

117TH CONGRESS
1ST SESSION

S. 1435

To amend the Federal Trade Commission Act to prohibit product hopping,
and for other purposes.

IN THE SENATE OF THE UNITED STATES

APRIL 28, 2021

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
product hopping, 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 2021”.

6 **SEC. 2. PRODUCT HOPPING.**

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.**

2 “(a) DEFINITIONS.—In this section:

3 “(1) ABBREVIATED NEW DRUG APPLICATION.—

4 The term ‘abbreviated new drug application’ means
5 any application under subsection (j) of section 505
6 of the Federal Food, Drug, and Cosmetic Act (21
7 U.S.C. 355) or an application under subsection
8 (b)(2) of such section 505 that seeks a therapeutic
9 equivalence rating to the reference product.

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

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

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

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

1 submitted under section 351(a) of the Public
2 Health Service Act (42 U.S.C. 262(a)) for a
3 change, modification, or reformulation to the
4 same manufacturer's previously approved drug
5 or biological product that shares an indication,
6 in whole or in part, with the same manufactur-
7 er's previously approved drug or biological prod-
8 uct; and

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

16 “(5) GENERIC DRUG.—The term ‘generic drug’
17 means any drug approved under an application sub-
18 mitted under subsection (j) of section 505 of the
19 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
20 355) or an application under subsection (b)(2) of
21 such section 505 that seeks a therapeutic equiva-
22 lence rating to the reference product.

23 “(6) LISTED DRUG.—The term ‘listed drug’
24 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 ‘manufac-
4 turer’ means the holder, licensee, or assignee of—

5 “(A) an approved application for a drug
6 under section 505(c) of the Federal Food,
7 Drug, 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
10 (42 U.S.C. 262(a)).

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

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

19 “(b) PROHIBITION ON PRODUCT HOPPING.—

20 “(1) PRIMA FACIE.—A manufacturer of a ref-
21 erence product or listed drug shall be considered to
22 have engaged in an unfair method of competition in
23 or affecting commerce in violation of section 5(a) if
24 complaint counsel or the Commission demonstrates
25 in an action or proceeding initiated by the Commis-

1 sion under subsection (c) that, during the period be-
2 ginning on the date on which the manufacturer of
3 the reference product or listed drug first receives no-
4 tice that an applicant has submitted to the Commis-
5 sioner of Food and Drugs an abbreviated new drug
6 application or biosimilar biological product license
7 application referencing the reference product or list-
8 ed drug and ending on the date that is the earlier
9 of 180 days after the date on which that generic
10 drug or biosimilar biological product or another ge-
11 neric drug or biosimilar biological product ref-
12 erencing the listed drug or reference product is first
13 marketed or 3 years after the date on which the fol-
14 low-on product is first marketed, the manufacturer
15 engaged in either of the following actions:

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

20 “(i) Upon the request of the manufac-
21 turer of the listed drug or reference prod-
22 uct, the Commissioner of Food and Drugs
23 withdrew the approval of the application
24 for the listed drug or reference product or
25 placed the listed drug or reference product

1 on the discontinued products list and the
2 manufacturer marketed or sold a follow-on
3 product.

4 “(ii) The manufacturer of the listed
5 drug or reference product—

6 “(I)(aa) withdrew, discontinued
7 the manufacture of, or announced
8 withdrawal of, discontinuance of the
9 manufacture of, or intent to withdraw
10 the application with respect to the
11 drug or reference product in a manner
12 that impedes competition from a ge-
13 neric drug or a biosimilar biological
14 product, which may be established by
15 objective circumstances, unless such
16 actions were taken by the manufac-
17 turer pursuant to a request of the
18 Commissioner of Food and Drugs; or

19 “(bb) destroyed the inventory of
20 the listed drug or reference product in
21 a manner that impedes competition
22 from a generic drug or a biosimilar bi-
23 ological product, which may be estab-
24 lished by objective circumstances; and

1 “(II) marketed or sold a follow-on
2 product.

3 “(B) The manufacturer engaged in a soft
4 switch, which shall be established by dem-
5 onstrating that the manufacturer engaged in
6 both of the following actions:

7 “(i) The manufacturer took actions
8 with respect to the listed drug or reference
9 product other than those described in sub-
10 paragraph (A) that unfairly disadvantage
11 the listed drug or reference product rel-
12 ative to the follow-on product described in
13 clause (ii) in a manner that impedes com-
14 petition from a generic drug or a bio-
15 similar biological product, which may be
16 established by objective circumstances.

17 “(ii) The manufacturer marketed or
18 sold a follow-on product.

