Calendar No. 21

118TH 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.

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''—

(A) means an individual or entity; and

(B) includes—

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

(ii) a joint venture, subsidiary, partnership, division, group, and affiliate controlled by an entity; and

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

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

(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.—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—

(A) the Secretary of Health and Human Services—

(i) has determined that the covered petition was submitted with the primary purpose of delaying the approval of a covered application; and

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

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

(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), 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 or the application of such provision to any person or circumstance is held to be unconstitutional, the remainder of this Act and the application of the provisions of such Act to any person or circumstance shall not be affected.~~

SECTION 1. SHORT TITLE.

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(6) SHAM.—The term "sham" means—

(A) a covered petition that—

(i) is objectively baseless; and

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

(B) 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.—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.

(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—

(A) the Secretary of Health and Human Services—

(i) has determined that the covered petition was submitted with the primary pur-

pose of delaying the approval of a covered application; and

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

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

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

(6) 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), 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.

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

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

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

SEC. 3. SEVERABILITY.

If any provision of this Act or the application of such provision to any person or circumstance is held to be unconstitutional, the remainder of this Act and the application of the provisions of such Act to any person or circumstance shall not be affected.

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