

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 and Mr. BLUMENTHAL) introduced the following bill;
which was read twice and 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 Act of 2019”.

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

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

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

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) COMPETITION WINDOW.—The term ‘com-

18 petition window’ means—

19 “(A) with respect to a listed drug, the pe-

20 riod between—

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

22 “(I) 8 years before any patent or

23 marketing exclusivity granted under

24 chapter V of the Federal Food, Drug,

25 and Cosmetic Act (21 U.S.C. 351 et

1 seq.) with respect to such listed drug
2 expires; and

3 “(II) the date on which the first
4 abbreviated new drug application that
5 references such listed drug is filed;
6 and

7 “(ii) the later of—

8 “(I) the date that is 180 days
9 after the first abbreviated new drug
10 application that references such listed
11 drug is filed; and

12 “(II) the date that is 1 year after
13 the date on which the generic drug
14 that is the subject of the abbreviated
15 new drug application described in sub-
16 clause (I) enters the marketplace; or

17 “(B) with respect to a reference product,
18 the period between—

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

20 “(I) 6 years before any patent or
21 marketing exclusivity (including any
22 extension of such exclusivity) granted
23 under section 351 of the Public
24 Health Service Act (42 U.S.C. 262)
25 or section 527 of the Federal Food,

1 Drug, and Cosmetic Act (21 U.S.C.
2 360cc) with respect to such reference
3 product expires; and

4 “(II) the date on which the first
5 biosimilar biological product license
6 application that references such ref-
7 erence product is filed; and

8 “(ii) the later of—

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

15 “(II) the date that is 1 year after
16 the date on which the biosimilar bio-
17 logical product that is the subject of
18 the biosimilar biological product li-
19 cense application described in sub-
20 clause (I) enters the marketplace.

21 “(5) EXPECTED REVENUE.—The term ‘ex-
22 pected revenue’, with respect to a follow-on product,
23 means the financial value represented by the number
24 of individuals in the target population multiplied by
25 the financial revenue generated by each member of

1 the target population over the 3-year period begin-
2 ning—

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

8 “(B) if 3 or more generic drugs ref-
9 erencing the same listed drug or 2 or more bio-
10 similar biological products referencing the same
11 reference product are already widely available in
12 the market, the day that the follow-on product
13 enters the market.

14 “(6) FOLLOW-ON PRODUCT.—The term ‘follow-
15 on product’ means a drug approved through an ap-
16 plication or supplement to an application submitted
17 under section 505(b) of the Federal Food, Drug,
18 and Cosmetic Act (21 U.S.C. 355(c)) or a biological
19 product licensed through an application or supple-
20 ment to an application submitted under section
21 351(a) of the Public Health Service Act (42 U.S.C.
22 262(a)) for a change, modification, or reformulation
23 to the same manufacturer’s previously approved
24 drug or biological product.

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

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

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

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

18 “(11) PATENT THICKETING.—

19 “(A) IN GENERAL.—The term ‘patent
20 thickening’ means an action taken to limit com-
21 petition by a patentee with respect to a drug
22 approved under section 505(c) of the Federal
23 Food, Drug, and Cosmetic Act (21 U.S.C.
24 355(c)) or a biological product licensed under

1 section 351(a) of the Public Health Service Act
2 (42 U.S.C. 262(a)) in which—

3 “(i)(I) the patentee obtains patents in
4 the same patent family or patent port-
5 folio—

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

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

20 “(II) the underlying composition of
21 matter patent is found invalid and the pat-
22 entee obtains patents in the same patent
23 family or patent portfolio that claim the
24 drug or biological product or a use of the
25 drug or biological product, a form of the

1 drug or biological product, a method of use
2 of the drug or biological product, or a
3 method of manufacture of the drug or bio-
4 logical product;

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

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

17 “(B) FACTORS TO CONSIDER.—The Com-
18 mission may establish that an action described
19 in subparagraph (A) improperly limits competi-
20 tion if the Commission establishes a reasonable
21 number of the following factors in a manner
22 that is sufficient to demonstrate anticompetitive
23 intent:

24 “(i) The additional patents described
25 in subparagraph (A)(i) (referred to in this

1 subparagraph as the ‘additional patents’)
2 stem from few patent families.

3 “(ii) The additional patents have com-
4 mon specifications.

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

11 “(iv) The additional patents have
12 overlapping or identical claims.

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

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

22 “(vii) Litigation with applicants under
23 section 351(k) of the Public Health Service
24 Act has been extended based on the addi-
25 tional patents.

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

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

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

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

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

22 “(B) would have bought the follow-on
23 product solely because of the significant health
24 improvement that those individuals would expe-
25 rience.

