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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.

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 Act of 2019”.

1 **SEC. 2. PRODUCT HOPPING; PATENT THICKETING.**

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

5 **“SEC. 27. PRODUCT HOPPING; PATENT THICKETING.**

6 “(a) DEFINITIONS.—In this section:

7 “(1) ABBREVIATED NEW DRUG APPLICATION.—

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

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

16 “(3) BIOSIMILAR BIOLOGICAL PRODUCT LI-
17 CENSE APPLICATION.—The term ‘biosimilar biologi-
18 cal product license application’ means an application
19 submitted under section 351(k) of the Public Health
20 Service Act (42 U.S.C. 262(k)).

21 “(4) COMPETITION WINDOW.—The term ‘com-
22 petition window’ means—

23 “(A) with respect to a listed drug, the pe-
24 riod between—

25 “(i) the date that is the earlier of—

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

7 “(II) the date on which the first
8 abbreviated new drug application that
9 references such listed drug is filed;
10 and

11 “(ii) the later of—

12 “(I) the date that is 180 days
13 after the first abbreviated new drug
14 application that references such listed
15 drug is filed; and

16 “(II) the date that is 1 year after
17 the date on which the generic drug
18 that is the subject of the abbreviated
19 new drug application described in sub-
20 clause (I) enters the marketplace; or

21 “(B) with respect to a reference product,
22 the period between—

23 “(i) the date that is the earlier of—

24 “(I) 6 years before any patent or
25 marketing exclusivity (including any

1 extension of such exclusivity) granted
2 under section 351 of the Public
3 Health Service Act (42 U.S.C. 262)
4 or section 527 of the Federal Food,
5 Drug, and Cosmetic Act (21 U.S.C.
6 360ee) with respect to such reference
7 product expires; and

8 “(H) the date on which the first
9 biosimilar biological product license
10 application that references such ref-
11 erence product is filed; and

12 “(ii) the later of—

13 “(I) the date that is 180 days
14 after the date on which the first bio-
15 similar biological product license ap-
16 plication that references such ref-
17 erence product enters the market-
18 place; and

19 “(H) the date that is 1 year after
20 the date on which the biosimilar bio-
21 logical product that is the subject of
22 the biosimilar biological product li-
23 cense application described in sub-
24 clause (I) enters the marketplace.

1 “(5) EXPECTED REVENUE.—The term ‘ex-
2 pected revenue’, with respect to a follow-on product,
3 means the financial value represented by the number
4 of individuals in the target population multiplied by
5 the financial revenue generated by each member of
6 the target population over the 3-year period begin-
7 ning—

8 “(A) on the day that 3 generic drugs ref-
9 erencing the same listed drug or 2 or more bio-
10 similar biological products referencing the same
11 reference product would have been widely avail-
12 able in the market; or

13 “(B) if 3 or more generic drugs ref-
14 erencing the same listed drug or 2 or more bio-
15 similar biological products referencing the same
16 reference product are already widely available in
17 the market, the day that the follow-on product
18 enters the market.

19 “(6) FOLLOW-ON PRODUCT.—The term ‘follow-
20 on product’ means a drug approved through an ap-
21 plication or supplement to an application submitted
22 under section 505(b) of the Federal Food, Drug,
23 and Cosmetic Act (21 U.S.C. 355(e)) or a biological
24 product licensed through an application or supple-
25 ment to an application submitted under section

1 351(a) of the Public Health Service Act (42 U.S.C.
2 262(a)) for a change, modification, or reformulation
3 to the same manufacturer's previously approved
4 drug or biological product.

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

9 “(8) LISTED DRUG.—The term ‘listed drug’
10 means a drug listed under section 505(j)(7) of the
11 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
12 355(j)(7)).

13 “(9) PATENT FAMILY.—The term ‘patent fam-
14 ily’ means a group of related patents that continue
15 the priority date of the underlying composition of
16 matter patent, all of which claim the same drug or
17 biological product or a use of the same drug or bio-
18 logical product.

19 “(10) PATENT PORTFOLIO.—The term ‘patent
20 portfolio’ means a group of related patents covering
21 the same or similar technical content.

