

116TH CONGRESS
1ST SESSION

H. R. 4398

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

IN THE HOUSE OF REPRESENTATIVES

SEPTEMBER 19, 2019

Mr. CICILLINE introduced the following bill; which was referred to the Committee on the Judiciary

A BILL

To amend the Federal Trade Commission Act to prohibit anticompetitive behaviors by drug product manufacturers, 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 “Affordable Prescrip-
5 tions for Patients Through Promoting Competition Act of
6 2019”.

7 **SEC. 2. PRODUCT HOPPING.**

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

1 **“SEC. 27. PRODUCT HOPPING.**

2 “(a) DEFINITIONS.—In this section:

3 “(1) ABBREVIATED NEW DRUG APPLICATION.—

4 The term ‘abbreviated new drug application’ means
5 an application under subsection (b)(2) or (j) of sec-
6 tion 505 of the Federal Food, Drug, and Cosmetic
7 Act (21 U.S.C. 355).

8 “(2) BIOSIMILAR BIOLOGICAL PRODUCT.—The

9 term ‘biosimilar biological product’ means a biologi-
10 cal product licensed under section 351(k) of the
11 Public Health Service Act (42 U.S.C. 262(k)).

12 “(3) BIOSIMILAR BIOLOGICAL PRODUCT LI-

13 CENSE APPLICATION.—The term ‘biosimilar biologi-
14 cal product license application’ means an application
15 submitted under section 351(k) of the Public Health
16 Service Act (42 U.S.C. 262(k)).

17 “(4) FOLLOW-ON PRODUCT.—The term ‘follow-
18 on product’—

19 “(A) means a drug approved through an
20 application or supplement to an application sub-
21 mitted under section 505(b) of the Federal
22 Food, Drug, and Cosmetic Act (21 U.S.C.
23 355(c)) or a biological product licensed through
24 an application or supplement to an application
25 submitted under section 351(a) of the Public
26 Health Service Act (42 U.S.C. 262(a)) for a

1 change, modification, or reformulation to the
2 same manufacturer’s previously approved drug
3 or biological product that treats the same med-
4 ical condition; and

5 “(B) excludes such an application or sup-
6 plement to an application for a change, modi-
7 fication, or reformulation of a drug or biological
8 product that is requested by the Secretary or
9 necessary to comply with law, including sections
10 505A and 505B of the Federal Food, Drug,
11 and Cosmetic Act (21 U.S.C. 355a, 355c).

12 “(5) GENERIC DRUG.—The term ‘generic drug’
13 means a drug approved under an application sub-
14 mitted under subsection (b)(2) or (j) of section 505
15 of the Federal Food, Drug, and Cosmetic Act (21
16 U.S.C. 355).

17 “(6) LISTED DRUG.—The term ‘listed drug’
18 means a drug listed under section 505(j)(7) of the
19 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
20 355(j)(7)).

21 “(7) MANUFACTURER.—The term ‘manufac-
22 turer’ means the holder, licensee, or assignee of—

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

1 “(B) a biological product license under sec-
2 tion 351(a) of the Public Health Service Act
3 (42 U.S.C. 262(a)).

4 “(8) REFERENCE PRODUCT.—The term ‘ref-
5 erence product’ has the meaning given the term in
6 section 351(i) of the Public Health Service Act (42
7 U.S.C. 262(i)).

8 “(9) ULTIMATE PARENT ENTITY.—The term
9 ‘ultimate parent entity’ has the meaning given the
10 term in section 801.1 of title 16, Code of Federal
11 Regulations, or any successor regulation.

12 “(b) PROHIBITION ON PRODUCT HOPPING.—

13 “(1) PRIMA FACIE.—Except as provided in
14 paragraph (2), a manufacturer of a reference prod-
15 uct or listed drug shall be considered to have en-
16 gaged in an unfair method of competition in or af-
17 fecting commerce in violation of section 5(a) if the
18 Commission demonstrates by a preponderance of the
19 evidence in a proceeding initiated by the Commission
20 under subsection (c)(1)(A), or in a suit brought
21 under subparagraph (B) or (C) of subsection (c)(1),
22 that, during the period beginning on the date on
23 which the manufacturer of the reference product or
24 listed drug first receives notice that an applicant has
25 submitted to the Commissioner of Food and Drugs

