submission of a covered petition or a series of covered petitions that is a sham shall be liable for engaging in an unfair method of competition

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

(c) CIVIL ACTION.—

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

(2) PRESUMPTION.—In a civil action under paragraph (1), a covered petition shall be presumed to be part of a series of covered petitions that is a sham under subsection (b) of this section if the Secretary of Health and Human Services has determined that the covered petition was submitted with the primary purpose of delaying the approval of a covered application, was part of a series of covered petitions, and has referred such determination to the Federal Trade Commission in writing, with a reasoned basis for the determination.

(3) EXCEPTION.—The presumption in paragraph (2) shall not apply if the defendant establishes, by a preponderance of the evidence, that the series of covered petitions that includes the covered petition referred to the Commission by the Secretary of Health and Human Services is not a sham.

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

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

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

(5) ANTITRUST LAWS.—Nothing in this section shall modify, impair, limit, or supersede the applicability of the antitrust laws as defined in subsection (a) of the first section of the Clayton Act (15 U.S.C. 12(a)), and of section 5 of the Federal Trade Commission Act (15 U.S.C. 45) to the extent that it applies to unfair methods of competition.

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

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

SEC. 3. SEVERABILITY.

If any provision of this Act, an amendment made by this Act, or the application of such provision or amendment to any person or circumstance is held to be unconstitutional, the remainder of this Act, the amendments made by this Act, and the application of the provisions of such

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

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