22 “(11) PATENT THICKETING.—

23 “(A) IN GENERAL.—The term ‘patent
24 thicketing’ means an action taken to limit com-
25 petition by a patentee with respect to a drug

1 approved under section 505(e) of the Federal
2 Food, Drug, and Cosmetic Act (21 U.S.C.
3 355(e)) or a biological product licensed under
4 section 351(a) of the Public Health Service Act
5 (42 U.S.C. 262(a)) in which—

6 “(i)(I) the patentee obtains patents in
7 the same patent family or patent port-
8 folio—

9 “(aa) that claim the drug or bio-
10 logical product or a use of the drug or
11 biological product, a form of the drug
12 or biological product, a method of use
13 of the drug or biological product, or a
14 method of manufacture of a drug or
15 biological product; and

16 “(bb) whose effective filing date
17 does not precede the date of filing the
18 application under section 505(b) of
19 the Federal Food, Drug, and Cos-
20 metic Act (21 U.S.C. 355(b)) or sec-
21 tion 351(a) of the Public Health Serv-
22 ice Act (42 U.S.C. 262(a)); or

23 “(II) the underlying composition of
24 matter patent is found invalid and the pat-
25 entee obtains patents in the same patent

1 family or patent portfolio that claim the
2 drug or biological product or a use of the
3 drug or biological product, a form of the
4 drug or biological product, a method of use
5 of the drug or biological product, or a
6 method of manufacture of the drug or bio-
7 logical product;

8 “(ii) an abbreviated new drug applica-
9 tion referencing such approved drug or a
10 biosimilar biological product license appli-
11 cation referencing such licensed biological
12 product could not be marketed without
13 practicing one or more of the inventions
14 claimed in the additional patents described
15 in subclause (I) or (II) of clause (i); and

16 “(iii) the Commission determines that
17 the patentee improperly limited competi-
18 tion by obtaining patents described in sub-
19 clause (I) or (II) of clause (i).

20 “(B) FACTORS TO CONSIDER.—The Com-
21 mission may establish that an action described
22 in subparagraph (A) improperly limits competi-
23 tion if the Commission establishes a reasonable
24 number of the following factors in a manner

1 that is sufficient to demonstrate anticompetitive
2 intent:

3 “(i) The additional patents described
4 in subparagraph (A)(i) (referred to in this
5 subparagraph as the ‘additional patents’)
6 stem from few patent families.

7 “(ii) The additional patents have com-
8 mon specifications.

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

15 “(iv) The additional patents have
16 overlapping or identical claims.

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

20 “(vi) One or more of the additional
21 patents have been invalidated in an inter
22 partes review conducted under chapter 31
23 of title 35, United States Code, or a post-
24 grant proceeding conducted under chapter
25 32 of that title.

1 “(vii) Litigation with applicants under
2 section 351(k) of the Public Health Service
3 Act has been extended based on the addi-
4 tional patents.

5 “(viii) The applications with respect
6 to the additional patents described in sub-
7 clause (I) or (II) of subparagraph (A)(i)
8 are submitted not more than 36 months
9 before the expiration of the underlying
10 composition of matter patent.

11 “(ix) A public or internal statement, a
12 shareholder call, or another demonstration
13 of purpose that the patentee intended to
14 use the number of patents or length of ex-
15 tended patent protection in order to unduly
16 limit competition.

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

21 “(13) TARGET POPULATION.—The term ‘target
22 population’, with respect to a drug, means the popu-
23 lation of individuals that—

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

1 “(B) would have bought the follow-on
2 product solely because of the significant health
3 improvement that those individuals would expe-
4 rience.

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

9 “(15) UNDERLYING COMPOSITION OF MATTER
10 PATENT.—The term ‘underlying composition of mat-
11 ter patent’ means a patent with respect to the mol-
12 ecules, compounds, or new formulations of the active
13 ingredient of a drug or biological product.

14 “(b) PROHIBITIONS.—

15 “(1) PATENT THICKETING.—

16 “(A) PRIMA FACIE.—Except as provided in
17 subparagraph (B), an action by a drug manu-
18 facturer that constitutes patent thicketing shall
19 be considered to be an unfair method of com-
20 petition in or affecting commerce in violation of
21 section 5(a).

22 “(B) REBUTTAL.—

23 “(i) IN GENERAL.—Subject to sub-
24 paragraph (C), an action that constitutes
25 patent thicketing shall not be considered to

1 be an unfair method of competition in or
2 affecting commerce in violation of section
3 5(a) if the manufacturer described in that
4 paragraph demonstrates to the Commis-
5 sion or a district court of the United
6 States, as applicable, by a preponderance
7 of the evidence in a proceeding initiated by
8 the Commission under subsection
9 (e)(1)(A), or in a suit brought under sub-
10 paragraph (B) or (C) of subsection (e)(1),
11 that the anticompetitive effects of the ac-
12 tion do not outweigh the pro-competitive
13 effects of the action.

