

Union Calendar No. 578

116TH CONGRESS
2^D SESSION

H. R. 5133

[Report No. 116-695]

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

IN THE HOUSE OF REPRESENTATIVES

NOVEMBER 18, 2019

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

DECEMBER 24, 2020

Additional sponsors: Mrs. MCBATH and Mr. CLINE

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 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:

11 **“SEC. 27. PRODUCT HOPPING.**

12 “(a) DEFINITIONS.—In this section:

13 “(1) ABBREVIATED NEW DRUG APPLICATION.—

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

18 “(2) BIOSIMILAR BIOLOGICAL PRODUCT.—The
19 term ‘biosimilar biological product’ means a biologi-
20 cal product licensed under section 351(k) of the
21 Public Health Service Act (42 U.S.C. 262(k)).

22 “(3) BIOSIMILAR BIOLOGICAL PRODUCT LI-
23 CENSE APPLICATION.—The term ‘biosimilar biologi-
24 cal product license application’ means an application

1 submitted under section 351(k) of the Public Health
2 Service Act (42 U.S.C. 262(k)).

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

5 “(A) means a drug approved through an
6 application or supplement to an application sub-
7 mitted under section 505(b) of the Federal
8 Food, Drug, and Cosmetic Act (21 U.S.C.
9 355(c)) or a biological product licensed through
10 an application or supplement to an application
11 submitted under section 351(a) of the Public
12 Health Service Act (42 U.S.C. 262(a)) for a
13 change, modification, or reformulation to the
14 same manufacturer’s previously approved drug
15 or biological product that treats the same or a
16 related indication;

17 “(B) excludes such an application or sup-
18 plement to an application for a change, modi-
19 fication, or reformulation of a drug or biological
20 product that is requested by the Secretary or
21 necessary to comply with law, including sections
22 505A and 505B of the Federal Food, Drug,
23 and Cosmetic Act (21 U.S.C. 355a, 355c);

24 “(C) excludes such an application or sup-
25 plement to an application submitted under sec-

1 tion 505(b) of the Federal Food, Drug, and
2 Cosmetic Act (21 U.S.C. 355(c)) that has been
3 granted New Chemical Entity exclusivity (21
4 U.S.C. 355(c)(3)(E)(ii)) by the Food and Drug
5 Administration; and

6 “(D) excludes such an application or sup-
7 plement submitted under section 351(a) of the
8 Public Health Service Act (42 U.S.C. 262(a))
9 that has been granted exclusivity pursuant to
10 section 351(k)(7) of such Act (42 U.S.C.
11 262(k)(7)).

12 “(5) COMMISSION.—The term ‘Commission’
13 means the Federal Trade Commission

14 “(6) DISADVANTAGE.—The term ‘disadvantage’
15 means to impede the listed drug or reference prod-
16 uct’s ability to compete on the merits with the fol-
17 low-on product. This term excludes actions that con-
18 sist solely of—

19 “(A) truthful, non-misleading promotional
20 marketing; or

21 “(B) ceasing promotional marketing for
22 the listed drug or reference product.

23 “(7) GENERIC DRUG.—The term ‘generic drug’
24 means a drug approved under an application sub-
25 mitted under subsection (b)(2) or (j) of section 505

1 of the Federal Food, Drug, and Cosmetic Act (21
2 U.S.C. 355).

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

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

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

12 “(B) a biological product license under sec-
13 tion 351(a) of the Public Health Service Act
14 (42 U.S.C. 262(a)).

15 “(10) REFERENCE PRODUCT.—The term ‘ref-
16 erence product’ has the meaning given the term in
17 section 351(i) of the Public Health Service Act (42
18 U.S.C. 262(i)).

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

23 “(b) PROHIBITION ON PRODUCT HOPPING.—

24 “(1) PRIMA FACIE.—Except as provided in
25 paragraph (2), a manufacturer of a reference prod-

1 uct or listed drug shall be considered to have en-
2 gaged in an unfair method of competition in or af-
3 fecting commerce in violation of section 5(a) of the
4 Federal Trade Commission Act if complaint counsel
5 or the Commission demonstrates by a preponderance
6 of the evidence in a proceeding initiated by the Com-
7 mission under subsection (c)(1), or in a suit brought
8 under subparagraph (B) or (C) of subsection (c)(1),
9 that, during the period beginning on the date on
10 which the manufacturer of the reference product or
11 listed drug first receives notice that an applicant has
12 submitted to the Commissioner of Food and Drugs
13 an abbreviated new drug application or biosimilar bi-
14 ological product license application and ending on
15 the date that is the earlier of 180 days after the
16 date on which that generic drug or biosimilar bio-
17 logical product or another generic drug or biosimilar
18 biological product referencing the listed drug or ref-
19 erence product is first marketed or 3 years after the
20 date on which the follow-on product is first mar-
21 keted, the manufacturer engaged in either of the fol-
22 lowing actions:

23 “(A) The manufacturer engaged in a hard
24 switch, which shall be established by dem-

1 onstrating that the manufacturer engaged in ei-
2 ther of the actions described in clause (i) or (ii):

3 “(i) Upon the request of the manufac-
4 turer of the listed drug or reference prod-
5 uct, the Commissioner of Food and Drugs
6 withdrew the approval of the application
7 for the listed drug or reference product or
8 placed the listed drug or reference product
9 on the discontinued products list; and

10 “(I) the manufacturer marketed or
11 sold a follow-on product.

