Calendar No. 132

116TH CONGRESS
1ST SESSION

S. 1416

To amend the Federal Trade Commission Act to prohibit anticompetitive behaviors by drug product manufacturers, and for other purposes.

IN THE SENATE OF THE UNITED STATES

MAY 9, 2019

Mr. CORNYN (for himself, Mr. BLUMENTHAL, Mrs. CAPITO, Mrs. MURRAY, Mr. SCOTT of Florida, Mr. KENNEDY, Mr. HAWLEY, and Mr. DURBIN) introduced the following bill; which was read twice and referred to the Committee on the Judiciary

JUNE 28 (legislative day, JUNE 27), 2019

Reported by Mr. GRAHAM, with an amendment

[Strike out all after the enacting clause and insert the part printed in italic]

A BILL

To amend the Federal Trade Commission Act to prohibit anticompetitive behaviors by drug product manufacturers, 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 "Affordable Prescriptions for Patients Act of 2019".~~

SEC. 2. PRODUCT HOPPING; PATENT THICKETING.

(a) IN GENERAL.—The Federal Trade Commission Act (15 U.S.C. 41 et seq.) is amended by inserting after section 26 (15 U.S.C. 57c–2) the following:

"SEC. 27. PRODUCT HOPPING; PATENT THICKETING.

"(a) DEFINITIONS.—In this section:

"(1) ABBREVIATED NEW DRUG APPLICATION.—The term 'abbreviated new drug application' means an application under subsection (b)(2) or (j) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355).

"(2) BIOSIMILAR BIOLOGICAL PRODUCT.—The term 'biosimilar biological product' means a biological product licensed under section 351(k) of the Public Health Service Act (42 U.S.C. 262(k)).

"(3) BIOSIMILAR BIOLOGICAL PRODUCT LICENSE APPLICATION.—The term 'biosimilar biological product license application' means an application submitted under section 351(k) of the Public Health Service Act (42 U.S.C. 262(k)).

"(4) COMPETITION WINDOW.—The term 'competition window' means—

"(A) with respect to a listed drug, the period between—

"(i) the date that is the earlier of—

"(I) 8 years before any patent or marketing exclusivity granted under chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) with respect to such listed drug expires; and

"(II) the date on which the first abbreviated new drug application that references such listed drug is filed; and

"(ii) the later of—

"(I) the date that is 180 days after the first abbreviated new drug application that references such listed drug is filed; and

"(II) the date that is 1 year after the date on which the generic drug that is the subject of the abbreviated new drug application described in subclause (I) enters the marketplace; or

"(B) with respect to a reference product, the period between—

"(i) the date that is the earlier of—

"(I) 6 years before any patent or marketing exclusivity (including any

~~extension of such exclusivity) granted under section 351 of the Public Health Service Act (42 U.S.C. 262) or section 527 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360cc) with respect to such reference product expires; and~~

~~"(II) the date on which the first biosimilar biological product license application that references such reference product is filed; and~~

~~"(ii) the later of—~~

~~"(I) the date that is 180 days after the date on which the first biosimilar biological product license application that references such reference product enters the marketplace; and~~

~~"(II) the date that is 1 year after the date on which the biosimilar biological product that is the subject of the biosimilar biological product license application described in subclause (I) enters the marketplace.~~

"(5) EXPECTED REVENUE.—The term 'expected revenue', with respect to a follow-on product, means the financial value represented by the number of individuals in the target population multiplied by the financial revenue generated by each member of the target population over the 3-year period beginning—

"(A) on the day that 3 generic drugs referencing the same listed drug or 2 or more biosimilar biological products referencing the same reference product would have been widely available in the market; or

"(B) if 3 or more generic drugs referencing the same listed drug or 2 or more biosimilar biological products referencing the same reference product are already widely available in the market, the day that the follow-on product enters the market.

"(6) FOLLOW-ON PRODUCT.—The term 'follow-on product' means a drug approved through an application or supplement to an application submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(c)) or a biological product licensed through an application or supplement to an application submitted under section

351(a) of the Public Health Service Act (42 U.S.C. 262(a)) for a change, modification, or reformulation to the same manufacturer's previously approved drug or biological product.