14 “(ii) EVIDENCE.—In making a dem-
15 onstration under clause (i) that the anti-
16 competitive effects of patent thickening do
17 not outweigh the pro-competitive effects of
18 that behavior, a manufacturer described in
19 subparagraph (A)—

20 “(I) may present evidence that—

21 “(aa) the inventions claimed
22 in the additional patents de-
23 scribed in subclauses (I) and (II)
24 of subsection (a)(11)(A)(i) re-
25 sulted in—

1 “(AA) clinically mean-
2 ingful and significant thera-
3 peutic or safety benefits;

4 “(BB) significantly im-
5 proved product purity or po-
6 tency;

7 “(CC) significant
8 gained efficiencies in manu-
9 facturing; or

10 “(DD) other improved
11 product attributes having
12 substantial benefits for con-
13 sumers or patients;

14 “(bb) a generic drug or bio-
15 similar biological product could
16 be marketed commercially with-
17 out incorporating the improve-
18 ments claimed in the additional
19 patents described in item (aa); or

20 “(ee) for each of the later
21 filed patents, the manufacturer
22 had substantial financial reason,
23 apart from the financial effects
24 of reduced competition, to file
25 each of the patents; and

1 “(H) in making a demonstration
2 under subelause (I), shall submit to
3 the Commission or the court, as appli-
4 cable, all research and development,
5 manufacturing, marketing, and other
6 costs associated with approval of the
7 original drug under section 505(e) of
8 the Federal Food, Drug, and Cos-
9 metic Act (21 U.S.C. 355(e)) or licen-
10 sure of the original biological product
11 under section 351(a) of the Public
12 Health Service Act (42 U.S.C.
13 262(a)), which—

14 “(aa) shall include—

15 “(AA) any documents
16 relating to the costs and
17 benefits of the later filed
18 patents with respect to pa-
19 tients who use the drug; and

20 “(BB) any applications
21 for patents that were filed
22 and rejected; and

23 “(bb) shall not be construed
24 to limit the information that the
25 Commission or the court, as ap-

1 plicable, may otherwise obtain in
2 any proceeding or action insti-
3 tuted with respect to a violation
4 of this section.

5 “(C) RESPONSE.—The Commission may
6 rebut any evidence presented by a drug manu-
7 facturer under subparagraph (B) by estab-
8 lishing by a preponderance of the evidence that
9 the harm to consumers from the action that is
10 the subject of that presentation is greater than
11 the benefits to consumers from that action.

12 “(2) PRODUCT HOPPING.—

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

19 “(i) If, during the period beginning on
20 the date on which the manufacturer of the
21 reference drug receives notice that an ap-
22 plicant has submitted to the Commissioner
23 of Food and Drugs an abbreviated new
24 drug application or biosimilar biological
25 product license application and ending on

1 the date that is 180 days after the date on
2 which that generic drug or biosimilar bio-
3 logical product first enters, or could enter,
4 the market, or is denied—

5 “(I) upon the request of the
6 manufacturer of the listed drug or
7 reference product, the Commissioner
8 of Food and Drugs—

9 “(aa) withdraws the ap-
10 proval of the application for the
11 listed drug or reference product;
12 or

13 “(bb) places the listed drug
14 or reference product on the dis-
15 continued products list; or

16 “(II) the manufacturer of the
17 listed drug or reference product an-
18 nounces discontinuance of, or intent
19 to withdraw, the application for the
20 reference product.

21 “(ii) The manufacturer of a previously
22 approved drug or biological product mar-
23 kets or sells a follow-on product during the
24 competition window.

25 “(B) REBUTTAL.—

1 “(i) IN GENERAL.—Subject to sub-
2 paragraph (C), an action described in sub-
3 paragraph (A) shall not be considered to
4 be an unfair method of competition in or
5 affecting commerce if—

6 “(I) with respect to an action de-
7 scribed in subparagraph (A)(i), the
8 manufacturer of the listed drug or
9 reference product demonstrates to the
10 Commission or a district court of the
11 United States, as applicable, by a pre-
12 ponderance of the evidence in a pro-
13 ceeding initiated by the Commission
14 under subsection (e)(1)(A), or in a
15 suit brought under subparagraph (B)
16 or (C) of subsection (e)(1), that the
17 manufacturer removed such drug
18 from the market for significant and
19 documented safety reasons; or

20 “(II) with respect to an action
21 described in subparagraph (A)(ii)—

22 “(aa) the manufacturer
23 demonstrates to the Commission
24 or a district court of the United
25 States, as applicable, by a pre-