19 “(2) EXCLUSIONS.—Nothing in this section
20 shall prohibit actions that consist solely of—

21 “(A) truthful, non-misleading promotional
22 marketing; or

23 “(B) ceasing promotional marketing for
24 the listed drug or reference product.

25 “(3) JUSTIFICATION.—

1 “(A) IN GENERAL.—Subject to paragraph
2 (4), the actions described in paragraph (1) by
3 a manufacturer of a listed drug or reference
4 product shall not be considered to be an unfair
5 method of competition in or affecting commerce
6 if the manufacturer demonstrates to the Com-
7 mission or a district court of the United States,
8 as applicable, in an action, suit or proceeding
9 initiated by the Commission under subsection
10 (c)(1) that—

11 “(i) the manufacturer would have
12 taken the actions regardless of whether a
13 generic drug that references the listed drug
14 or biosimilar biological product that ref-
15 erences the reference product had already
16 entered the market; and

17 “(ii)(I) with respect to a hard switch
18 under paragraph (1)(A), the manufacturer
19 took the action for reasons relating to the
20 safety risk to patients of the listed drug or
21 reference product;

22 “(II) with respect to an action de-
23 scribed in paragraph (1)(A)(ii)(I)(aa),
24 there is a supply disruption that—

1 “(aa) is outside of the control of
2 the manufacturer;

3 “(bb) prevents the production or
4 distribution of the applicable listed
5 drug or reference product; and

6 “(cc) cannot be remedied by rea-
7 sonable efforts; or

8 “(III) with respect to a soft switch
9 under paragraph (1)(B), the manufacturer
10 had legitimate pro-competitive reasons,
11 apart from the financial effects of reduced
12 competition, to take the action.

13 “(B) RULE OF CONSTRUCTION.—Nothing
14 in subparagraph (A) may be construed to limit
15 the information that the Commission may oth-
16 erwise obtain in any proceeding or action insti-
17 tuted with respect to a violation of this section.

18 “(4) RESPONSE.—With respect to a justifica-
19 tion offered by a manufacturer under paragraph (3),
20 the Commission may—

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

23 “(B) establish by a preponderance of the
24 evidence that—

1 “(i) on balance, the pro-competitive
 2 benefits from the conduct described in sub-
 3 paragraph (A) or (B) of paragraph (1), as
 4 applicable, do not outweigh any anti-
 5 competitive effects of the conduct, even in
 6 consideration of the justification so offered;
 7 or

8 “(ii)(I) the conduct described in para-
 9 graph (1) is not reasonably necessary to
 10 address or achieve the justifications de-
 11 scribed in clause (ii) of paragraph (2)(A);
 12 or

13 “(II) the justifications described in
 14 clause (ii) of paragraph (2)(A) could be
 15 reasonably addressed or achieved through
 16 less anticompetitive means.

17 “(c) ENFORCEMENT.—

18 “(1) IN GENERAL.—If the Commission has rea-
 19 son to believe that any manufacturer has violated, is
 20 violating, or is about to violate this section, or a rule
 21 promulgated under this section, the Commission
 22 may take any of the following actions:

23 “(A) Institute a proceeding under section
 24 5(b).

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

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

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

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

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

“(2) JUDICIAL REVIEW.—

“(A) IN GENERAL.—Notwithstanding any provision of section 5, any manufacturer that is subject to a final cease and desist order issued in a proceeding to enforce this section, or a rule promulgated under this section, may, not later than 30 days after the date on which the Commission issues the order, petition for review of the order in—

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

1 “(ii) the court of appeals of the
2 United States for the circuit in which the
3 ultimate parent entity of the manufacturer
4 is incorporated.

5 “(B) TREATMENT OF FINDINGS.—In a re-
6 view of a final cease and desist order conducted
7 by a court of appeals of the United States
8 under subparagraph (A), the factual findings of
9 the Commission shall be conclusive if those
10 facts are supported by the evidence.

11 “(3) EQUITABLE REMEDIES.—

12 “(A) DISGORGEMENT.—

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

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

24 “(iii) LIMITATIONS PERIOD.—The
25 Commission may seek disgorgement under

1 this subparagraph not later than 5 years
 2 after the latest date on which the person
 3 from which the disgorgement is sought re-
 4 ceives any unjust enrichment from the ef-
 5 fects of the violation that gives rise to the
 6 suit in which the Commission seeks the
 7 disgorgement.

8 “(B) RESTITUTION.—

9 “(i) IN GENERAL.—In a suit brought
 10 under paragraph (1)(C), the Commission
 11 may seek, and the court may order, res-
 12 titution with respect to the violation that
 13 gives rise to the suit.