"(7) GENERIC DRUG.—The term 'generic drug' means a drug approved under subsection (b)(2) or (j) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355).

"(8) LISTED DRUG.—The term 'listed drug' means a drug listed under section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)).

"(9) PATENT FAMILY.—The term 'patent family' means a group of related patents that continue the priority date of the underlying composition of matter patent, all of which claim the same drug or biological product or a use of the same drug or biological product.

"(10) PATENT PORTFOLIO.—The term 'patent portfolio' means a group of related patents covering the same or similar technical content.

"(11) PATENT THICKETING.—

"(A) IN GENERAL.—The term 'patent thicketing' means an action taken to limit competition by a patentee with respect to a drug

approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(c)) or a biological product licensed under section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)) in which—

"(i)(I) the patentee obtains patents in the same patent family or patent portfolio—

"(aa) that claim the drug or biological product or a use of the drug or biological product, a form of the drug or biological product, a method of use of the drug or biological product, or a method of manufacture of a drug or biological product; and

"(bb) whose effective filing date does not precede the date of filing the application under section 505(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)) or section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)); or

"(II) the underlying composition of matter patent is found invalid and the patentee obtains patents in the same patent

family or patent portfolio that claim the drug or biological product or a use of the drug or biological product, a form of the drug or biological product, a method of use of the drug or biological product, or a method of manufacture of the drug or biological product;

"(ii) an abbreviated new drug application referencing such approved drug or a biosimilar biological product license application referencing such licensed biological product could not be marketed without practicing one or more of the inventions claimed in the additional patents described in subclause (I) or (II) of clause (i); and

"(iii) the Commission determines that the patentee improperly limited competition by obtaining patents described in subclause (I) or (II) of clause (i).

"(B) FACTORS TO CONSIDER.—The Commission may establish that an action described in subparagraph (A) improperly limits competition if the Commission establishes a reasonable number of the following factors in a manner

that is sufficient to demonstrate anticompetitive intent.

"(i) The additional patents described in subparagraph (A)(i) (referred to in this subparagraph as the 'additional patents') stem from few patent families.

"(ii) The additional patents have common specifications.

"(iii) The additional patents did not issue on an application with respect to which a requirement for restriction under section 121 of title 35, United States Code, has been made, or on an application filed as a result of such a requirement.

"(iv) The additional patents have overlapping or identical claims.

"(v) The additional patents have been granted to the patentee on formulations or compositions of the product and not used.

"(vi) One or more of the additional patents have been invalidated in an inter partes review conducted under chapter 31 of title 35, United States Code, or a post-grant proceeding conducted under chapter 32 of that title.

''(vii) Litigation with applicants under section 351(k) of the Public Health Service Act has been extended based on the additional patents.

''(viii) The applications with respect to the additional patents described in subclause (I) or (II) of subparagraph (A)(i) are submitted not more than 36 months before the expiration of the underlying composition of matter patent.

''(ix) A public or internal statement, a shareholder call, or another demonstration of purpose that the patentee intended to use the number of patents or length of extended patent protection in order to unduly limit competition.

''(12) REFERENCE PRODUCT.—The term 'reference product' has the meaning given the term in section 351(i) of the Public Health Service Act (42 U.S.C. 262(i)).

''(13) TARGET POPULATION.—The term 'target population', with respect to a drug, means the population of individuals that—

''(A) would experience a significant health improvement from a follow-on product; and

"(B) would have bought the follow-on product solely because of the significant health improvement that those individuals would experience.

"(14) ULTIMATE PARENT ENTITY.—The term 'ultimate parent entity' has the meaning given the term in section 801.1 of title 16, Code of Federal Regulations, or any successor regulation.

"(15) UNDERLYING COMPOSITION OF MATTER PATENT.—The term 'underlying composition of matter patent' means a patent with respect to the molecules, compounds, or new formulations of the active ingredient of a drug or biological product.

"(b) PROHIBITIONS.—

"(1) PATENT THICKETING.—

"(A) PRIMA FACIE.—Except as provided in subparagraph (B), an action by a drug manufacturer that constitutes patent thicketing shall be considered to be an unfair method of competition in or affecting commerce in violation of section 5(a).