1 ponderance of the evidence in a
2 proceeding initiated by the Com-
3 mission under subsection
4 (c)(1)(A), or in a suit brought
5 under subparagraph (B) or (C)
6 of subsection (c)(1), that—

7 “(AA) the follow-on
8 product described in such
9 subparagraph (A)(ii) (re-
10 ferred to in this subclause as
11 the ‘follow-on product’) pro-
12 vides a clinically meaningful
13 and significant additional
14 health benefit to the target
15 population beyond that pro-
16 vided by the previously ap-
17 proved drug or biological
18 product;

19 “(BB) the follow-on
20 product was the available
21 means that was least likely
22 to reduce competition; and

23 “(CC) the manufac-
24 turer had substantive finan-
25 cial reasons, apart from the

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

5 “(bb) in making the dem-
6 onstration required under item
7 (aa); the manufacturer provides
8 to the Commission—

9 “(AA) all research and
10 development, manufacturing,
11 marketing, and other related
12 costs associated with the
13 drug or biological product
14 previously approved under
15 section 505(c) of the Fed-
16 eral Food, Drug, and Cos-
17 metic Act (21 U.S.C.
18 355(c)) or section 351(a) of
19 the Public Health Service
20 Act (42 U.S.C. 262(a)) and
21 the follow-on product, in-
22 cluding all documents,
23 memos, or other business
24 documents that explain,
25 mention, or otherwise justify

1 the decision of the manufac-
2 turer to develop and manu-
3 facture the follow-on prod-
4 uct; and

5 “(BB) the revenue ob-
6 tained by the manufacturer
7 with respect to the drug or
8 biological product previously
9 approved under section
10 505(e) of the Federal Food,
11 Drug, and Cosmetic Act (21
12 U.S.C. 355(e)) or section
13 351(a) of the Public Health
14 Service Act (42 U.S.C.
15 262(a)) and the expected
16 revenue of the manufacturer
17 with respect to the pre-
18 viously approved drug or bi-
19 ological product and the fol-
20 low-on product.

21 “(ii) RULE OF CONSTRUCTION.—

22 Nothing in clause (i) may be construed to
23 limit the information that the Commission
24 may otherwise obtain in any proceeding or

1 action instituted with respect to a violation
2 of this section.

3 “(C) RESPONSE.—The Commission may
4 rebut any evidence presented by a drug manu-
5 facturer under subparagraph (B) by estab-
6 lishing by a preponderance of the evidence
7 that—

8 “(i) the harm to consumers of the
9 drug or biological product that is the sub-
10 ject of the product from the action that is
11 the subject of that presentation is greater
12 than the benefits to consumers of the drug
13 or biological product that is the subject of
14 challenged action; or

15 “(ii) a primary purpose of the manu-
16 facturer in pursuing the challenged action
17 was to block or otherwise hinder the entry
18 into the market of a generic drug or bio-
19 similar biological product.

20 “(e) ENFORCEMENT.—

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

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 drug manufac-
13 turer.

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

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

19 “(I) any of the remedies described in
20 paragraph (3); and

21 “(II) any other equitable remedy, in-
22 cluding ancillary equitable relief.

23 “(2) JUDICIAL REVIEW.—

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

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

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

10 “(ii) the court of appeals of the
11 United States for the circuit in which the
12 ultimate parent entity of the manufacturer
13 is incorporated, as of the date on which the
14 manufacturer obtains the underlying com-
15 position of matter patent with respect to
16 the proceeding or files a new drug applica-
17 tion under section 505(b) of the Federal
18 Food, Drug, and Cosmetic Act (21 U.S.C.
19 355(b)) or biological product license appli-
20 cation under section 351(a) of the Public
21 Health Service Act (42 U.S.C. 262(a))
22 that is the subject of the proceeding, as
23 applicable.

24 “(B) TREATMENT OF FINDINGS.—In a re-
25 view of an order issued by the Commission con-

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

5 “(3) EQUITABLE REMEDIES.—

6 “(A) DISGORGEMENT.—

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

14 “(ii) CALCULATION.—Any disgorge-
15 ment that is ordered with respect to a per-
16 son under clause (i) shall be offset by any
17 amount of restitution that the person is or-
18 dered to pay under subparagraph (B).

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

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

3 “(B) RESTITUTION.—

4 “(i) IN GENERAL.—In a suit brought
5 under paragraph (1)(C), the Commission
6 may seek, and the court may order, res-
7 titution with respect to the violation that
8 gives rise to the suit in which the Commis-
9 sion seeks the claim.