12 “(ii)(I) The manufacturer of the listed
13 drug or reference product—

14 “(aa) withdrew, discontinued the
15 manufacture of, or withdrew the ap-
16 plication with respect to, or an-
17 nounced withdrawal of, discontinuance
18 of the manufacture of, or withdrawal
19 of the application with respect to, the
20 drug or reference product in a manner
21 that impedes competition from a ge-
22 neric drug or a biosimilar biological
23 product, as established by objective
24 circumstances, unless such actions
25 were taken by the manufacturer pur-

1 suant to a request of the Commis-
2 sioner of Food and Drugs; or

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

9 “(II) marketed or sold a follow-on
10 product.

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

15 “(i) The manufacturer took one or
16 more actions with respect to the listed
17 drug or reference product other than those
18 described in subparagraph (A) that un-
19 fairly disadvantage the listed drug or ref-
20 erence product relative to the follow-on
21 product described in clause (ii) in a man-
22 ner that impedes competition from either a
23 generic drug or a biosimilar biological
24 product, which may be established by ob-
25 jective circumstances.

1 “(ii) The manufacturer marketed or
2 sold a follow-on product.

3 “(2) JUSTIFICATION.—

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

10 “(i) the manufacturer demonstrates to
11 the Commission or a district court of the
12 United States, as applicable, by a prepon-
13 derance of the evidence in a proceeding ini-
14 tiated by the Commission under subsection
15 (c)(1), or in a suit brought under subpara-
16 graph (B) or (C) of subsection (c)(1),
17 that—

18 “(I) the manufacturer would
19 have taken the actions regardless of
20 whether a generic drug that ref-
21 erences the listed drug or biosimilar
22 biological product that references the
23 reference product had already entered
24 the market; and

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

7 “(bb) with respect to an action
8 described in item (aa) or (bb) of para-
9 graph (1)(A)(ii)(I), there is a supply
10 disruption that—

11 “(AA) is outside of the con-
12 trol of the manufacturer;

13 “(BB) prevents the produc-
14 tion or distribution of the appli-
15 cable listed drug or reference
16 product; and

17 “(CC) cannot be remedied
18 by reasonable efforts; or

19 “(cc) with respect to a soft
20 switch under paragraph (1)(B), the
21 manufacturer had legitimate pro-com-
22 petitive reasons, apart from the finan-
23 cial effects of reduced competition, to
24 take the action.

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

6 “(3) RESPONSE.—With respect to a justifica-
7 tion offered by a manufacturer under paragraph (2),
8 complaint counsel or the Commission, as applicable,
9 will prevail in its case if it establishes by a prepon-
10 derance of the evidence that—

11 “(A) the conduct described in subsection
12 (b)(1) is not reasonably necessary to address or
13 achieve the justifications claimed under para-
14 graph (2)(A)(II)(aa–cc), or such justifications
15 could be reasonably addressed or achieved
16 through less anticompetitive means; or

17 “(B) the pro-competitive benefits from the
18 conduct described in subparagraph (A) or (B)
19 of paragraph (1), as applicable, do not outweigh
20 any anticompetitive effects of the conduct, even
21 in consideration of the justification so offered.

22 “(c) ENFORCEMENT.—

23 “(1) ENFORCEMENT BY THE FEDERAL TRADE
24 COMMISSION.—Except as provided in paragraph (2),
25 the Commission shall enforce this section in the

1 same manner, by the same means, and with the
2 same jurisdiction, powers, duties, and remedies pro-
3 vided for by all applicable terms and provisions of
4 the Federal Trade Commission Act (15 U.S.C. 45 et
5 seq.).

6 “(2) JUDICIAL REVIEW.—

7 “(A) IN GENERAL.—Notwithstanding any
8 provision of section 5 of the Federal Trade
9 Commission Act, any manufacturer that is sub-
10 ject to a final order of the Commission that is
11 issued in a proceeding initiated under para-
12 graph (1) may, not later than 30 days after the
13 date on which the Commission issues the order,
14 petition for review of the order in—

15 “(i) the United States Court of Ap-
16 peals for the District of Columbia Circuit;
17 or

18 “(ii) the court of appeals of the
19 United States for the circuit in which the
20 ultimate parent entity of the manufacturer
21 is incorporated.

22 “(B) TREATMENT OF FINDINGS.—In a re-
23 view of an order issued by the Commission con-
24 ducted by a court of appeals of the United
25 States under subparagraph (A), the factual

1 findings of the Commission shall be conclusive
2 if those facts are supported by the evidence.

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

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

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

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

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

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

21 (c) ANTITRUST LAWS.—Nothing in this section, or
22 the amendments made by this section, shall modify, im-
23 pair, limit, or supersede the applicability of the antitrust
24 laws as defined in subsection (a) of the first section of
25 the Clayton Act (15 U.S.C. 12(a)), and of section 5 of

1 the Federal Trade Commission Act (15 U.S.C. 45) to the
2 extent that it applies to unfair methods of competition.

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

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