"(B) REBUTTAL.—

"(i) IN GENERAL.—Subject to subparagraph (C), an action that constitutes patent thicketing shall not be considered to

be an unfair method of competition in or affecting commerce in violation of section 5(a) if the manufacturer described in that paragraph demonstrates to the Commission or a district court of the United States, as applicable, by a preponderance of the evidence in a proceeding initiated by the Commission under subsection (c)(1)(A), or in a suit brought under subparagraph (B) or (C) of subsection (c)(1), that the anticompetitive effects of the action do not outweigh the pro-competitive effects of the action.

"(ii) EVIDENCE.—In making a demonstration under clause (i) that the anticompetitive effects of patent thicketing do not outweigh the pro-competitive effects of that behavior, a manufacturer described in subparagraph (A)—

"(I) may present evidence that—

"(aa) the inventions claimed in the additional patents described in subclauses (I) and (II) of subsection (a)(11)(A)(i) resulted in—

~~"(AA) clinically meaningful and significant therapeutic or safety benefits;~~

~~"(BB) significantly improved product purity or potency;~~

~~"(CC) significant gained efficiencies in manufacturing; or~~

~~"(DD) other improved product attributes having substantial benefits for consumers or patients;~~

~~"(bb) a generic drug or biosimilar biological product could be marketed commercially without incorporating the improvements claimed in the additional patents described in item (aa); or~~

~~"(cc) for each of the later filed patents, the manufacturer had substantial financial reason, apart from the financial effects of reduced competition, to file each of the patents; and~~

"(II) in making a demonstration under subclause (I), shall submit to the Commission or the court, as applicable, all research and development, manufacturing, marketing, and other costs associated with approval of the original drug under section 505(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(c)) or licensure of the original biological product under section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)), which—

"(aa) shall include—

"(AA) any documents relating to the costs and benefits of the later filed patents with respect to patients who use the drug; and

"(BB) any applications for patents that were filed and rejected; and

"(bb) shall not be construed to limit the information that the Commission or the court, as ap-

plicable, may otherwise obtain in any proceeding or action instituted with respect to a violation of this section.

"(C) RESPONSE.—The Commission may rebut any evidence presented by a drug manufacturer under subparagraph (B) by establishing by a preponderance of the evidence that the harm to consumers from the action that is the subject of that presentation is greater than the benefits to consumers from that action.

"(2) PRODUCT HOPPING.—

"(A) PRIMA FACIE.—Except as provided in subparagraph (B), any of the following actions by a manufacturer of a reference product or listed drug shall be considered to be an unfair method of competition in or affecting commerce in violation of section 5(a):

"(i) If, during the period beginning on the date on which the manufacturer of the reference drug receives notice that an applicant has submitted to the Commissioner of Food and Drugs an abbreviated new drug application or biosimilar biological product license application and ending on

the date that is 180 days after the date on which that generic drug or biosimilar biological product first enters, or could enter, the market, or is denied—

"(I) upon the request of the manufacturer of the listed drug or reference product, the Commissioner of Food and Drugs—

"(aa) withdraws the approval of the application for the listed drug or reference product; or

"(bb) places the listed drug or reference product on the discontinued products list; or

"(II) the manufacturer of the listed drug or reference product announces discontinuance of, or intent to withdraw, the application for the reference product.

"(ii) The manufacturer of a previously approved drug or biological product markets or sells a follow-on product during the competition window.

"(B) REBUTTAL.—

"(i) IN GENERAL.—Subject to subparagraph (C), an action described in subparagraph (A) shall not be considered to be an unfair method of competition in or affecting commerce if—

"(I) with respect to an action described in subparagraph (A)(i), the manufacturer of the listed drug or reference product demonstrates to the Commission or a district court of the United States, as applicable, by a preponderance of the evidence in a proceeding initiated by the Commission under subsection (c)(1)(A), or in a suit brought under subparagraph (B) or (C) of subsection (c)(1), that the manufacturer removed such drug from the market for significant and documented safety reasons; or