10 “(ii) LIMITATIONS PERIOD.—The
11 Commission may bring a claim for restitu-
12 tion under this subparagraph not later
13 than 5 years after the latest date on which
14 the person against which the claim is
15 brought receives any unjust enrichment
16 from the effects of the violation that gives
17 rise to the suit in which the Commission
18 seeks the claim.

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

21 “(A) requiring the Commission to bring a
22 suit seeking a temporary injunction under para-
23 graph (1)(B) before bringing a suit seeking a
24 permanent injunction under paragraph (1)(C);
25 or

1 “(B) affecting any other authority of the
2 Commission under this Act to seek relief or ob-
3 tain a remedy with respect to a violation of this
4 Act.”.

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

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

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

12 (c) **ANTITRUST LAWS.**—Nothing in this section, or
13 the amendments made by this section, shall modify, im-
14 pair, limit, or supersede the applicability of the antitrust
15 laws as defined in subsection (a) of the first section of
16 the Clayton Act (15 U.S.C. 12(a)), and of section 5 of
17 the Federal Trade Commission Act (15 U.S.C. 45) to the
18 extent that it applies to unfair methods of competition.

19 (d) **RULEMAKING.**—The Federal Trade Commission
20 may issue rules under section 553 of title 5, United States
21 Code, to carry out section 27 of the Federal Trade Com-
22 mission Act, as added by subsection (a), including by de-
23 fining any terms used in such section 27.

1 **SECTION 1. SHORT TITLE.**

2 *This Act may be cited as the “Affordable Prescriptions*
 3 *for Patients Act of 2019”.*

4 **SEC. 2. PRODUCT HOPPING.**

5 (a) *IN GENERAL.*—*The Federal Trade Commission Act*
 6 *(15 U.S.C. 41 et seq.) is amended by inserting after section*
 7 *26 (15 U.S.C. 57c–2) the following:*

8 **“SEC. 27. PRODUCT HOPPING.**

9 “(a) *DEFINITIONS.*—*In this section:*

10 “(1) *ABBREVIATED NEW DRUG APPLICATION.*—
 11 *The term ‘abbreviated new drug application’ means*
 12 *an application under subsection (b)(2) or (j) of sec-*
 13 *tion 505 of the Federal Food, Drug, and Cosmetic Act*
 14 *(21 U.S.C. 355).*

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

19 “(3) *BIOSIMILAR BIOLOGICAL PRODUCT LICENSE*
 20 *APPLICATION.*—*The term ‘biosimilar biological prod-*
 21 *uct license application’ means an application sub-*
 22 *mitted under section 351(k) of the Public Health*
 23 *Service Act (42 U.S.C. 262(k)).*

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

1 “(A) means a drug approved through an
2 application or supplement to an application sub-
3 mitted under section 505(b) of the Federal Food,
4 Drug, and Cosmetic Act (21 U.S.C. 355(b)) or a
5 biological product licensed through an applica-
6 tion or supplement to an application submitted
7 under section 351(a) of the Public Health Service
8 Act (42 U.S.C. 262(a)) for a change, modifica-
9 tion, or reformulation to the same manufactur-
10 er’s previously approved drug or biological prod-
11 uct that treats the same medical condition; and

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

19 “(5) *GENERIC DRUG*.—The term ‘generic drug’
20 means a drug approved under an application sub-
21 mitted under subsection (b)(2) or (j) of section 505 of
22 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
23 355).

24 “(6) *LISTED DRUG*.—The term ‘listed drug’
25 means a drug listed under section 505(j)(7) of the

1 *Federal Food, Drug, and Cosmetic Act (21 U.S.C.*
2 *355(j)(7)).*

3 “(7) *MANUFACTURER.*—*The term ‘manufacturer’*
4 *means the holder, licensee, or assignee of—*

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

8 “(B) *a biological product license under sec-*
9 *tion 351(a) of the Public Health Service Act (42*
10 *U.S.C. 262(a)).*

11 “(8) *REFERENCE PRODUCT.*—*The term ‘reference*
12 *product’ has the meaning given the term in section*
13 *351(i) of the Public Health Service Act (42 U.S.C.*
14 *262(i)).*

15 “(9) *ULTIMATE PARENT ENTITY.*—*The term ‘ul-*
16 *timite parent entity’ has the meaning given the term*
17 *in section 801.1 of title 16, Code of Federal Regula-*
18 *tions, or any successor regulation.*