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

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

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

6 “(B) affecting the authority of the Federal
7 Trade Commission under any other provision of
8 law.”.

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

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

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

16 (c) ANTITRUST LAWS.—Except to the extent sub-
17 section (a) establishes an additional basis for liability
18 under the Federal Trade Commission Act (15 U.S.C. 41
19 et seq.), nothing in this section, or the amendments made
20 by this section, shall modify, impair, limit, or supersede
21 the applicability of the antitrust laws as defined in sub-
22 section (a) of the first section of the Clayton Act (15
23 U.S.C. 12(a)), and of section 5 of the Federal Trade Com-
24 mission Act (15 U.S.C. 45) to the extent that it applies
25 to unfair methods of competition.

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

7 **SEC. 3. TITLE 35 AMENDMENTS.**

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

10 (1) in paragraph (2)(C), in the flush text fol-
 11 lowing clause (ii), by adding at the end the fol-
 12 lowing: “With respect to a submission described in
 13 clause (ii), the act of infringement shall extend to
 14 any patent that claims the biological product, a
 15 method of using the biological product, or a method
 16 or product used to manufacture the biological prod-
 17 uct.”; and

18 (2) by adding at the end the following:

19 “(7)(A) Subject to subparagraphs (C), (D), and
 20 (E), if the sponsor of an approved application for a
 21 reference product, as defined in section 351(i) of the
 22 Public Health Service Act (42 U.S.C. 262(i)) (re-
 23 ferred to in this paragraph as the ‘reference product
 24 sponsor’), brings an action for infringement under
 25 this section against an applicant for approval of a

1 biological product under section 351(k) of such Act
2 that references that reference product (referred to in
3 this paragraph as the ‘subsection (k) applicant’), the
4 reference product sponsor may assert in the action
5 a total of not more than 20 patents of the type de-
6 scribed in subparagraph (B), not more than 10 of
7 which shall have issued after the date specified in
8 section 351(l)(7)(A) of such Act.

9 “(B) The patents described in this sub-
10 paragraph are patents that satisfy each of the
11 following requirements:

12 “(i) Patents that claim the biological
13 product that is the subject of an applica-
14 tion under section 351(k) of the Public
15 Health Service Act (42 U.S.C. 262(k)) (or
16 a use of that product) or a method or
17 product used in the manufacture of such
18 biological product.

19 “(ii) Patents that are included on the
20 list of patents described in section
21 351(l)(3)(A) of the Public Health Service
22 Act (42 U.S.C. 262(l)(3)(A)), including as
23 provided under section 351(l)(7) of such
24 Act.

25 “(iii) Patents that—

1 “(I) have an actual filing date of
2 more than 4 years after the date on
3 which the reference product is ap-
4 proved; or

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

8 “(C) The court in which an action de-
9 scribed in subparagraph (A) is brought may in-
10 crease the number of patents limited under that
11 subparagraph—

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

14 “(ii)(I) if the interest of justice so re-
15 quires; or

16 “(II) for good cause shown, which—

17 “(aa) shall be established if the
18 subsection (k) applicant fails to pro-
19 vide information required section
20 351(k)(2)(A) of the Public Health
21 Service Act (42 U.S.C. 262(k)(2)(A))
22 that would enable the reference prod-
23 uct sponsor to form a reasonable be-
24 lief with respect to whether a claim of

1 infringement under this section could
2 reasonably be asserted; and

3 “(bb) may be established—

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

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

1 “(CC) for another reason
2 that shows good cause, as deter-
3 mined appropriate by the court.

4 “(D) In determining whether good cause
5 has been shown for the purposes of subpara-
6 graph (C)(ii)(II), a court may consider whether
7 the reference product sponsor has provided a
8 reasonable description of the identity and rel-
9 evance of any information beyond the sub-
10 section (k) application that the court believes is
11 necessary to enable the court to form a belief
12 with respect to whether a claim of infringement
13 under this section could reasonably be asserted.

14 “(E) The limitation imposed under sub-
15 paragraph (A)—

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

22 “(ii) shall not apply with respect to
23 any patent that claims, with respect to a
24 biological product, a method for using that
25 product in therapy, diagnosis, or prophy-

1 laxis, such as an indication or method of
2 treatment or other condition of use.”.

3 (b) APPLICABILITY.—The amendments made by sub-
4 section (a) shall apply with respect to an application sub-
5 mitted under section 351(k) of the Public Health Service
6 Act (42 U.S.C. 262(k)) on or after the date of enactment
7 of this Act.

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