"(II) with respect to an action described in subparagraph (A)(ii)—

"(aa) the manufacturer demonstrates to the Commission or a district court of the United States, as applicable, by a pre-

ponderance of the evidence in a proceeding initiated by the Commission under subsection (c)(1)(A), or in a suit brought under subparagraph (B) or (C) of subsection (c)(1), that—

"(AA) the follow-on product described in such subparagraph (A)(ii) (referred to in this subclause as the 'follow-on product') provides a clinically meaningful and significant additional health benefit to the target population beyond that provided by the previously approved drug or biological product;

"(BB) the follow-on product was the available means that was least likely to reduce competition; and

"(CC) the manufacturer had substantive financial reasons, apart from the

financial effects of reduced competition, to introduce the follow-on product to the market; and

''(bb) in making the demonstration required under item (aa), the manufacturer provides to the Commission—

''(AA) all research and development, manufacturing, marketing, and other related costs associated with the drug or biological product previously approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(c)) or section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)) and the follow-on product, including all documents, memos, or other business documents that explain, mention, or otherwise justify

the decision of the manufacturer to develop and manufacture the follow-on product; and

"(BB) the revenue obtained by the manufacturer with respect to the drug or biological product previously approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(c)) or section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)) and the expected revenue of the manufacturer with respect to the previously approved drug or biological product and the follow-on product.

"(ii) RULE OF CONSTRUCTION.—Nothing in clause (i) may be construed to limit the information that the Commission may otherwise obtain in any proceeding or

action instituted with respect to a violation of this section.

''(C) RESPONSE.—The Commission may rebut any evidence presented by a drug manufacturer under subparagraph (B) by establishing by a preponderance of the evidence that—

''(i) the harm to consumers of the drug or biological product that is the subject of the product from the action that is the subject of that presentation is greater than the benefits to consumers of the drug or biological product that is the subject of challenged action; or

''(ii) a primary purpose of the manufacturer in pursuing the challenged action was to block or otherwise hinder the entry into the market of a generic drug or biosimilar biological product.

''(c) ENFORCEMENT.—

''(1) IN GENERAL.—If the Commission has reason to believe that any drug manufacturer has violated, is violating, or is about to violate this section, the Commission may take any of the following actions:

"(A) Institute a proceeding—

"(i) that, except as provided in paragraph (2), complies with the requirements under section 5(b); and

"(ii) in which the Commission may impose on the manufacturer any penalty that the Commission may impose for a violation of section 5.

"(B) In the same manner and to the same extent as provided in section 13(b), bring suit in a district court of the United States to temporarily enjoin the action of the drug manufacturer.

"(C)(i) Bring suit in a district court of the United States to permanently enjoin the action of the drug manufacturer.

"(ii) In a suit brought under clause (i), the Commission may seek—

"(I) any of the remedies described in paragraph (3); and

"(II) any other equitable remedy, including ancillary equitable relief.

"(2) JUDICIAL REVIEW.—

"(A) IN GENERAL.—Notwithstanding any provision of section 5, any drug manufacturer

that is subject to a final order of the Commission that is issued in a proceeding initiated under paragraph (1)(A) may, not later than 30 days after the date on which the Commission issues the order, petition for review of the order in—

"(i) the United States Court of Appeals for the District of Columbia Circuit; or

"(ii) the court of appeals of the United States for the circuit in which the ultimate parent entity of the manufacturer is incorporated, as of the date on which the manufacturer obtains the underlying composition of matter patent with respect to the proceeding or files a new drug application under section 505(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)) or biological product license application under section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)) that is the subject of the proceeding, as applicable.

"(B) TREATMENT OF FINDINGS.—In a review of an order issued by the Commission con-

ducted by a court of appeals of the United States under subparagraph (A), the factual findings of the Commission shall be conclusive if those facts are supported by the evidence.

"(3) EQUITABLE REMEDIES.—

"(A) DISGORGEMENT.—

"(i) IN GENERAL.—In a suit brought under paragraph (1)(C), the Commission may seek, and the court may order, disgorgement of any unjust enrichment that a person obtained as a result of the violation that gives rise to the suit in which the Commission seeks the claim.