19 “(b) *PROHIBITION ON PRODUCT HOPPING.*—

20 “(1) *PRIMA FACIE.*—*Except as provided in para-*
21 *graph (2), a manufacturer of a reference product or*
22 *listed drug shall be considered to have engaged in an*
23 *unfair method of competition in or affecting com-*
24 *merce in violation of section 5(a) if the Commission*
25 *demonstrates by a preponderance of the evidence in a*

1 *proceeding initiated by the Commission under sub-*
2 *section (c)(1)(A), or in a suit brought under subpara-*
3 *graph (B) or (C) of subsection (c)(1), that, during the*
4 *period beginning on the date on which the manufac-*
5 *turer of the reference product or listed drug first re-*
6 *ceives notice that an applicant has submitted to the*
7 *Commissioner of Food and Drugs an abbreviated new*
8 *drug application or biosimilar biological product li-*
9 *cence application and ending on the date that is 180*
10 *days after the date on which that generic drug or bio-*
11 *similar biological product is first marketed, the man-*
12 *ufacturer engaged in either of the following actions:*

13 *“(A) The manufacturer engaged in a hard*
14 *switch, which shall be established by dem-*
15 *onstrating that the manufacturer engaged in ei-*
16 *ther of the following actions:*

17 *“(i) Upon the request of the manufac-*
18 *turer of the listed drug or reference product,*
19 *the Commissioner of Food and Drugs with-*
20 *drew the approval of the application for the*
21 *listed drug or reference product or placed*
22 *the listed drug or reference product on the*
23 *discontinued products list and the manufac-*
24 *turer marketed or sold a follow-on product.*

1 “(ii) *The manufacturer of the listed*
2 *drug or reference product—*

3 “(I)(aa) *announced withdrawal*
4 *of, discontinuance of the manufacture*
5 *of, or intent to withdraw the applica-*
6 *tion with respect to the drug or ref-*
7 *erence product in a manner that im-*
8 *pedes competition from a generic drug*
9 *or a biosimilar biological product, as*
10 *established by objective circumstances;*
11 *or*

12 “(bb) *destroyed the inventory of*
13 *the listed drug or reference product in*
14 *a manner that impedes competition*
15 *from a generic drug or a biosimilar bi-*
16 *ological product, which may be estab-*
17 *lished by objective circumstances; and*

18 “(II) *marketed or sold a follow-on*
19 *product.*

20 “(B) *The manufacturer engaged in a soft*
21 *switch, which shall be established by dem-*
22 *onstrating that the manufacturer engaged in*
23 *both of the following actions:*

24 “(i) *The manufacturer took actions*
25 *with respect to the listed drug or reference*

1 *product other than those described in sub-*
2 *paragraph (A) that unfairly disadvantage*
3 *the listed drug or reference product relative*
4 *to the follow-on product described in clause*
5 *(ii) in a manner that impedes competition*
6 *from a generic drug or a biosimilar biologi-*
7 *cal product that is highly similar to, and*
8 *has no clinically meaningful difference with*
9 *respect to safety, purity, and potency from,*
10 *the reference product, which may be estab-*
11 *lished by objective circumstances.*

12 *“(ii) The manufacturer marketed or*
13 *sold a follow-on product.*

14 “(2) *JUSTIFICATION.—*

15 *“(A) IN GENERAL.—Subject to paragraph*
16 *(3), the actions described in paragraph (1) by a*
17 *manufacturer of a listed drug or reference prod-*
18 *uct shall not be considered to be an unfair meth-*
19 *od of competition in or affecting commerce if—*

20 *“(i) the manufacturer demonstrates to*
21 *the Commission or a district court of the*
22 *United States, as applicable, by a prepon-*
23 *derance of the evidence in a proceeding ini-*
24 *tiated by the Commission under subsection*
25 *(c)(1)(A), or in a suit brought under sub-*

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

3 “(I) the manufacturer would have
4 taken the actions regardless of whether
5 a generic drug that references the listed
6 drug or biosimilar biological product
7 that references the reference product
8 had already entered the market; and

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

15 “(bb) with respect to an action de-
16 scribed in item (aa) or (bb) of para-
17 graph (1)(A)(i)(I), there is a supply
18 disruption that—

19 “(AA) is outside of the con-
20 trol of the manufacturer;

21 “(BB) prevents the produc-
22 tion or distribution of the appli-
23 cable listed drug or reference
24 product; and

1 “(CC) cannot be remedied by
2 reasonable efforts; or

3 “(cc) with respect to a soft switch
4 under paragraph (1)(B), the manufac-
5 turer had legitimate pro-competitive
6 reasons, apart from the financial ef-
7 fects of reduced competition, to take the
8 action.