1 an abbreviated new drug application or biosimilar bi-
2 ological product license application and ending on
3 the date that is 180 days after the date on which
4 that generic drug or biosimilar biological product is
5 first marketed, the manufacturer engaged in either
6 of the following actions:

7 “(A) The manufacturer engaged in a hard
8 switch, which shall be established by dem-
9 onstrating that the manufacturer engaged in ei-
10 ther of the following actions:

11 “(i) Upon the request of the manufac-
12 turer of the listed drug or reference prod-
13 uct, the Commissioner of Food and Drugs
14 withdrew the approval of the application
15 for the listed drug or reference product or
16 placed the listed drug or reference product
17 on the discontinued products list and the
18 manufacturer marketed or sold a follow-on
19 product.

20 “(ii)(I) The manufacturer of the listed
21 drug or reference product—

22 “(aa) announced withdrawal of,
23 discontinuance of the manufacture of,
24 or intent to withdraw the application
25 with respect to the drug or reference

1 product in a manner that impedes
2 competition from a generic drug or a
3 biosimilar biological product, as estab-
4 lished by objective circumstances; or

5 “(bb) destroyed the inventory of
6 the listed drug or reference product in
7 a manner that impedes competition
8 from a generic drug or a biosimilar bi-
9 ological product, which may be estab-
10 lished by objective circumstances; and

11 “(II) marketed or sold a follow-on
12 product.

13 “(B) The manufacturer engaged in a soft
14 switch, which shall be established by dem-
15 onstrating that the manufacturer engaged in
16 both of the following actions:

17 “(i) The manufacturer took actions
18 with respect to the listed drug or reference
19 product other than those described in sub-
20 paragraph (A) that unfairly disadvantage
21 the listed drug or reference product rel-
22 ative to the follow-on product described in
23 clause (ii) in a manner that impedes com-
24 petition from a generic drug or a bio-
25 similar biological product that is highly

1 similar to, and has no clinically meaningful
2 difference with respect to safety, purity,
3 and potency from, the reference product,
4 which may be established by objective cir-
5 cumstances.

6 “(ii) The manufacturer marketed or
7 sold a follow-on product.

8 “(2) JUSTIFICATION.—

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

15 “(i) the manufacturer demonstrates to
16 the Commission or a district court of the
17 United States, as applicable, by a prepon-
18 derance of the evidence in a proceeding ini-
19 tiated by the Commission under subsection
20 (c)(1)(A), or in a suit brought under sub-
21 paragraph (B) or (C) of subsection (c)(1),
22 that—

23 “(I) the manufacturer would
24 have taken the actions regardless of
25 whether a generic drug that ref-

1 erences the listed drug or biosimilar
2 biological product that references the
3 reference product had already entered
4 the market; and

5 “(II)(aa) with respect to a hard
6 switch under paragraph (1)(A), the
7 manufacturer took the action for rea-
8 sons relating to the safety risk to pa-
9 tients of the listed drug or reference
10 product;

11 “(bb) with respect to an action
12 described in item (aa) or (bb) of para-
13 graph (1)(A)(ii)(I), there is a supply
14 disruption that—

15 “(AA) is outside of the con-
16 trol of the manufacturer;

17 “(BB) prevents the produc-
18 tion or distribution of the appli-
19 cable listed drug or reference
20 product; and

21 “(CC) cannot be remedied
22 by reasonable efforts; or

23 “(cc) with respect to a soft
24 switch under paragraph (1)(B), the
25 manufacturer had legitimate pro-com-

1 petitive reasons, apart from the finan-
2 cial effects of reduced competition, to
3 take the action.

4 “(B) RULE OF CONSTRUCTION.—Nothing
5 in subparagraph (A) may be construed to limit
6 the information that the Commission may oth-
7 erwise obtain in any proceeding or action insti-
8 tuted with respect to a violation of this section.

9 “(3) RESPONSE.—With respect to a justifica-
10 tion offered by a manufacturer under paragraph (2),
11 the Commission may—

12 “(A) rebut any evidence presented by a
13 manufacturer during that justification; or

14 “(B) establish by a preponderance of the
15 evidence that, on balance, the pro-competitive
16 benefits from the conduct described in subpara-
17 graph (A) or (B) of paragraph (1), as applica-
18 ble, do not outweigh any anticompetitive effects
19 of the conduct, even in consideration of the jus-
20 tification so offered.