"(ii) CALCULATION.—Any disgorgement that is ordered with respect to a person under clause (i) shall be offset by any amount of restitution that the person is ordered to pay under subparagraph (B).

"(iii) LIMITATIONS PERIOD.—The Commission may bring a claim for disgorgement under this subparagraph not later than 5 years after the latest date on which the person against which the claim is brought receives any unjust enrichment from the effects of the violation that gives

rise to the suit in which the Commission seeks the claim.

"(B) RESTITUTION.—

"(i) IN GENERAL.—In a suit brought under paragraph (1)(C), the Commission may seek, and the court may order, restitution with respect to the violation that gives rise to the suit in which the Commission seeks the claim.

"(ii) LIMITATIONS PERIOD.—The Commission may bring a claim for restitution under this subparagraph not later than 5 years after the latest date on which the person against which the claim is brought receives any unjust enrichment from the effects of the violation that gives rise to the suit in which the Commission seeks the claim.

"(4) RULES OF CONSTRUCTION.—Nothing in this subsection may be construed as—

"(A) requiring the Commission to bring a suit seeking a temporary injunction under paragraph (1)(B) before bringing a suit seeking a permanent injunction under paragraph (1)(C); or

''(B) affecting any other authority of the Commission under this Act to seek relief or obtain a remedy with respect to a violation of this Act.''.

(b) APPLICABILITY.—Section 27 of the Federal Trade Commission Act, as added by subsection (a), shall apply with respect to any—

(1) conduct that occurs on or after the date of enactment of this Act; and

(2) action or proceeding that is commenced on or after the date of enactment of this Act.

(c) ANTITRUST LAWS.—Nothing in this section, or the amendments made by 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.

(d) RULEMAKING.—The Federal Trade Commission may issue rules under section 553 of title 5, United States Code, to carry out section 27 of the Federal Trade Commission Act, as added by subsection (a), including by defining any terms used in such section 27.

SECTION 1. SHORT TITLE.

This Act may be cited as the "Affordable Prescriptions for Patients Act of 2019".

SEC. 2. PRODUCT HOPPING.

(a) IN GENERAL.—The Federal Trade Commission Act (15 U.S.C. 41 et seq.) is amended by inserting after section 26 (15 U.S.C. 57c–2) the following:

"SEC. 27. PRODUCT HOPPING.

"(a) DEFINITIONS.—In this section:

"(1) ABBREVIATED NEW DRUG APPLICATION.—The term 'abbreviated new drug application' means an application under subsection (b)(2) or (j) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355).

"(2) BIOSIMILAR BIOLOGICAL PRODUCT.—The term 'biosimilar biological product' means a biological product licensed under section 351(k) of the Public Health Service Act (42 U.S.C. 262(k)).

"(3) BIOSIMILAR BIOLOGICAL PRODUCT LICENSE APPLICATION.—The term 'biosimilar biological product license application' means an application submitted under section 351(k) of the Public Health Service Act (42 U.S.C. 262(k)).

"(4) FOLLOW-ON PRODUCT.—The term 'follow-on product'—

"(A) means a drug approved through an application or supplement to an application submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)) or a biological product licensed through an application or supplement to an application submitted under section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)) for a change, modification, or reformulation to the same manufacturer's previously approved drug or biological product that treats the same medical condition; and

"(B) excludes such an application or supplement to an application for a change, modification, or reformulation of a drug or biological product that is requested by the Secretary or necessary to comply with law, including sections 505A and 505B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a, 355c).

"(5) GENERIC DRUG.—The term 'generic drug' means a drug approved under an application submitted under subsection (b)(2) or (j) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355).

"(6) LISTED DRUG.—The term 'listed drug' means a drug listed under section 505(j)(7) of the

Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)).

"(7) MANUFACTURER.—The term 'manufacturer' means the holder, licensee, or assignee of—

"(A) an approved application for a drug under section 505(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(c)); or

"(B) a biological product license under section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)).

"(8) REFERENCE PRODUCT.—The term 'reference product' has the meaning given the term in section 351(i) of the Public Health Service Act (42 U.S.C. 262(i)).