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

14 “(3) *RESPONSE.*—With respect to a justification
15 offered by a manufacturer under paragraph (2), the
16 Commission may—

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

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

1 “(c) *ENFORCEMENT.*—

2 “(1) *IN GENERAL.*—*If the Commission has rea-*
3 *son to believe that any manufacturer has violated, is*
4 *violating, or is about to violate this section, the Com-*
5 *mission may take any of the following actions:*

6 “(A) *Institute a proceeding—*

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

10 “(ii) *in which the Commission may*
11 *impose on the manufacturer any penalty*
12 *that the Commission may impose for a vio-*
13 *lation of section 5.*

14 “(B) *In the same manner and to the same*
15 *extent as provided in section 13(b), bring suit in*
16 *a district court of the United States to tempo-*
17 *rarily enjoin the action of the manufacturer.*

18 “(C) *Bring suit in a district court of the*
19 *United States, in which the Commission may*
20 *seek—*

21 “(i) *to permanently enjoin the action*
22 *of the manufacturer;*

23 “(ii) *any of the remedies described in*
24 *paragraph (3); and*

1 “(iii) any other equitable remedy, in-
2 cluding ancillary equitable relief.

3 “(2) JUDICIAL REVIEW.—

4 “(A) IN GENERAL.—Notwithstanding any
5 provision of section 5, any manufacturer that is
6 subject to a final order of the Commission that
7 is issued in a proceeding instituted under para-
8 graph (1)(A) may, not later than 30 days after
9 the date on which the Commission issues the
10 order, petition for review of the order in—

11 “(i) the United States Court of Appeals
12 for the District of Columbia Circuit; or

13 “(ii) the court of appeals of the United
14 States for the circuit in which the ultimate
15 parent entity of the manufacturer is incor-
16 porated.

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

23 “(3) EQUITABLE REMEDIES.—

24 “(A) DISGORGEMENT.—

1 “(i) *IN GENERAL.*—*In a suit brought*
2 *under paragraph (1)(C), the Commission*
3 *may seek, and the court may order,*
4 *disgorgement of any unjust enrichment that*
5 *a person obtained as a result of the viola-*
6 *tion that gives rise to the suit.*

7 “(ii) *CALCULATION.*—*Any*
8 *disgorgement that is ordered with respect to*
9 *a person under clause (i) shall be offset by*
10 *any amount of restitution ordered under*
11 *subparagraph (B).*

12 “(iii) *LIMITATIONS PERIOD.*—*The*
13 *Commission may seek disgorgement under*
14 *this subparagraph not later than 5 years*
15 *after the latest date on which the person*
16 *from which the disgorgement is sought re-*
17 *ceives any unjust enrichment from the ef-*
18 *fects of the violation that gives rise to the*
19 *suit in which the Commission seeks the*
20 *disgorgement.*

21 “(B) *RESTITUTION.*—

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

1 *tion with respect to the violation that gives*
2 *rise to the suit.*

3 “(ii) *LIMITATIONS PERIOD.*—*The Com-*
4 *mission may seek restitution under this sub-*
5 *paragraph not later than 5 years after the*
6 *latest date on which the person from which*
7 *the restitution is sought receives any unjust*
8 *enrichment from the effects of the violation*
9 *that gives rise to the suit in which the Com-*
10 *mission seeks the restitution.*

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

13 “(A) *requiring the Commission to bring a*
14 *suit seeking a temporary injunction under para-*
15 *graph (1)(B) before bringing a suit seeking a*
16 *permanent injunction under paragraph (1)(C);*
17 *or*

18 “(B) *affecting any other authority of the*
19 *Commission under this Act to seek relief or ob-*
20 *tain a remedy with respect to a violation of this*
21 *Act.”.*

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

1 (1) *conduct that occurs on or after the date of en-*
 2 *actment of this Act; and*

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

5 (c) *ANTITRUST LAWS.*—*Nothing in this section, or the*
 6 *amendments made by this section, shall modify, impair,*
 7 *limit, or supersede the applicability of the antitrust laws*
 8 *as defined in subsection (a) of the first section of the Clay-*
 9 *ton Act (15 U.S.C. 12(a)), and of section 5 of the Federal*
 10 *Trade Commission Act (15 U.S.C. 45) to the extent that*
 11 *it applies to unfair methods of competition.*

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

18 **SEC. 3. TITLE 35 AMENDMENTS.**

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

21 (1) *in paragraph (2)(C), in the flush text fol-*
 22 *lowing clause (ii), by adding at the end the following:*
 23 *“With respect to a submission described in clause (ii),*
 24 *the act of infringement shall extend to any patent*
 25 *that claims the biological product, a method of using*