21 “(c) ENFORCEMENT.—

22 “(1) IN GENERAL.—If the Commission has rea-
23 son to believe that any manufacturer has violated, is
24 violating, or is about to violate this section, the
25 Commission may take any of the following actions:

1 “(A) Institute a proceeding—

2 “(i) that, except as provided in para-
3 graph (2), complies with the requirements
4 under section 5(b); and

5 “(ii) in which the Commission may
6 impose on the manufacturer any penalty
7 that the Commission may impose for a vio-
8 lation of section 5.

9 “(B) In the same manner and to the same
10 extent as provided in section 13(b), bring suit
11 in a district court of the United States to tem-
12 porarily enjoin the action of the manufacturer.

13 “(C) Bring suit in a district court of the
14 United States, in which the Commission may
15 seek—

16 “(i) to permanently enjoin the action
17 of the manufacturer;

18 “(ii) any of the remedies described in
19 paragraph (3); and

20 “(iii) any other equitable remedy, in-
21 cluding ancillary equitable relief.

22 “(2) JUDICIAL REVIEW.—

23 “(A) IN GENERAL.—Notwithstanding any
24 provision of section 5, any manufacturer that is
25 subject to a final order of the Commission that

1 is issued in a proceeding initiated under para-
2 graph (1)(A) may, not later than 30 days after
3 the date on which the Commission issues the
4 order, petition for review of the order in—

5 “(i) the United States Court of Ap-
6 peals for the District of Columbia Circuit;
7 or

8 “(ii) the court of appeals of the
9 United States for the circuit in which the
10 ultimate parent entity of the manufacturer
11 is incorporated.

12 “(B) TREATMENT OF FINDINGS.—In a re-
13 view of an order issued by the Commission con-
14 ducted by a court of appeals of the United
15 States under subparagraph (A), the factual
16 findings of the Commission shall be conclusive
17 if those facts are supported by the evidence.

18 “(3) EQUITABLE REMEDIES.—

19 “(A) DISGORGEMENT.—

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

1 “(ii) CALCULATION.—Any disgorge-
2 ment that is ordered with respect to a per-
3 son under clause (i) shall be offset by any
4 amount of restitution ordered under sub-
5 paragraph (B).

6 “(iii) LIMITATIONS PERIOD.—The
7 Commission may seek disgorgement under
8 this subparagraph not later than 5 years
9 after the latest date on which the person
10 from which the disgorgement is sought re-
11 ceives any unjust enrichment from the ef-
12 fects of the violation that gives rise to the
13 suit in which the Commission seeks the
14 disgorgement.

15 “(B) RESTITUTION.—

16 “(i) IN GENERAL.—In a suit brought
17 under paragraph (1)(C), the Commission
18 may seek, and the court may order, res-
19 titution with respect to the violation that
20 gives rise to the suit.

21 “(ii) LIMITATIONS PERIOD.—The
22 Commission may seek restitution under
23 this subparagraph not later than 5 years
24 after the latest date on which the person
25 from which the restitution is sought re-

1 ceives any unjust enrichment from the ef-
2 fects of the violation that gives rise to the
3 suit in which the Commission seeks the
4 restitution.

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

7 “(A) requiring the Commission to bring a
8 suit seeking a temporary injunction under para-
9 graph (1)(B) before bringing a suit seeking a
10 permanent injunction under paragraph (1)(C);
11 or

12 “(B) affecting any other authority of the
13 Commission under this Act to seek relief or ob-
14 tain a remedy with respect to a violation of this
15 Act.”.

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

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

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

23 (c) ANTITRUST LAWS.—Nothing in this section, or
24 the amendments made by this section, shall modify, im-
25 pair, limit, or supersede the applicability of the antitrust

1 laws as defined in subsection (a) of the first section of
2 the Clayton Act (15 U.S.C. 12(a)), and of section 5 of
3 the Federal Trade Commission Act (15 U.S.C. 45) to the
4 extent that it applies to unfair methods of competition.

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

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