"(9) ULTIMATE PARENT ENTITY.—The term 'ultimate parent entity' has the meaning given the term in section 801.1 of title 16, Code of Federal Regulations, or any successor regulation.

"(b) PROHIBITION ON PRODUCT HOPPING.—

"(1) PRIMA FACIE.—Except as provided in paragraph (2), a manufacturer of a reference product or listed drug shall be considered to have engaged in an unfair method of competition in or affecting commerce in violation of section 5(a) if the Commission demonstrates by a preponderance of the evidence in a

proceeding initiated by the Commission under subsection (c)(1)(A), or in a suit brought under subparagraph (B) or (C) of subsection (c)(1), that, during the period beginning on the date on which the manufacturer of the reference product or listed drug first receives notice that an applicant has submitted to the Commissioner of Food and Drugs an abbreviated new drug application or biosimilar biological product license application and ending on the date that is 180 days after the date on which that generic drug or biosimilar biological product is first marketed, the manufacturer engaged in either of the following actions:

"(A) The manufacturer engaged in a hard switch, which shall be established by demonstrating that the manufacturer engaged in either of the following actions:

"(i) Upon the request of the manufacturer of the listed drug or reference product, the Commissioner of Food and Drugs withdrew the approval of the application for the listed drug or reference product or placed the listed drug or reference product on the discontinued products list and the manufacturer marketed or sold a follow-on product.

"(ii) The manufacturer of the listed drug or reference product—

"(I)(aa) announced withdrawal of, discontinuance of the manufacture of, or intent to withdraw the application with respect to the drug or reference product in a manner that impedes competition from a generic drug or a biosimilar biological product, as established by objective circumstances; or

"(bb) destroyed the inventory of the listed drug or reference product in a manner that impedes competition from a generic drug or a biosimilar biological product, which may be established by objective circumstances; and

"(II) marketed or sold a follow-on product.

"(B) The manufacturer engaged in a soft switch, which shall be established by demonstrating that the manufacturer engaged in both of the following actions:

"(i) The manufacturer took actions with respect to the listed drug or reference

product other than those described in subparagraph (A) that unfairly disadvantage the listed drug or reference product relative to the follow-on product described in clause (ii) in a manner that impedes competition from a generic drug or a biosimilar biological product that is highly similar to, and has no clinically meaningful difference with respect to safety, purity, and potency from, the reference product, which may be established by objective circumstances.

"(ii) The manufacturer marketed or sold a follow-on product.

"(2) JUSTIFICATION.—

"(A) IN GENERAL.—Subject to paragraph (3), the actions described in paragraph (1) by a manufacturer of a listed drug or reference product shall not be considered to be an unfair method of competition in or affecting commerce if—

"(i) the manufacturer demonstrates to the Commission or a district court of the United States, as applicable, by a preponderance of the evidence in a proceeding initiated by the Commission under subsection (c)(1)(A), or in a suit brought under sub-

paragraph (B) or (C) of subsection (c)(1), that—

"(I) the manufacturer would have taken the actions regardless of whether a generic drug that references the listed drug or biosimilar biological product that references the reference product had already entered the market; and

"(II)(aa) with respect to a hard switch under paragraph (1)(A), the manufacturer took the action for reasons relating to the safety risk to patients of the listed drug or reference product;

"(bb) with respect to an action described in item (aa) or (bb) of paragraph (1)(A)(ii)(I), there is a supply disruption that—

"(AA) is outside of the control of the manufacturer;

"(BB) prevents the production or distribution of the applicable listed drug or reference product; and

"(CC) cannot be remedied by reasonable efforts; or

"(cc) with respect to a soft switch under paragraph (1)(B), the manufacturer had legitimate pro-competitive reasons, apart from the financial effects of reduced competition, to take the action.

"(B) RULE OF CONSTRUCTION.—Nothing in subparagraph (A) may be construed to limit the information that the Commission may otherwise obtain in any proceeding or action instituted with respect to a violation of this section.