1 *the biological product, or a method or product used*
2 *to manufacture the biological product.”; and*

3 *(2) by adding at the end the following:*

4 *“(7)(A) Subject to subparagraphs (C), (D), and (E),*
5 *if the sponsor of an approved application for a reference*
6 *product, as defined in section 351(i) of the Public Health*
7 *Service Act (42 U.S.C. 262(i)) (referred to in this para-*
8 *graph as the ‘reference product sponsor’), brings an action*
9 *for infringement under this section against an applicant*
10 *for approval of a biological product under section 351(k)*
11 *of such Act that references that reference product (referred*
12 *to in this paragraph as the ‘subsection (k) applicant’), the*
13 *reference product sponsor may assert in the action a total*
14 *of not more than 20 patents of the type described in sub-*
15 *paragraph (B), not more than 10 of which shall have issued*
16 *after the date specified in section 351(l)(7)(A) of such Act.*

17 *“(B) The patents described in this subparagraph are*
18 *patents that satisfy each of the following requirements:*

19 *“(i) Patents that claim the biological product*
20 *that is the subject of an application under section*
21 *351(k) of the Public Health Service Act (42 U.S.C.*
22 *262(k)) (or a use of that product) or a method or*
23 *product used in the manufacture of such biological*
24 *product.*

1 “(ii) Patents that are included on the list of pat-
2 ents described in section 351(l)(3)(A) of the Public
3 Health Service Act (42 U.S.C. 262(l)(3)(A)), includ-
4 ing as provided under section 351(l)(7) of such Act.

5 “(iii) Patents that—

6 “(I) have an actual filing date of more than
7 4 years after the date on which the reference
8 product is approved; or

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

12 “(C) The court in which an action described in sub-
13 paragraph (A) is brought may increase the number of pat-
14 ents limited under that subparagraph—

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

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

18 “(II) for good cause shown, which—

19 “(aa) shall be established if the subsection
20 (k) applicant fails to provide information re-
21 quired under section 351(l)(2)(A) of the Public
22 Health Service Act (42 U.S.C. 262(l)(2)(A)) that
23 would enable the reference product sponsor to
24 form a reasonable belief with respect to whether

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

3 “(bb) may be established—

4 “(AA) if there is a material change to
5 *the biological product (or process with re-*
6 *spect to the biological product) of the sub-*
7 *section (k) applicant that is the subject of*
8 *the application;*

9 “(BB) if, with respect to a patent on
10 *the supplemental list described in section*
11 *351(l)(7)(A) of Public Health Service Act*
12 *(42 U.S.C. 262(l)(7)(A)), the patent would*
13 *have issued before the date specified in such*
14 *section 351(l)(7)(A) but for the failure of the*
15 *Office to issue the patent or a delay in the*
16 *issuance of the patent, as described in para-*
17 *graph (1) of section 154(b) and subject to*
18 *the limitations under paragraph (2) of such*
19 *section 154(b); or*

20 “(CC) for another reason that shows
21 *good cause, as determined appropriate by*
22 *the court.*

23 “(D) In determining whether good cause has been
24 *shown for the purposes of subparagraph (C)(i)(II), a court*
25 *may consider whether the reference product sponsor has pro-*

1 *vided a reasonable description of the identity and relevance*
2 *of any information beyond the subsection (k) application*
3 *that the court believes is necessary to enable the court to*
4 *form a belief with respect to whether a claim of infringe-*
5 *ment under this section could reasonably be asserted.*

6 “(E) *The limitation imposed under subparagraph*
7 *(A)—*

8 “(i) *shall apply only if the subsection (k) appli-*
9 *cant completes all actions required under paragraphs*
10 *(2)(A), (3)(B)(ii), (5), (6)(C)(i), (7), and (8)(A) of*
11 *section 351(l) of the Public Health Service Act (42*
12 *U.S.C. 262(l)); and*

13 “(ii) *shall not apply with respect to any patent*
14 *that claims, with respect to a biological product, a*
15 *method for using that product in therapy, diagnosis,*
16 *or prophylaxis, such as an indication or method of*
17 *treatment or other condition of use.”.*

18 (b) *APPLICABILITY.—The amendments made by sub-*
19 *section (a) shall apply with respect to an application sub-*
20 *mitted under section 351(k) of the Public Health Service*
21 *Act (42 U.S.C. 262(k)) on or after the date of enactment*
22 *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