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

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

10 “(b) PROHIBITIONS.—

11 “(1) PATENT THICKETING.—

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

18 “(B) REBUTTAL.—

19 “(i) IN GENERAL.—Subject to sub-
20 paragraph (C), an action that constitutes
21 patent thicketing shall not be considered to
22 be an unfair method of competition in or
23 affecting commerce in violation of section
24 5(a) if the manufacturer described in that
25 paragraph demonstrates to the Commis-

1 sion or a district court of the United
2 States, as applicable, by a preponderance
3 of the evidence in a proceeding initiated by
4 the Commission under subsection
5 (c)(1)(A), or in a suit brought under sub-
6 paragraph (B) or (C) of subsection (c)(1),
7 that the anticompetitive effects of the ac-
8 tion do not outweigh the pro-competitive
9 effects of the action.

10 “(ii) EVIDENCE.—In making a dem-
11 onstration under clause (i) that the anti-
12 competitive effects of patent thicketing do
13 not outweigh the pro-competitive effects of
14 that behavior, a manufacturer described in
15 subparagraph (A)—

16 “(I) may present evidence that—

17 “(aa) the inventions claimed
18 in the additional patents de-
19 scribed in subclauses (I) and (II)
20 of subsection (a)(11)(A)(i) re-
21 sulted in—

22 “(AA) clinically mean-
23 ingful and significant thera-
24 peutic or safety benefits;

1 “(BB) significantly im-
2 proved product purity or po-
3 tency;

4 “(CC) significant
5 gained efficiencies in manu-
6 facturing; or

7 “(DD) other improved
8 product attributes having
9 substantial benefits for con-
10 sumers or patients;

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

17 “(cc) for each of the later
18 filed patents, the manufacturer
19 had substantial financial reason,
20 apart from the financial effects
21 of reduced competition, to file
22 each of the patents; and

23 “(II) in making a demonstration
24 under subclause (I), shall submit to
25 the Commission or the court, as appli-

1 cable, all research and development,
2 manufacturing, marketing, and other
3 costs associated with approval of the
4 original drug under section 505(c) of
5 the Federal Food, Drug, and Cos-
6 metic Act (21 U.S.C. 355(c)) or licen-
7 sure of the original biological product
8 under section 351(a) of the Public
9 Health Service Act (42 U.S.C.
10 262(a)), which—

11 “(aa) shall include—

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

17 “(BB) any applications
18 for patents that were filed
19 and rejected; and

20 “(bb) shall not be construed
21 to limit the information that the
22 Commission or the court, as ap-
23 plicable, may otherwise obtain in
24 any proceeding or action insti-

1 tuted 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 that
7 the harm to consumers from the action that is
8 the subject of that presentation is greater than
9 the benefits to consumers from that action.

10 “(2) PRODUCT HOPPING.—

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

17 “(i) If, during the period beginning on
18 the date on which the manufacturer of the
19 reference drug receives notice that an ap-
20 plicant has submitted to the Commissioner
21 of Food and Drugs an abbreviated new
22 drug application or biosimilar biological
23 product license application and ending on
24 the date that is 180 days after the date on
25 which that generic drug or biosimilar bio-

logical 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 ap-
proval of the application for the
listed drug or reference product;
or

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

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

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

“(B) REBUTTAL.—

“(i) IN GENERAL.—Subject to sub-
paragraph (C), an action described in sub-

1 paragraph (A) shall not be considered to
2 be an unfair method of competition in or
3 affecting commerce if—

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

18 “(II) with respect to an action
19 described in subparagraph (A)(ii)—

20 “(aa) the manufacturer
21 demonstrates to the Commission
22 or a district court of the United
23 States, as applicable, by a pre-
24 ponderance of the evidence in a
25 proceeding initiated by the Com-

mission 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) (re-
ferred to in this subclause as
the ‘follow-on product’) pro-
vides a clinically meaningful
and significant additional
health benefit to the target
population beyond that pro-
vided by the previously ap-
proved drug or biological
product;

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

“(CC) the manufac-
turer had substantive finan-
cial reasons, apart from the
financial effects of reduced
competition, to introduce the

1 follow-on product to the
2 market; and

3 “(bb) in making the dem-
4 onstration required under item
5 (aa), the manufacturer provides
6 to the Commission—

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

1 facture the follow-on prod-
2 uct; and

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

19 “(ii) RULE OF CONSTRUCTION.—
20 Nothing in clause (i) may be construed to
21 limit the information that the Commission
22 may otherwise obtain in any proceeding or
23 action instituted with respect to a violation
24 of this section.

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

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

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

18 “(c) ENFORCEMENT.—

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

24 “(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 Commis-

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

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

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

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

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

4 “(3) EQUITABLE REMEDIES.—

5 “(A) DISGORGEMENT.—

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

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

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

○