"(3) RESPONSE.—With respect to a justification offered by a manufacturer under paragraph (2), the Commission may—

"(A) rebut any evidence presented by a manufacturer during that justification; or

"(B) establish by a preponderance of the evidence that, on balance, the pro-competitive benefits from the conduct described in subparagraph (A) or (B) of paragraph (1), as applicable, do not outweigh any anticompetitive effects of the conduct, even in consideration of the justification so offered.

"(c) ENFORCEMENT.—

"(1) IN GENERAL.—If the Commission has reason to believe that any manufacturer has violated, is violating, or is about to violate this section, the Commission may take any of the following actions:

"(A) Institute a proceeding—

"(i) that, except as provided in paragraph (2), complies with the requirements under section 5(b); and

"(ii) in which the Commission may impose on the manufacturer any penalty that the Commission may impose for a violation of section 5.

"(B) In the same manner and to the same extent as provided in section 13(b), bring suit in a district court of the United States to temporarily enjoin the action of the manufacturer.

"(C) Bring suit in a district court of the United States, in which the Commission may seek—

"(i) to permanently enjoin the action of the manufacturer;

"(ii) any of the remedies described in paragraph (3); and

"(iii) any other equitable remedy, including ancillary equitable relief.

"(2) JUDICIAL REVIEW.—

"(A) IN GENERAL.—Notwithstanding any provision of section 5, any manufacturer that is subject to a final order of the Commission that is issued in a proceeding instituted under paragraph (1)(A) may, not later than 30 days after the date on which the Commission issues the order, petition for review of the order in—

"(i) the United States Court of Appeals for the District of Columbia Circuit; or

"(ii) the court of appeals of the United States for the circuit in which the ultimate parent entity of the manufacturer is incorporated.

"(B) TREATMENT OF FINDINGS.—In a review of an order issued by the Commission conducted by a court of appeals of the United States under subparagraph (A), the factual findings of the Commission shall be conclusive if those facts are supported by the evidence.

"(3) EQUITABLE REMEDIES.—

"(A) DISGORGEMENT.—

"(i) IN GENERAL.—In a suit brought under paragraph (1)(C), the Commission may seek, and the court may order, disgorgement of any unjust enrichment that a person obtained as a result of the violation that gives rise to the suit.

"(ii) CALCULATION.—Any disgorgement that is ordered with respect to a person under clause (i) shall be offset by any amount of restitution ordered under subparagraph (B).

"(iii) LIMITATIONS PERIOD.—The Commission may seek disgorgement under this subparagraph not later than 5 years after the latest date on which the person from which the disgorgement is sought receives any unjust enrichment from the effects of the violation that gives rise to the suit in which the Commission seeks the disgorgement.

"(B) RESTITUTION.—

"(i) IN GENERAL.—In a suit brought under paragraph (1)(C), the Commission may seek, and the court may order, restitu-

tion with respect to the violation that gives rise to the suit.

"(ii) LIMITATIONS PERIOD.—The Commission may seek restitution under this subparagraph not later than 5 years after the latest date on which the person from which the restitution is sought receives any unjust enrichment from the effects of the violation that gives rise to the suit in which the Commission seeks the restitution.

"(4) RULES OF CONSTRUCTION.—Nothing in this subsection may be construed as—

"(A) requiring the Commission to bring a suit seeking a temporary injunction under paragraph (1)(B) before bringing a suit seeking a permanent injunction under paragraph (1)(C); or

"(B) affecting any other authority of the Commission under this Act to seek relief or obtain a remedy with respect to a violation of this Act.".

(b) APPLICABILITY.—Section 27 of the Federal Trade Commission Act, as added by subsection (a), shall apply with respect to any—

(1) conduct that occurs on or after the date of enactment of this Act; and

(2) action or proceeding that is commenced on or after the date of enactment of this Act.

(c) ANTITRUST LAWS.—Nothing in this section, or the amendments made by 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.

(d) RULEMAKING.—The Federal Trade Commission may issue rules under section 553 of title 5, United States Code, to carry out section 27 of the Federal Trade Commission Act, as added by subsection (a), including by defining any terms used in such section 27 (other than terms that are defined in subsection (a) of such section 27).

SEC. 3. TITLE 35 AMENDMENTS.

(a) IN GENERAL.—Section 271(e) of title 35, United States Code, is amended—

(1) in paragraph (2)(C), in the flush text following clause (ii), by adding at the end the following: "With respect to a submission described in clause (ii), the act of infringement shall extend to any patent that claims the biological product, a method of using

the biological product, or a method or product used to manufacture the biological product.''; and

(2) by adding at the end the following:

''(7)(A) Subject to subparagraphs (C), (D), and (E), if the sponsor of an approved application for a reference product, as defined in section 351(i) of the Public Health Service Act (42 U.S.C. 262(i)) (referred to in this paragraph as the 'reference product sponsor'), brings an action for infringement under this section against an applicant for approval of a biological product under section 351(k) of such Act that references that reference product (referred to in this paragraph as the 'subsection (k) applicant'), the reference product sponsor may assert in the action a total of not more than 20 patents of the type described in subparagraph (B), not more than 10 of which shall have issued after the date specified in section 351(l)(7)(A) of such Act.

''(B) The patents described in this subparagraph are patents that satisfy each of the following requirements:

''(i) Patents that claim the biological product that is the subject of an application under section 351(k) of the Public Health Service Act (42 U.S.C. 262(k)) (or a use of that product) or a method or product used in the manufacture of such biological product.

"(ii) Patents that are included on the list of patents described in section 351(l)(3)(A) of the Public Health Service Act (42 U.S.C. 262(l)(3)(A)), including as provided under section 351(l)(7) of such Act.

"(iii) Patents that—

"(I) have an actual filing date of more than 4 years after the date on which the reference product is approved; or

"(II) include a claim to a method in a manufacturing process that is not used by the reference product sponsor.

"(C) The court in which an action described in subparagraph (A) is brought may increase the number of patents limited under that subparagraph—

"(i) if the request to increase that number is made without undue delay; and

"(ii)(I) if the interest of justice so requires; or

"(II) for good cause shown, which—

"(aa) shall be established if the subsection (k) applicant fails to provide information required under section 351(l)(2)(A) of the Public Health Service Act (42 U.S.C. 262(l)(2)(A)) that would enable the reference product sponsor to form a reasonable belief with respect to whether

a claim of infringement under this section could reasonably be asserted; and

"(bb) may be established—

"(AA) if there is a material change to the biological product (or process with respect to the biological product) of the subsection (k) applicant that is the subject of the application;

"(BB) if, with respect to a patent on the supplemental list described in section 351(l)(7)(A) of Public Health Service Act (42 U.S.C. 262(l)(7)(A)), the patent would have issued before the date specified in such section 351(l)(7)(A) but for the failure of the Office to issue the patent or a delay in the issuance of the patent, as described in paragraph (1) of section 154(b) and subject to the limitations under paragraph (2) of such section 154(b); or

"(CC) for another reason that shows good cause, as determined appropriate by the court.

"(D) In determining whether good cause has been shown for the purposes of subparagraph (C)(ii)(II), a court may consider whether the reference product sponsor has pro-

vided a reasonable description of the identity and relevance of any information beyond the subsection (k) application that the court believes is necessary to enable the court to form a belief with respect to whether a claim of infringement under this section could reasonably be asserted.

"(E) The limitation imposed under subparagraph (A)—

"(i) shall apply only if the subsection (k) applicant completes all actions required under paragraphs (2)(A), (3)(B)(ii), (5), (6)(C)(i), (7), and (8)(A) of section 351(l) of the Public Health Service Act (42 U.S.C. 262(l)); and

"(ii) shall not apply with respect to any patent that claims, with respect to a biological product, a method for using that product in therapy, diagnosis, or prophylaxis, such as an indication or method of treatment or other condition of use.".

(b) APPLICABILITY.—The amendments made by subsection (a) shall apply with respect to an application submitted under section 351(k) of the Public Health Service Act (42 U.S.C. 262(k)) on or after the date of enactment of this Act.

Calendar No. 132

116TH CONGRESS
1ST SESSION

S. 1416

A BILL

To amend the Federal Trade Commission Act to prohibit anticompetitive behaviors by drug product manufacturers, and for other purposes.

JUNE 28 (legislative day, JUNE 27), 2019

Reported with an amendment